Commissioner's Decision # 1388

Décision du Commissaire # 1388

TOPICS: A11, K11, F01, O00

SUJETS: A11, K11, F01, O00

Application No. : 2,579,611

Demande № : 2,579,611

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,579,611, having been rejected under subsection 30(3) of the *Patent Rules*, has subsequently been reviewed in accordance with paragraph 30(6)(*c*) of the *Patent Rules*. The recommendation of the Board and the decision are as follows:

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INTRODUCTION

[1] This matter concerns a review of patent application no. 2,579,611 ["the '611 application"] entitled "A Method for Oral Delivery of a Healing Substance to a Target Place in Gastrointestinal Tract of Human or Animals". The Applicant is Mr. Igor Stukanov. The application relates to a system and method for delivery of a healing substance to a targeted area in the gastrointestinal tract.

[2] For the reasons that follow, we recommend that the application be refused.

PROSECUTION HISTORY

[3] The '611 application was filed on February 21, 2007.

[4] The Final Action (FA), dated October 3, 2013, states that claims 1 and 3-5 and the description fail to comply with section 38.2 of the *Patent Act* for including new matter. The FA further states that the claims on file (claims 1-8) claim non-statutory subject matter falling outside the definition of invention in section 2 of the *Patent Act*. The FA also states that claims 1-8 fail to comply with paragraph 28.2(1)(*b*) and section 28.3 of the *Patent Act* for comprising subject matter that was anticipated and obvious, respectively.

[5] In a letter of response to the FA, dated June 19, 2014, the Applicant argued that the claims and description on file were not defective.

[6] Having determined the Applicant's arguments did not render the application allowable, pursuant to subsection 30(6) of the *Patent Rules* the file was forwarded to the Patent Appeal Board ("the Board"). The file included a Summary of Reasons (SOR) for maintaining that the application did not comply with the *Patent Act*. The SOR stated that

the application stood rejected on the same grounds as stated in the FA.

[7] In a letter dated October 31, 2014, the Board offered the Applicant an opportunity to make further written submissions and/or attend an oral hearing. A copy of the SOR was sent with the letter.

[8] In a letter dated November 24, 2014, the Applicant provided written submissions concerning each of the defects noted in the FA and SOR. The Applicant declined the invitation to an oral hearing.

ISSUES

[9] The issues for determination are those set out in the Final Action and the Summary of Reasons, namely:

- Do claims 1 and 3-5 and the description fail to comply with section 38.2 of the *Patent Act* for including improperly added new matter?
- Do claims 1-8 fail to comply with section 2 of the *Patent Act* for comprising a non-statutory method of medical treatment (MMT)?
- Do claims 1-8 fail to comply with paragraph 28.2(1)(*b*) of the *Patent Act* for comprising subject matter that lacks novelty in view of cited reference D1?
- Do claims 1-8 fail to comply with section 28.3 of the *Patent Act* for comprising subject matter that would have been obvious to the skilled person in view of D1?

LEGAL PRINCIPLES

Purposive construction

[10] Purposive construction is an interpretive exercise in determining the meaning and scope of the claims. Claims construction is antecedent to consideration of validity: *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para. 43 ["*Whirlpool*"]. Purposive construction requires that the claims be interpreted from the point of view of the person skilled in the art, who possesses the common general knowledge of the particular art: *Whirlpool* at para. 53. During purposive construction, the elements of the claimed invention are identified as essential or non-essential: *Free World Trust v Électro Santé Inc*, 2000 SCC 66, at para. 31 ["*Free World Trust*"]. An element is considered non-essential if, based on a purposive construction, the skilled addressee would appreciate an element of the claim could be omitted or substituted without having a material effect on the working of the invention (*Free World Trust*, para. 55). According to the guidance provided in the Office Exam Memo *Examination Practice Respecting Purposive Construction* - PN2013-02, the essential elements of a claim are those elements that provide the proposed solution to the problem identified in the application.

[11] Subsection 27(5) of the *Patent Act* clarifies how a claim which defines subject matter in the alternative is to be interpreted when considering issues relating to anticipation, obviousness or utility:

> For greater certainty, where a claim defines the subject-matter of an invention in the alternative, each alternative is a separate claim for the purposes of sections 2, 28.1 to 28.3 and 78.3.

[12] In *Abbott Laboratories v Canada (Minister of Health)*, 2005 FC 1332 ["*Abbott*"], at para. 52, Phelan J stated the following with respect to subsection 27(5):

> S. 27(5) is part of the provisions under the heading "Application for Patents". The section requires that if there are alternative claims, each alternative meet the test for patentability – novelty, utility and inventiveness. Failure to establish that each alternative meets the test for patentability would result in the alternative being invalid as well as the whole of the claim.

New matter

[13] Section 38.2 of the *Patent Act* sets forth the conditions under which amendments may be made to the specification and drawings of a patent application:

> 38.2 (1) Subject to subsections (2) and (3) 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 on amendments to specifications
> (2) The specification may not be amended to describe matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application.
>
> Restriction on amendments to drawings
> (3) Drawings may not be amended to add matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application.

[14] The question as to whether matter added to the specification 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 at the time the application was filed: *Re Uni-Charm Corp* (2013), 119 CPR (4th) 462, CD No 1353, and the Commissioner's Decisions cited therein.

[15] The assessment as to the presence of new matter therefore requires a comparison of the pending specification and drawings with those of the originally filed application, and a determination as to whether the subject-matter of the amendments is that which would have been reasonably inferred from the original specification or drawings by the person skilled in the art at the time of filing.

Statutory subject matter

[16] The definition of invention is set out in section 2 of the *Patent Act*:

> "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

[17] Canadian jurisprudence has determined that certain types of subject matter are excluded from patentability in that they fall outside this definition. In the particular case of methods of medical treatment, in *Tennessee Eastman Co v Commissioner of Patents* (1972), [1974] SCR 111, the Court concluded, at p. 119:

> Having come to the conclusion that methods of medical treatment are not contemplated in the definition of "invention" as a kind of "process", the same must, on the same basis, be true of a method of surgical treatment. [underlining added]

Novelty

[18] The statutory provision relevant for assessing novelty is subsection 28.2(1) of the *Patent Act*. This subsection provides, in part:

> The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
>
> (*a*) 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 subject-matter became available to the public in Canada or elsewhere;
>
> (*b*) before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in

> Canada or elsewhere.

[19] In *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 [“*Sanofi*”], the Supreme Court of Canada reviewed the principles of novelty. The Court held that two requirements must be established in order for there to be lack of novelty, or anticipation: disclosure and enablement. That is, an allegedly anticipating disclosure must not only describe the features of the claimed invention, it must also enable the skilled person to practice the claimed invention.

Obviousness

[20] The subject-matter of a patent claim must not have been obvious to persons skilled in the art or science on the claim date. Section 28.3 of the *Patent Act* provides:

> 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.

[21] In *Sanofi*, the Supreme Court of Canada indicated that it is useful in an obviousness inquiry to follow a four-step approach, as follows:

> (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?

THE CLAIMED INVENTION

Purposive construction

[22] Since claims must be considered from the point of view of the skilled person in view of their common general knowledge, it is first necessary to identify such a person and such knowledge.

The person skilled in the art and the common general knowledge of this person

[23] The identification of the skilled person and the common general knowledge of this person were not addressed in the FA, the SOR, the Applicant's response to the FA and the Applicant's response to the SOR. We therefore base our identification on the specification and on the cited prior art reference.

[24] The person skilled in the art is a specialist in the oral delivery of therapeutic substances, including drugs, into the body through the digestive tract. The skilled person would have knowledge of conventional methods and devices for such delivery of therapeutic substances, including the use of capsule systems having the following features: imaging

sensors on the capsule, means for opening the capsule, means for directing a therapeutic substance at a targeted location in the digestive tract, and an external control unit in wireless communication with the capsule (see extensive discussion of known devices in background (pp. 1-14) of cited reference D1).

Problem identified in the application

[25] The description of the present application states that "the present invention is directed to a method for oral delivery of new drugs, big molecules, proteins, electromagnetic radiation, ultrasound and other healing substances to a targeted area of the body, via the digestive tract, using currently available technologies of mobile wireless controlled capsules with sensors" (p. 1, para. 1).

[26] The problem addressed by the inventor was to provide a method for delivering healing substances to a targeted area of the body without "the problem of high precision targeting of damaged regions and avoiding exposure of non-damaged regions to healing substances" (p. 1, para. 4).

The proposed solution to the problem

[27] The solution proposed by the description was a therapeutic substance delivery method that addresses the above problem and has the following advantages:

- "delivery of peptides, proteins, and other big molecule structures, which are normally decomposed in digestive tract if taken orally, into blood stream without their exposure to digestive machinery and without modifications in their structure and function" (p. 4, para. 3);
- "high accuracy of targeting the damaged regions" (p. 4, para. 4); and
- "high degree of safety for using this method" (p. 4, para. 5).

Essential elements of the claims

Claim 1

[28] Claim 1 reads:

> 1. A method for delivery of a healing substance to a target place in gastrointestinal tract comprising the following steps:
>
> a) a healing substance or source of a healing substance is placed into a mobile wireless controlled capsule with sensors;
>
> b) the capsule enters into the gastrointestinal tract via mouth of a patient with food or water and moves toward the targeted place;
>
> c) the capsule is directed to the targeted place via control signals sent from a control unit wirelessly;
>
> d) the capsule send signals from the sensors to a monitor connected to the control unit;
>
> e) when the capsule reaches the targeted place, the control unit sends signal to release the healing substance by a delivery device and this healing substance is released from the capsule and directed to the targeted place via signals from the control unit.

[29] The skilled person would determine that the following elements form part of the solution to the problem identified at para. [26] and are thus essential elements of claim 1:

> a. placing a healing substance or source of a healing substance into a mobile wireless controlled capsule having sensors;

b. providing the capsule to be swallowed along with food or water by the patient so that it enters into the GI tract and moves toward the targeted area;

d. receiving signals wirelessly from the capsule's sensors at a monitor connected to a control unit; and

e. when the capsule reaches the targeted area, sending signals from the control unit to release the healing substance from the capsule and direct the substance to the targeted area by a delivery device.

[30] Regarding step (c) of the claim, we note that the description does not support an embodiment in which the capsule is "directed" to the targeted area via control signals sent from a control unit wirelessly. The description is silent regarding any means for moving the capsule along the GI tract. The skilled person would understand from reading the description that the invention relies, as prior art devices rely, on the natural contraction of the GI tract to propel the capsule through the tract at about the same speed as any other ingested object such as food or medicine. Rather than the capsule being "directed" to the targeted area, the description simply states that the capsule, once swallowed, "travels in the tract" (Examples 1-4), which the skilled person would understand to mean travel according to the natural contraction of the GI tract. It would be apparent to the skilled person from the description that the extent of the control unit's influence on the delivery of a healing substance to a target area is limited to monitoring images sent wirelessly by the capsule's sensors as the capsule progresses naturally through the GI tract in order to detect that the capsule has reached the targeted area, and then sending signals to the capsule to release the healing substance from the capsule and direct the substance to the target area by a delivery device (Examples 1-4).

[31] Consequently, the skilled person would understand that the step of "directing" the

capsule does not refer to the dictionary meaning of the term, but rather refers to the step provided in the description, that of monitoring the progress of the capsule from the control unit. Thus, step (c) is construed as:

> c. monitoring the capsule's progress along the GI tract via wireless signals between the capsule and the control unit;

Claim 2

[32] Claim 2 reads:

> 2. The method as in claim 1, where the healing substance is a composition of chemical elements in solid or fluid or gases form.

[33] The essential elements of claim 2 comprise the essential elements of claim 1 and the additional feature of the healing substance being a chemical composition in three alternative forms: solid, fluid or gas.

Claim 3

[34] Claim 3 reads:

> 3. The method as in claim 1, where the healing substance is a source of electromagnetic waves.

[35] The essential elements of claim 3 comprise the essential elements of claim 1 and the additional feature of the healing substance being a source of electromagnetic waves.

Claim 4

[36] Claim 4 reads:

> 4. The method as in claim 1, where the healing substance is a source of mechanical waves.

[37] The essential elements of claim 4 comprise the essential elements of claim 1 and the additional feature of the healing substance being a source of mechanical waves. The description states that the source is "a generator of mechanical waves or vibrator" (p. 4, para. 1).

Claim 5

[38] Claim 5 reads:

> 5. The method as in claim 1, where the healing substance is a source of sound or ultrasound waves.

[39] The essential elements of claim 5 comprise the essential elements of claim 1 and the additional feature of the healing substance being a source of sound or ultrasound waves. The description states that the source is "a generator of sound or ultrasound waves" (p. 4, para. 2).

Claim 6

[40] Claim 6 reads:

> 6. The method as in claim 1, where the healing substance is a flow of physical particles.

[41] The essential elements of claim 6 comprise the essential elements of claim 1 and the

additional feature of the healing substance being a flow of physical particles. This feature does not appear in the description. However, rather than concluding that the feature is insufficiently described, we consider that the skilled person, reading the claim in view of the common general knowledge in the art, would understand it to refer to the process of removing material from the walls of the intestine through the use of erosive materials.

Claim 7

[42] Claim 7 reads:

> 7. The method as in claim 1, where the signal to release or direct the healing substance is sent by a human operator.

[43] The essential elements of claim 7 comprise the essential elements of claim 1 and the additional feature of the signals from the control unit to release the healing substance from the capsule and direct the substance to the targeted area by a delivery device being initiated by a human operator. While claim 7 recites the expression “release or direct”, the skilled person would understand from claim 1, upon which claim 7 depends, as well as from described examples 1 and 2, that the signal is intended to release and direct the healing substance.

Claim 8

[44] Claim 8 reads:

> 8. The method as in claim 1, where the signal to release or direct the healing substance is sent by the control unit automatically.

[45] The essential elements of claim 8 comprise the essential elements of claim 1 and the additional feature of the signals from the control unit to release the healing substance

from the capsule and direct the substance to the targeted area by a delivery device being sent automatically. While claim 8 recites the expression “release or direct”, the skilled person would understand from claim 1, upon which claim 8 depends, as well as from the described examples, that the signal is intended to release and direct the healing substance.

DO CLAIMS 1 AND 3-5 AND THE DESCRIPTION CONTAIN NEW MATTER?

Analysis

[46] The FA states that the following subject matter does not comply with section 38.2 of the *Patent Act* as it cannot be found or reasonably inferred from the specification as originally filed, and therefore must be removed from the application:

- claim 1: “or source of a healing substance”;
- claims 3-5: “a source”;
- description p. 2, line12: “In this capsule is embedded… several devices”;
- description p. 3, last line: “Treatment with… vibrations”;
- description p. 4, lines 2, 6: “vibrator”; and
- description pp. 3-4: Examples 3 and 4, including “a generator”, and signaling/activation/deactivation of the generator.

[47] As stated at para. [15], the assessment as to the presence of new matter requires a comparison of the pending specification and drawings with those of the originally filed application, and a determination as to whether the subject-matter of the amendments would have been reasonably inferred from the original specification or drawings by the person skilled in the art at the time of filing.

[48] Claims 3-5 as originally filed recite the features of the capsule including a set of electromagnetic waves, a set of mechanical waves, and a set of sound or ultrasound

waves, respectively.

[49] The skilled person would infer from a purposive construction the originally-filed claims that for each of these embodiments the capsule would not include merely the waves themselves, but would necessarily also require a means for generating such waves. A source of the waves, *e.g.*, a wave generator or a vibrator, while not explicitly set out in the claims or description as filed, is an implicit feature in a capsule including a set of waves.

[50] Accordingly, the skilled person would understand that the subject matter added to claims 1 and 3-5 and the description (see para. [46], above) is reasonably to be inferred from the specification as filed, and thus complies with section 38.2 of the *Patent Act*.

DO CLAIMS 1-8 COMPRISE A NON-STATUTORY MMT?

Analysis

[51] The FA states at p. 2:

> Claims 1-8 are directed to subject-matter that lies outside the definition of 'invention' and do not comply with section 2 of the *Patent Act*. The defined method is a method of medical treatment and is consequently not a statutory 'art or 'process' (see section 17.02.03 of the *Manual of Patent Office Practice [MOPOP]*).

[52] The response to the FA argues (at p. 1) that the claims define a method for delivery, not a method of treatment, and therefore are not directed to non-statutory subject matter.

[53] However, as purposively construed the claims are directed to a method for delivery of a healing substance to a targeted place in the gastrointestinal tract. The clear intent of the

method, taken from the use of the term "healing" in the claims as well as from the specification as a whole, is the therapeutic benefit to a subject. As such, it is a method of treatment.

[54] The response to the FA further argues (at p. 1) that if the cited section of *MOPOP* is correct, "then nothing can be patented in the medical field because anything (any action or even thought) may have therapeutic effect."

[55] However, it is notable that *MOPOP* refers to methods having a therapeutic effect, not anything having a therapeutic effect. Claims 1-8 relate to methods having a therapeutic effect.

[56] The response to the FA references (at pp. 1-2) a number of Canadian patents relating to drug delivery methods that have issued (1188260, 1190111, 1229019, 1272090, 2104699 and 2544291) as support for its contention that drug delivery methods comprise statutory subject matter.

[57] However, the grant of a patent is not evidence of patentability; after a patent is issued it is *presumed*, in the absence of any evidence to the contrary, to be valid. A granted patent is subject to review, and possible invalidation, by the Federal Court.

[58] Furthermore, we have reviewed the patents referenced by the Applicant, and found that only the first of these patents contains method claims. These claims are directed to a method for selectively mixing two separately stored components in a closed system under sterile conditions, not a method providing a therapeutic benefit. The remaining claims of the referenced patents are claims directed to systems, devices or uses, bearing no resemblance to the method claims of the instant application.

[59] The response to the FA also argues (at p. 2):

> If a method not always provides a practical therapeutic benefit it is not non-statutory, therefore is patentable. Methods of a drug or healing substance delivery **NOT ALWAYS** provide a practical therapeutic benefit, therefore they are patentable. [emphasis in original]

[60] However, as stated above, the claims as purposively construed are directed to a method that has for its intended purpose the therapeutic benefit to a subject. As for the Applicant's argument that the claimed method of drug or healing substance delivery will not always lead to healing in a subject (in other words, the method when carried out will not always produce the desired result), is not relevant to the question of statutory subject matter.

[61] Finally, the response to the FA argues (at p. 2) that the Applicant had previously provided historical background of *MOPOP* 17.02.03 to help interpret this exclusion but this information was not duly considered.

[62] The Applicant's reference to historical background relates to the Applicant's letter of October 5, 2012, which was a response to an Office action dated September 21, 2012. The relevant portion of the Applicant's letter (at p. 7) is presented below:

> The Examiner states: "The applicant's attention is directed to section 17.02.03 Medical and surgical Methods of the *Manual of Patent Office Practice* wherein it is stated "a method which provides a practical therapeutic benefit to a subject, even if this is not its primary or intended purpose, is considered to be a method of medical treatment and is therefore not patentable.
>
> First of all, the section 17.02.03 had arisen largely from 1972 Supreme Court decisions, for example ***Tennessee Eastman Co. et al. v. Commissioner of Patents***. In these decisions it was argued that
>
> a) method of medical treatment requires skills of a doctor;

> b) methods of medical treatment do not produce a result in relation to trade, commerce or industry nor a result that is essentially economic.
>
> The proposed by the Applicant method **does not** require skills of a doctor, because it uses natural parts of the body to deliver a healing substance. The proposed method **do has** an economic result, which is a reduction of health care costs.

[63] Regarding Applicant's argument that only methods requiring the skills of a doctor can be considered as falling within the exclusion from patentability of methods of medical treatment, we note, firstly, that of the eight claims on file, only claim 8, which defines an automated method, precludes the involvement of a physician in carrying out the method.

[64] Secondly, we note that in *Tennessee Eastman Co v Commissioner of Patents* (1972), [1974] SCR 111, the Court did not state that only methods requiring the skills of a doctor are considered as falling within the exclusion from patentability of methods of medical treatment. Nor did the Court provide an explicit definition of a method of medical treatment. The Court simply stated that methods of medical treatment and methods of surgical treatment were not contemplated in the definition of "invention" as kinds of processes.

[65] However, in discussing a UK decision that was brought to the Court's attention, *Re Schering AG's Application*, [1971] RPC 337 (Patents Appeal Tribunal) ["*Schering*"], the Court reproduced an excerpt, from p. 345, emphasizing by its use of italics the following phrase: "patents for medical treatment in the strict sense must be excluded". In *Schering*, the Tribunal made a distinction between treatment in the broad sense of *any* treatment of the human body (as used in the UK Manual of Office Practice), and treatment in the narrow sense of methods of medical treatment of human beings to cure or prevent disease, and concluded that the exclusion from patentability applied to the latter, narrow sense of the term.

[66] This characterization of a method of medical treatment has since been applied by the Commissioner of Patents on a number of occasions (see, for example, *Re Application No 880,719 (Patent No 944,693)* (1973), 18 CPR (2d) 114, CD 147; *Re Application for Patent of Goldenberg (now Patent No 1,244,344)* (1988), 22 CPR (3d) 159, CD 1119; *Re Senentek plc Patent Application* (1997), 77 CPR (3d) 321, CD 1213), and is reflected in *MOPOP* 17.02.03, as referenced above.

[67] While we agree that a patent claim over a method of medical treatment that, by its nature, covers an area for which a physician's skill or judgment is expected to be exercised is not patentable in Canada, it does not follow that a claim for a method of medical treatment that does not require the skills of a physician necessarily comprises patentable subject matter: see *Imperial Chemical Industries Ltd v Commissioner of Patents*, [1986] 3 FC 40 (CA), in which the Federal Court of Appeal found that a method of cleaning dental plaque or stains, which method could be practised without the involvement of a skilled physician, was excluded from patentability as comprising a method of medical treatment.

[68] Consequently, with respect to the instant application, even if the method of claim 8 is intended to be carried out without requiring a physician's skill or judgment, it nevertheless comprises a method of medical treatment to cure or prevent disease, and is therefore considered unpatentable.

[69] As for the Applicant's argument concerning an essentially economic result, the reduction of health care costs, the Applicant provides no evidence to support this assertion. In any case, we consider that such a result could also be attributed to the claimed method in *Tennessee Eastman*. And in the Exchequer Court decision in that case ((1970), 62 CPR 117), Justice Kerr stated:

> In my view the method here does not lay in the field of the manual or productive arts nor, when applied to the human body, does it produce a result in relation to

> trade, commerce or industry or a result that is essentially economic. The adhesive itself may enter into commerce, and the patent for the process, if granted, may also be sold and its use licensed for financial considerations, but it does not follow that the method and its result are related to commerce or are essentially economic in the sense that those expressions have been used in patent case judgments. [underlining added]

[70] In view of the above, the skilled person would construe claims 1-8 to be directed to a method of medical treatment. Accordingly, claims 1-8 fall outside the definition of "invention" in section 2 of the *Patent Act*.

DO CLAIMS 1-8 LACK NOVELTY IN VIEW OF D1?

Analysis

[71] In the Final Action and Summary of Reasons, the following reference was cited as forming part of the state of the art:

Patent Application
D1: CA 2,514,392 A1 laid open 12 August, 2004 Gross et al.

[72] In the response to the FA the Applicant identifies differences between the claim 1 of the instant application and claim 1 of D1. However, a novelty assessment requires a comparison of the essential elements of the claims under consideration to the entire disclosure of the cited prior art reference, and we proceed on this basis.

[73] The following table provides a comparison of the essential elements of the claims, identified earlier, to the elements disclosed by D1:

Claim	Essential elements of the claim	Elements disclosed by D1

1	A method of delivery of a healing substance to a targeted area in a GI tract of a patient comprising: a. placing a healing substance or source of a healing substance into a mobile wireless controlled capsule having sensors; b. providing the capsule to be swallowed along with food or water by the patient so that it enters into the GI tract and moves toward the targeted area; c. monitoring the capsule's progress along the GI tract via wireless signals between the capsule and the control unit; d. receiving signals wirelessly from the capsule's sensors at a monitor connected to a control unit; and e. when the capsule reaches the targeted area, sending signals from the control unit to release the healing substance from the capsule and direct the substance to the targeted area by a delivery device.	A method of delivery of a drug [healing substance] to a targeted area in a GI tract of a patient (p. 14, lines 16-17) a. placing a drug into a mobile wireless controlled capsule having sensors (p. 14, lines 16-17; p. 40, line 32 to p. 41, line 14; p. 53, lines 16-20) b. providing the capsule to be swallowed along with food or water by the patient so that it enters into the GI tract and moves toward the targeted area (p. 39, lines 25-28; p. 52, lines 29-30) c. monitoring the capsule's progress along the GI tract via wireless signals between the capsule and the control unit (p. 39, lines 28 to p. 40, line 1; p. 61, lines 4-7) d. receiving signals wirelessly from the capsule's sensors at a monitor connected to a control unit (p. 41, lines 6-14; p. 61, lines 4-7) e. when the capsule reaches the targeted area, sending signals from the control unit to release the healing substance from the capsule and direct the substance to the targeted area by a delivery device (p. 61, lines 8-12)
2	the essential elements of claim 1, plus the healing substance is a chemical composition in three alternative forms: solid, fluid or gas	the drug is a chemical composition in several alternative forms: solid, powder, liquid or gel (p. 53, lines 16-20)
3	the essential elements of claim 1, plus the healing substance is a source of electromagnetic waves	the delivery device (not the healing substance) includes a source of electromagnetic waves (p. 40, lines 3-9)
4	the essential elements of claim 1, plus the healing substance is a source of mechanical waves (generator of mechanical waves or vibrator)	- -
5	the essential elements of claim 1, plus the healing substance is a source of sound or ultrasound waves (generator of sound or ultrasound waves)	the delivery device (not the healing substance) includes a source of sound or ultrasound waves (p. 40, lines 10-16)
6	the essential elements of claim 1, plus the healing substance is a flow of physical particles for ablating the walls of the intestine	the delivery device (not the healing substance) includes a flow of physical particles (p. 53, lines 25-27)

7	the essential elements of claim 1, plus the signal to release and direct the healing substance is sent by a human operator	the signal to release and direct the healing substance is sent by a human operator (p. 61, lines 8-12)
8	the essential elements of claim 1, plus the signal to release and direct the healing substance is sent by the control unit automatically	the signal to release and direct the healing substance is sent by the control unit automatically (p. 61, lines 8-12)

[74] D1 discloses the essential elements of claim 1. With respect to essential element (a), although we note that D1 does not disclose a "*source of* a healing substance", we also note that claim 1 refers to a healing substance or source of a healing substance. In view of the reasoning from *Abbott* (above at para. [12]), if a claim defines subject matter in the alternative, and one of the alternatives is anticipated, the claim is anticipated. Since a healing substance and a source of a healing substance are set forth as alternatives, and D1 discloses one of the alternatives as well as the remaining essential elements of the claim, claim 1 is anticipated by D1.

[75] D1 discloses the essential elements of claim 2. Although we note that D1 does not disclose a healing substance in gas form, we also note that the further essential element of claim 2 refers to a healing substance in solid, fluid or gas form. Since solid, fluid and gas forms are set forth as alternatives, and D1 discloses two of the alternatives as well as the remaining essential elements of the claim, claim 2 is anticipated by D1.

[76] D1 does not disclose the essential elements of claims 3-6 (see table above).

[77] D1 discloses the essential elements of claims 7-8 (see table above).

[78] In summary, claims 1-2 and 7-8 are anticipated by D1, while claims 3-6 are novel in view of D1.

ARE CLAIMS 1-8 OBVIOUS IN VIEW OF D1?

Analysis

[79] In following the four step *Sanofi* framework, we will consider the claims for which differences over the cited state of the art reference were identified at step (3). It is unnecessary to further consider the obviousness of claims that have been found to be anticipated, since there are no differences, and therefore nothing to which inventive ingenuity could be attributed. Accordingly, claims 1, 2, 7 and 8 are considered to be not only anticipated, but also obvious, and we need only further assess obviousness with respect to claims 3-6.

(1)(a) Identify the notional person skilled in the art

[80] The person skilled in the art was identified at para. [24].

(1)(b) Identify the relevant common general knowledge of that person

[81] Our conclusions regarding the common general knowledge of the skilled person are stated at para. [24].

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

[82] In this case, the inventive concepts of claims 3-6 comprise the essential elements of these claims, as identified at paras. [35], [37], [39] and [41], respectively.

(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

[83] The differences between D1 and the inventive concept of each of claims 3-6 comprise the

further essential elements of each of these claims (see table above). That is, the differences with respect to claims 3, 4, 5 and 6 are that the healing substance comprises a source of electromagnetic waves, a source of mechanical waves, a source of sound or ultrasound waves, and a flow of physical particles for ablating the walls of the intestine, respectively.

(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?

[84] The skilled person would have known at the claim date of the instant application of remote-controlled devices designed to be ingested and to pass through the GI tract of a subject, such devices providing a diagnostic tool for monitoring the GI tract. From D1 (see entire document) the skilled person would learn that such devices are suitable for drug delivery to targeted areas of the GI tract.

[85] It would have been obvious to the skilled person to consider that such well-known devices would also be suitable for other well-known types of treatment of the GI tract, such as the application of electromagnetic waves, mechanical waves (vibrations), sound or ultrasound waves, and a flow of physical particles for ablation of the walls of the tract.

[86] The skilled person would consider that there is no inventiveness in the idea of using such ingestible devices in these ways. Further, the scant description of these embodiments in the specification indicates that no ingenuity was required in the practical implementation of the idea. Otherwise, if ingenuity had been required to achieve practical implementation of the idea, the specification would be considered insufficient for failing to disclose the technical details of such implementation.

[87] There being no inventiveness required to conceive the idea, and no ingenuity needed to

achieve practical implementation of the idea, claims 3-6 are considered to be obvious.

[88] In summary, claims 1-8 are obvious and do not comply with section 28.3 of the *Patent Act*.

RECOMMENDATION OF THE BOARD

[89] The Board recommends that the application be refused because: the claims on file (claims 1-8), comprise a method of medical treatment and fall outside the definition of "invention" in section 2 of the *Patent Act*; claims 1-2 and 7-8 are anticipated and do not comply with paragraph 28.2(1)(*b*) of the *Patent Act*; and claims 1-8 would have been obvious to the person skilled in the art on the claim date and thus do not comply with section 28.3 of the *Patent Act*.

Paul Fitzner	Paul Sabharwal	Andrew Strong
Membre	Membre	Membre

DECISION

[90] I concur with the Patent Appeal Board's findings and its recommendation that the application be refused because: the claims on file (claims 1-8) comprise a method of medical treatment and fall outside the definition of "invention" in section 2 of the *Patent Act*; claims 1-2 and 7-8 are anticipated and do not comply with paragraph 28.2(1)(*b*) of the *Patent Act*; and claims 1-8 would have been obvious to the person skilled in the art on the claim date and thus do not comply with section 28.3 of the *Patent Act*.

[91] Accordingly, in accordance with section 40 of the *Patent Act*, I refuse to grant a patent on this application. Under section 41 of the *Patent Act*, the Applicant has six months within which to appeal my decision to the Federal Court of Canada.

Agnès Lajoie
Assistant Commissioner of Patents

Dated at Gatineau, Quebec,
this 5th day of August, 2015