Citation: Stukanov, Igor (Re), 2021 CACP 44
Commissioner's Decision #1597
Décision du commissaire nº 1597
Date: 2021-10-22

TOPIC:	A11	New Matter
	B00	Ambiguity or Indefiniteness
	B22	Not Supported by Disclosure
	C00	Adequacy or Deficiency of Description
	G00	Utility
	J00	Meaning of Art
	J50	Mere Plan
	O00	Obviousness
SUJET:	A11	Nouvelle matière
	B00	Caractère ambigu ou indéfini
	B22	Non appuyée par la divulgation
	C00	Caractère Adéquat ou Inadéquat de la Description
	G00	Utilité
	J00	Signification de la technique
	J50	Simple plan
	O00	Évidence

Application No. : 2,674,487

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,674,487, 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 2,674,487, entitled "A Low-Cost Method For Reducing Rates Of Side Effects From Using Drugs, Healing Substances And Medical Procedures" and owned by Igor Stukanov.

[2] A review of the rejected application has been conducted by the Patent Appeal Board (PAB) 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 2,674,487 (the instant application) was filed in Canada on August 17, 2009 and was laid open to the public on February 17, 2011.

[4] The application relates to methods for reducing rates of side effects in humans or animals from using drugs, healing substances, or medical procedures. The methods segment a set of variables affecting efficiency of a medical treatment and determine segments with minimal or acceptable rates of side effects.

Prosecution history

[5] On March 1, 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 July 28, 2015 are not reasonably inferable and do not comply with section 38.2 of the *Patent Act*.
- The claims 1-5 lack support and do not comply with section 84 of the former *Rules*.
- The claims 1-5 are directed to matter outside of the categories of invention, and do not comply within section 2 of the *Patent Act*.
- Claims 1 and 4 are indefinite and do not comply with subsection 27(4) 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 a April 30, 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 August 30, 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.

[8] With a letter dated September 13, 2018, the PAB sent the Applicant a copy of the SOR and asked the Applicant to confirm continued interest in having the application reviewed. In a response dated November 5, 2018, the Applicant confirmed his continued interest in having the application reviewed by the PAB. We also note the Applicant's requests for information regarding the status of this review dated February 25, 2020 and March 8, 2021.

[9] 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.

[10] In a Preliminary Review letter (PR letter) dated April 30, 2021, 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 supported by the description. However, the Panel also set out its preliminary analysis and rationale that:

- Claims 1 and 4 are indefinite and do not comply with subsection 27(4) of the *Patent Act*;
- The specification is insufficient and does not comply with subsection 27(3) of the *Patent Act*;
- The claims 1-5 are directed to non-patentable subject matter prohibited under subsection 27(8) of the *Patent Act* and that falls outside the definition of "invention" in section 2 of the *Patent Act*;
- The claims 1-5 are directed to subject matter that lacks utility and do not comply with section 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*.

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

[12] In a response to the PR letter (RPR) dated May 11, 2021, the Applicant argued for

allowance of the application and included a set of proposed claims 1-6.

[13] As a result of several email exchanges with the Applicant, an oral hearing was scheduled and held June 3, 2021.

ISSUES

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

- Whether the claims and description encompass new matter and are non-compliant with section 38.2 of the *Patent Act*;
- Whether claims 1 and 4 are indefinite and do not comply with subsection 27(4) of the *Patent Act*;
- Whether the claims 1-5 are supported by the description and comply with section 60 of the *Patent Rules* (equivalent to section 84 of the former *Rules*);
- Whether the specification is insufficient and does not comply with subsection 27(3) of the *Patent Act*;
- Whether the claims 1-5 define non-patentable subject matter and are non-compliant with section 2 and subsection 27(8) of the *Patent Act*;
- Whether the claims 1-5 encompass subject matter that lacks utility and are non-compliant with section 2 of the *Patent Act*; and
- Whether the claims 1-5 are obvious and are non-compliant with section 28.3 of the *Patent Act*.

[15] 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

[16] 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.

[17] "Patentable Subject-Matter under the *Patent Act*" (CIPO, November 2020) [*PN2020–04*] also discusses the application of these principles, pointing out that all elements set out in a claim are presumed essential unless it is established otherwise or such presumption is contrary to the claim language.

New matter

[18] 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.
> …

[19] 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.

Indefiniteness

[20] 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.

[21] 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.

Lack of support

[22] Section 60 of the *Patent Rules* (equivalent to section 84 of the former *Rules*) states:

> The claims must be clear and concise and must be fully supported by the description independently of any document referred to in the description.

[23] We note that there is little judicial guidance on the requirements of that section, or any of its predecessor equivalents. *Manual of Patent Office Practice* [*MOPOP*] section 16.05 (CIPO, October 2019) states:

> A claim must be fully supported by the description as required by section 60 of the *Patent Rules*. All the characteristics of the embodiment of the invention which are set forth in the claim must be fully set forth in the description (Section 60 of the *Patent Rules*). However, since any claims included in the application at the time of filing are part of the specification (see subsection 27(4) of the *Patent Act* and the definition of "description" in subsection 1(1) of the *Patent Rules*), any matter in the originally filed claims that was not included in the description as filed may be added to the description (except for divisional applications which have further requirements regarding new subject-matter see section 20.01.02a for more details).

Insufficient specification

[24] 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;
> …

[25] 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*].

[26] 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).

[27] 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".

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

Patentable subject matter

[29] 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.

[30] Subsection 27(8) of the *Patent Act* also prescribes that:

> No patent shall be granted for any mere scientific principle or abstract theorem.

[31] *PN2020–04* describes the Patent Office's approach to determining if a claim is patentable subject matter:

> To be both patentable subject-matter and not be prohibited under subsection 27(8) of the *Patent Act*, the subject-matter defined by a claim must be limited to or narrower than an actual invention that either has physical existence or manifests a discernible physical effect or change and that relates to the manual or productive arts, meaning those arts involving or concerned with applied and industrial sciences as distinguished in particular from the fine arts or works of art that are inventive only in an artistic or aesthetic sense.

This references, in part, *Canada (Attorney General) v Amazon.com, Inc*, 2011 FCA 328 [*Amazon*] at paras 42 and 66-69.

[32] *PN2020–04* further describes the Patent Office's approach to determining if a computer-related invention is patentable subject matter. For example, the mere fact that a computer is among the essential elements of the claimed invention does not necessarily mean that the claimed invention is patentable subject matter. An algorithm itself is abstract and unpatentable subject matter. A computer programmed to merely process the algorithm in a well-known manner without solving any problem in the functioning of the computer will not make it patentable subject matter because the computer and the algorithm do not form part of a single actual invention that solves a problem related to the manual or productive arts. On the other hand, if processing the algorithm improves the functionality of the computer, then the computer and the algorithm would together form a single actual invention that solves a problem related to the manual or productive arts and the subject matter defined by the claim would be patentable.

[33] In *Schlumberger Canada Ltd v Commissioner of Patents*, [1982] 1 FC 845 (CA) [*Schlumberger*], the court concluded that, although computers were necessary for the invention to be put into practice, the computer did not form part of "what has been discovered" and thus was not relevant in determining whether the claimed invention was patentable subject matter; the computer was merely being used to make the kind of

calculations it was invented to make.

[34] Furthermore, methods of medical treatment are not patentable: "[a] method which provides a practical therapeutic benefit to a subject … is considered to be a method of medical treatment and is therefore not patentable" according to *MOPOP* section 23.03.01 (CIPO, January 2009), supported by case law, for example, *Tennessee Eastman v. Commissioner of Patents*, (1972), 8 C.P.R. (2nd), 203 (S.C.C.).

Lack of utility

[35] Section 2 of the *Patent Act* requires that the subject matter of a claim be "useful":

> **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; [emphasis added]

[36] *MOPOP* section 19.01.01 (CIPO, November 2017) states:

> To be considered to have utility an invention must be controllable and be reliably reproducible; the desired result must inevitably follow when the invention is put into practice and may not be left up to chance.
> …
> Inventions which are arrived at by chance and which cannot be reliably reproduced lack utility. An invention that relies upon the judgment or reasoning of an operator is considered to lack reproducibility and thus, lacks utility. Certain mental steps involving the ascertaining and sensing facilities have precise and predictable results, and do not of themselves cause the art or process that relies on them to lack utility. Whenever a person is called upon to perform a subjective judgement, however, the result will invariably be subject to factors such as intuition, creativity, conjecture and approximation, and the result will not be objectively controllable or reproducible.

Obviousness

[37] 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.

[38] 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?

ANALYSIS

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

Overview of the instant application

[39] As stated above, the instant application relates to methods for reducing rates of side effects in humans or animals from using drugs, healing substances, or medical procedures. The methods segment a set of variables affecting efficiency of a medical treatment and determine segments with minimal or acceptable rates of side effects.

[40] The application at the time of the FA includes five claims. There is one independent claim, claim 1. Dependent claims 2 to 5 all depend on claim 1. All claims are directed to a low-cost method for reducing rates of side effects from using drugs, healing substances, and medical procedures for medical treatments of humans or animals.

[41] 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, assess the new matter defect to determine the appropriate claim set for review, and finally construe the appropriate claim set.

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

[42] The PR letter at pages 3-4 preliminarily adopted the characterization of the person skilled in the art as identified in the FA:

> The FA at page 4 identified the person skilled in the art … as follows:
>
> > *The person skilled in the art (POSITA)*
> >
> > The person skilled in the art is a person, or a team of people, skilled generally in the field of drug harm-reduction, and more specifically in the field of statistical and numerical analysis relating to drug side-effects data from clinical research. The person or team would be familiar with extracting data resulting from clinical trials and applying known optimization techniques in order to formulate policies, recommendations, and mappings in using drugs, healing substances, and medical procedures. The team would also comprise computer hardware and software engineers skilled in computer programming to realize a computerized implementation.

[43] There is nothing in the prosecution record, including in the RPR or in the oral submissions at the hearing, that the Applicant disagreed with this characterization of the person skilled in the art and thus we adopt it for the purposes of this review.

[44] The PR letter at pages 4-5 reviewed the CGK from the FA and from cited prior art D1-D3 in the FA. The PR letter also introduced prior art document D4 as evidence of both the CGK and relevant to our analysis:

D1:	US 7,542,961	Gogolak	June 2, 2009
D2:	US 2004/0162835	Ghouri	August 19, 2004
D3:	US 2001/0001144	Kapp	May 10, 2001
D4:	WO 2006/113987	Dranitsaris et al.	November 2, 2006

[45] Referencing the FA, the PR letter at pages 3-4 identified the CGK as follows:

> The FA at page 4 identified … the relevant CGK as follows:

> *Common general knowledge*
>
> The common general knowledge of the person skilled in the art is demonstrated by the background of the invention and includes knowledge of various approaches to reduce rates of side-effects of drugs using numerical optimization techniques in order to determine an optimal policy.
>
> In addition, given the lack of detail in the present description, it is presumed that the optimization techniques and their implementation on a computer system would have been within the common general knowledge of the person skilled in the art.

[46] Referencing the cited prior art, the PR letter at page 4 identified further insights to the CGK:

> Prior art documents D1-D4, in their background sections and other references to known techniques in the art, offer further insights into the CGK relevant to our review:
>
> - Researchers and drug companies seek to analyse and predict adverse reactions in clinical trials of drugs (D1, column 1, lines 45-50);
> - The use of public databases to monitor and track adverse events related to drug use as reported to regulatory authorities (D1, column 8, lines 8-33);
> - The use of algorithms to correlate data (D1, column 16, lines 18-22);
> - Physicians estimate both the probability/extent of benefits and the probability/extent of harm for any treatment (D4, page 4, line 10 to page 3, line 35);
> - Quantifiable characteristics provide an indication of the presence or absence of toxic events (D4, page 17, lines 12-26);
> - The use of diagnostic tests to determine side effects of drugs (D2, paragraph [0070]); and
> - The acquisition and publication of clinical information regarding drug interactions (D2, paragraphs [0003]-[0015]; D3, paragraphs [0005]-[0011]).

[47] Finally, the PR letter at page 4 noted that the Applicant also made assertions with respect to the CGK during the prosecution of this application:

> The Panel notes that the Applicant has emphasized during the examination of the application that the CGK includes:
>
> - The determination of segmentation [parameters] and partitions levels by experts (Applicant's response May 28, 2014, page 1); and

- The result of each step of claim 1 "is obtained by any method available in the public domain and which is well known to any person skilled in the art" (Applicant's response July 28, 2015, page 21) supported by an Appendix (Applicant's response July 28, 2015, page 23) citing:
    - Rl::: Artificial Neural Nets and Genetic Algorithms: Proceedings of the International Conference in Ales, France, 1995
    - R2::: Expert judgement as an estimating method. R.T. Hughes, Information and Software Technology, Vol.38, Issue 2, 1996, p.67-75.
    - R3::: Parametric Optimization and Related Topics V: Proceedings of the International Conference on Parametric Optimization and Related Topics, Tokyo (Japan), October 6-10, 1997.

[48] Again, there is nothing in the prosecution record, including in the RPR or in the oral submissions at the hearing, that the Applicant disagreed with this characterization of the CGK. Thus we adopt all the preceding elements as CGK for the purposes of this review.

New Matter

[49] Claims and a description were originally filed August 17, 2009. Amendments were made to both the claims and the description on July 28, 2015 in response to an Office Action. Subsequently, the Examiner raised a new matter defect on the amendments in an Office Action dated March 1, 2016. Subsequent amendments were made to the claims and description on March 9, 2016 and on November 14, 2016. The Examiner continued to identify a new matter defect in each subsequent Office Action, including the FA. We assess both the claims and the description for new matter.

The claims as amended

[50] The claims on file at the time of the FA (the claims on file), that is, the claims amended November 14, 2016, are as follows (emphasis added, with underlines and strikethroughs representing additions and deletions as compared to the claims as originally filed):

1. A low-cost method for reducing rates of side effects from using drugs, healing substances, and medical procedures for medical treatments of humans or animals, comprising the following steps:
    a. segmentation parameters affecting efficiency of the medical treatment are determined by experts or a computer system;
    b. a partition levels of a parametric set, defined by the segmentation parameters, is

are determined by the experts or a computer system;

c. the boundaries of the partition levels determine segments of the parametric set;
d. for each segment defined by the partition levels, a number of side effects is calculated based on the results of clinical trials;
e. segments with minimal rate of side effects are selected, which define category of patients for which this treatment has minimal rate of side effects.

2. A method as in claim 1, where instead of segments with minimal rate of side effects, segments with minimal rate of side effects and maximal efficiency are selected.

3. A method as in claim 1, where instead of segments with minimal rate of side effects, segments with maximal efficiency and limited rate of side effects are selected.

4. A method as in claim 1, where instead of segments with minimal rate of side effects segments with defined by the experts criteria are selected.

5. A method as in claim 1, where segmentation parameters and partitions are selected by a computer program, based on a supplied set of variables.

[51] The PR letter at page 6 assessed the amendments follows:

> With respect to the recitation of "a computer system" to the amended claim 1 steps a and b, in our preliminary view, this amendment does not represent new matter as the originally filed claim 5 recited that both segmentation parameters and partitions are selected by a computer program.
>
> With respect to the recitation of "partition levels" by which its boundaries define "segments" in the amended claim 1 steps b and c, in our preliminary view, this amendment does not represent new matter. The person skilled in the art would have reasonably inferred from the original specification, specifically Example 1 on pages 2-7 of the originally filed description, that this distinction merely clarifies that "partitions" have levels and that such levels define segments as recited in the originally filed claims.

[52] The Applicant did not dispute this analysis in either the RPR or in oral submissions at the hearing. Thus, our view is that the claims amended November 14, 2016 on file at the time of the FA do not encompass new matter and comply with section 38.2 of the *Patent Act*. We will analyze these claims in our review below.

The description as amended

[53] The FA at page 2 identified a new matter defect for the amended description:

> …support for the added pages of 9 to 15 outlining features of new Example 2 is not provided by the original specification or drawings. The features of maximization of efficiency for a drug and its derivatives as outlined by Example 2, and finding segmentations and a mapping which maximise the efficiency of treatments is not found in the originally filed specification or drawings.

[54] The FA on page 2 also considered the Applicant's arguments in response to the new matter defect identified in previous Office Actions. The Applicant emphasized in the RFA on page 2 that since the original specification was disclosed in general terms, then any specifics added by the amendment are considered disclosed as well.

[55] The PR letter on pages 7-8 detailed differences between the description amended November 14, 2016 and the originally filed description, namely: amendments to the "Brief Summary of the Invention"; added text and a Table 1 to the originally described Example 1; and a new Example 2. The PR letter at pages 8-9 preliminarily assessed these amendments as follows:

> With respect to the amended text in the "Brief Summary of the Invention", the question is whether the various means to select segmentation parameters, the various means to partition the segmentation parameters, and the criteria for optimization would have been reasonably inferred from the original specification by the person skilled in the art.
>
> The characterization of the person skilled in the art (see above) and their CGK included skills in the field of statistical and numerical analysis relating to drug side-effects data from clinical research. The originally filed Example 1 and the originally filed claims would have led the person skilled in the art to reasonably infer these details.
>
> With respect to the additional text and Table 1 further describing Example 1, this text is merely an extension of the originally filed Example 1 to drug derivatives. The Table is representative of potential results from the method as originally claimed. Thus, the person skilled in art would reasonably infer these details.
>
> With respect to the addition of the new Example 2, an objective to maximize efficiency, rather than reduce side effects, was recited in the originally filed claims 2 and 3. Determining segmentation parameters through neural network means are within the skill of the person skilled in art in the field of statistical and numerical analysis, as argued above. Segmentations/partitions based on blood type and glycemic index were disclosed in the originally description for Example 1. The text and Table 1 further describing Example 2 for drug derivatives is merely an extension of the example. As in the amendments for Example 1, Table

> 2 represents potential results from the method as originally claimed. Thus, the person skilled in art would reasonably infer all these details.

[56] The Applicant did not dispute this analysis in either the RPR or in oral submissions at the hearing. Thus, our view is that the description amended November 14, 2016 on file at the time of the FA does not encompass new matter and complies with section 38.2 of the *Patent Act*.

[57] In summary with respect to the new matter defect, we consider that the instant application under review includes both the claims and the description as amended November 14, 2016, on file at the time of the FA.

Purposive construction: Construing the claims on file

The person skilled in the art and the relevant CGK

[58] We adopt the characterization of the person skilled in the art and the relevant CGK as discussed above in the section "Purposive Construction: The person skilled in the art and the relevant CGK".

The claims

[59] As discussed above in the section "New matter", the claims as amended November 14, 2016 on file at the time of the FA will be reviewed.

Meaning of claim terms

[60] The PR letter at page 10 preliminarily construed the following terms:

> Although no claim terms were at issue during the examination of this application, our preliminary view is that the person skilled in the art with their common general knowledge would construe the following terms, when considering the whole of the specification, as follows:
>
> - A "segmentation parameter", determined by either experts or a computer system (claim 1, step a), is construed as any suitable patient attribute, such as blood type or glycemic index (see the description, Example 1);
> - A "partition level", determined by either experts or a computer system (claim 1, step b), is construed as a refinement of the segmentation parameter, based on determined levels, such as low, medium, or high values for a glycemic index (see the description, Example 1); and

- A "segment" (claim 1, step c) is construed as a combination of the various partitions levels for each segmentation parameter. For example, as per Example 1 in the description, two segmentation parameters were determined (blood type or glycemic index), with one segmentation parameter having four partition levels (blood groups based on the presence or absence of antigens) and the other segmentation parameter having three partition levels (glycemic index having low, medium, or high levels), thus resulting in a total of 12 segments when combined.

[61] As the Applicant did not comment on these claim terms as construed in either the RPR or in oral submissions at the hearing, we adopt them in this review.

The essential elements of the claims

[62] The PR letter at pages 10-11 identified the essential elements of the claims on file:

> The FA at pages 4-5 performed a purposive construction that resulted in a set of essential elements for certain claims according to a previous Patent Office practice, now superseded by *PN2020-04*. We undertake anew the identification of essential elements.
>
> Considering the claims on file and the whole of the specification, in our preliminary view, the person skilled in the art would understand that all the claim elements as written are essential: there is no use of language indicating that any of the steps in each claim are optional, a preferred embodiment or one of a list of alternatives.
>
> We do note however that claim 1 is directed to a set of essential elements comprising two optional embodiments, indicating by the use of language that steps a and b may be performed by either an expert or a computer system:
>
> - one embodiment in which <u>an expert determines</u> segmentation parameters and partition levels that determine segments of a parametric set for which a number of side effects is calculated based on the results of clinical trials of a treatment, wherein segments with minimal rate of side effects are selected that define a category of patients for which the treatment has minimal rate of side effects; and
> - a second embodiment in which <u>a computer system determines</u> segmentation parameters and partition levels that determine segments of a parametric set for which a number of side effects is calculated based on the results of clinical trials of a treatment, wherein segments with minimal rate of side effects are selected that define a category of patients for which the treatment has minimal rate of side effects.

> Dependent claim 2 refines the claim 1 step e that selects segments with minimal rate of side effects and maximal efficiency, instead of segments with minimal rate of side effects.
>
> Dependent claim 3 refines the claim 1 step e that selects segments with maximal efficiency and limited rate of side effects, instead of segments with minimal rate of side effects.
>
> Dependent claim 4 refines the claim 1 step e that selects segments defined by the experts criteria, instead of segments with minimal rate of side effects.
>
> Finally, dependent claim 5 restricts the two optional embodiments in claim 1 to the single embodiment by which the computer system determines segmentation parameters and partition levels.

[63] As the Applicant did not dispute this preliminary view in either the RPR or in oral submissions at the hearing, we consider that all method steps of the claims are essential.

Indefiniteness

[64] The FA at page 6 identified an indefiniteness defect with respect to claims 1 and 4:

> Claim 1 is further indefinite and does not comply with subsection 27(4) of the *Patent Act*. The claim outlines as a step: "c) the boundaries of the partition levels determine segments of the parametric set". However, this is not drafted as a method step and results in a lack of clarity.
>
> Claim 4 is indefinite and does not comply with subsection 27(4) of the *Patent Act*. The claim outlines "A method ... where instead of segments with minimal rate of side effects segments with defined by experts criteria are selected". It is unclear what is meant by "side effects segments", and it is suggested that a comma was intended to be placed between the words "effects" and segments". It is also unclear what is meant by "segments with defined by experts criteria".

[65] The RFA does not appear to address this particular defect.

[66] The PR letter at page 12 preliminarily assessed this defect as follows:

> With respect to the wording of claim 1 step c, while we agree the wording is not precise, our preliminary view is that the person skilled in the art, considering the specification as a whole, would have no difficulty in understanding that segments are determined by the partition levels of the segmentation parameters as described in the section "Meaning of claim terms" above. An editorial correction may be sufficient to address this defect, such as, "c) wherein the boundaries of the partition levels determine segments of the parametric set".

> With respect to the claim 4 term "side effects segments", we preliminarily agree that its wording appears to be missing a comma after the word "effects". With respect to the claim 4 phrase "segments with defined by experts criteria are selected", in our preliminary view, this too appears to be imprecise language and may be corrected by the deletion of the word "with", resulting in a phrase "segments ~~with~~ defined by experts criteria are selected". In our preliminary view, both these editorial issues identified in claim 4 would not affect the skilled person's understanding of the claim.
>
> In light of the above, we preliminarily agree with the FA that claims 1 and 4 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. However, we acknowledge that the person skilled in the art would have no difficulty in understanding these claims with suitable editorial corrections. We continue our analysis based on this understanding. As will be shown later in our analysis, other defects are determinative regarding the disposition of this rejected application.

[67] 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 these editorial corrections in the proposed claims.

[68] In light of the above, claims 1 and 4 on file are indefinite and do 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).

Lack of support

[69] The FA at page 3 identified a lack of support defect as follows:

> Regarding claim 1, the claim outlines the determination of segmentation parameters and partitions; however, these features are not supported by the description. Regarding claim 5, the claim outlines a selection to be made by a computer program, "based on a supplied set of variables"; however, details about a supplied set of variables or how a selection is made based on the set are also not found in the description.

[70] The FA continued with a summary of the Applicant's responses to several Office Actions identifying this defect during the examination of the application. The Applicant argued that such features were supported by Example 1 of the description or within the relevant public domain and thus would be understood by the person skilled in the art with their CGK. The FA at page 3 counters the Applicant's arguments asserting:

> In response, while "segmentation parameters" are at least explicitly outlined by Example 1 of the description pages, no enabling description is provided about what they are or how they are used, much less how they affect efficiency, as outlined in the claims. Furthermore, "partitions" are not supported in any way in the specification.

[71] The PR letter at page 13 preliminarily assessed this defect as follows:

> With respect to the literal support in the description of the features "segmentation parameters" and "partitions", we have already construed the meaning of these terms in the equivalent section above on "Purposive construction" based on Example 1 of the description. Thus, in our preliminary view, these features have support in the description.
>
> We also note that although the FA identified this defect under section 84 of the former *Rules*, the justifications provided in the FA regarding indefiniteness regarding the term "segmentation parameters", the term "partitions", and the recited claim 5 phrase "based on a supplied set of variables" more accurately describe non-compliance with the requirements for an enabling disclosure, that is, a defect under subsection 27(3) of the *Patent Act*. Since a defect under subsection 27(3) of the *Patent Act* has also been identified in the FA, any further concerns over non-compliance with section 60 of the *Patent Rules* are subsumed within our analysis of that defect below.

[72] The Applicant did not dispute this analysis in either the RPR or in oral submissions at the hearing. Thus, our view is that the claims are supported by the description and thus comply with section 60 of the *Patent Rules*.

Insufficient specification

[73] Although presented within the context of other defects, the FA at pages 3 and 5-6 argued that the specification does not enable the person skilled in the art to practice the invention, in particular the determination of segmentation parameters and partitions as recited in claim 1:

> In response, while "segmentation parameters" are at least explicitly outlined by Example 1 of the description pages, no enabling description is provided about what they are or how they are used, much less how they affect efficiency, as outlined in the claims. [FA, page 3; emphasis added]
> …
>
> The description does not set out clearly the various steps and their necessary sequence in the process in such full, clear, concise and exact terms as to enable a person skilled in the art to practice the invention. [FA, page 6]

[74] The PR letter at pages 15-16 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 invention identifies segments of patient categories in clinical trials with minimal side effects, or other defined criteria, as demonstrated by the claims and Example 1; and
> - the invention works by constructing segments of a parametric set, defined by segmentation parameters and partition levels, for which a number of side effects, or other defined criteria, is calculated for each segment based on the results of clinical trials, as demonstrated by the claims and Example 1.
>
> 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 the determination of the segmentation parameters and partition levels.
>
> Although the RFA did not directly address enablement, the Applicant submitted (Applicant's response dated April 25, 2013 at pages 1-2 to a previous Office Action, albeit in response to a different defect) the following:
>
> > Thirdly, there is a difference, when an expert provides information as input to the method versus when an expert makes decision to get the output during the execution of the method. In the case [where] only input is provided professional skills for execution of the method are not required; therefore in such case the method is patentable.
> >
> > Forthly [*sic*], theoretically and technically such partitions may be done by software algorithms based on knowledge available in public domain, but such software also must (as required by the Law) be approved by qualified persons.
>
> The Panel notes that the Applicant's submission confirms the language of the claim 1 (emphasis added):
>
> > a. segmentation parameters … are <u>determined by experts or a computer system</u>;
> > b. partition levels … are <u>determined by the experts or a computer system</u>;
>
> Given the Applicant's submission and the recited claim 1 steps a and b, the segmentation parameters and partition levels are determined by either experts or a computer system; the claimed steps of "determining" appears to be wholly outside the domain of the person skilled in the art and therefore is not described in the disclosure.

> Once the segmentation parameters and partition levels are determined through these external means, such data is then used by the person skilled in the art to perform the subsequent claimed method steps (claim 1, steps c, d, and e) of determining segments based on the segmentation parameters and partitions levels, calculating the number of side effects, or other defined criteria, for each segment, and selecting segments with minimal side effects, or other defined criteria. The claim 1, steps c, d, and e are described in Example 1.
>
> Since the person of skill in the art would not be able to perform the method claim 1 steps a and b of the invention using only the instructions contained in the disclosure, as these steps are within the domain of others, the specification does not enable the person of skill in the art to produce the invention as claimed.

[75] In the RPR at page 2, the Applicant disagreed with the preliminary assessment and asserted that "there are many methods for a person skilled in the arts to perform claim 1 steps a and b" (emphasis in the original) and then provided several examples of such methods:

> Case of humans as experts.
>
> > Method 1: -asks the experts about their opinions on the issues of interest and take a statistical average to eliminate a subjectivity bias, if it is needed.
> >
> > Method 2: -get books/articles/published works written by the experts and extract the required information from the sources.
> >
> > Method 3: -get medical data (results of treatments) and ask experts to perform the statistical analysis (correlations, regressions, classifications, segmentations, etc.) on the data to determine segmentation parameters and partitions affecting efficiency of the medical treatments and/or rates of side effects.
>
> Case of computers as experts.
>
> > Method 1: -use any open source AI (artificial intelligence) program to determine segmentation parameters and partitions affecting efficiency of the medical treatments and/or rates of side effects.
> >
> > Method 2: -program any relevant algorithm, for example the "backward propagation network" algorithm, to determine segmentation parameters and partitions affecting efficiency of the medical treatments and/or rates of side effects.

[76] With respect, the examples do not comport with the claim language. In each example under the heading "Case of humans as experts", the expert does something to create the necessary data and then the person skilled in the art manipulates that data for use in subsequent

method steps as claimed. However, as we asserted in the PR letter, the claim recites that segmentation parameters or partition levels are determined by experts. The claim does not say, for example, segmentation parameters or partition levels are determined using the data provided by experts. Thus the claim language itself puts the claim out-of-reach of the person skilled of the art. The claimed method steps of "determining" are wholly outside the domain of the person skilled in the art and are not enabled by the disclosure.

[77] Similar argument exists for the examples under the heading "Case of computers as experts". Once again, in each example given by the Applicant, the computer determines the segmentation parameters or partition levels through some algorithm programmed by an expert, something outside the domain of the person skilled in the art and not enabled by the disclosure.

[78] Alternatively, if the claim scope were interpreted to include the determination of values based on data provided by experts or computers, and if the steps involved in determination were considered to be part of the CGK, the "disclosure" requirement would be met. Nonetheless, the "enablement" requirement would not be met [see *MOPOP* 22.05.01 (CIPO, October 2010)].

[79] In such an alternative claim construction, our assessment is that the examples provided by the Applicant necessitate "undue experimentation" by the person skilled in the art to determine segmentation parameters or partition levels based on data produced by experts or a computer. These examples indicate significant experimentation would be necessary to determine segmentation parameters or partition levels: Which experts or computer algorithms should be solicited for data? What specific data from experts or computers should be used? Which statistical analysis techniques should be used to generate the desired parameters based on the data produced by the experts or computer algorithms?

[80] Therefore, in our view, even in the alternative, the description is not enabling, as the steps required of the person skilled in the art would rely on undue experimentation to determine segmentation parameters or partition levels.

[81] 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*.

Patentable subject matter

[82] In the FA at pages 4-5, having identified that the essential elements of the claims were directed to an abstract scheme, the Examiner concluded that the claims encompass subject matter that lies outside the definition of "invention" and does not comply with section 2 of the *Patent Act*. Given that our preliminary view of essential elements was identified under the guidance of a different Office Practice from that of the FA, we undertake anew the assessment of patentable subject matter.

[83] We consider the two optional embodiments of claim 1 identified above in the section "Purposive construction: Construing the claims on file" under the sub-heading "The essential elements of the claims", one involving an expert and the other involving a computer system. If either embodiment is considered to encompass unpatentable subject matter, then the claim does not comply with the *Patent Act*.

Optional embodiment involving experts

[84] The PR letter at page 17 set out its preliminary analysis with respect to patentable subject matter for the optional embodiment involving experts:

> We previously identified that the essential elements of independent claim 1 comprise a first optional embodiment in which an expert determines segmentation parameters and partition levels that determine segments of a parametric set for which a number of side effects is calculated based on the results of clinical trials of a treatment, wherein segments with minimal rate of side effects are selected that define a category of patients for which this treatment has minimal rate of side effects. Dependent claims 2-4 selects segments with different criteria instead of segments with minimal rate of side effects.
>
> This set of essential elements is directed to a disembodied idea. No physicality is involved in performing these methods steps. Rather, the subject matter of the claims is directed to an expert's evaluation of clinical trial data, something without physical existence and something that does not manifest a discernible effect or change.
>
> In addition, this set of essential elements is considered to be directed to pure mental processes and thus not directed to patentable subject matter: see, for example, [*Schlumberger*] at 206:
>
> > What is new here is the discovery of the various calculations to be made and of the mathematical formulae to be used in making those calculations. If those calculations were not to be effected by computers but by men, the subject-matter of the application would clearly be mathematical formulae and a series of purely mental operations; as such, in my view, it would not be patentable.

> …
> As to mental operations and processes, it is clear, in my view, that they are not the kind of processes that are referred to in the definition of invention in s. 2.
>
> In light of the above, our preliminary view is that with respect to the optional embodiment involving experts, claims 1-4 is directed to subject matter that is prohibited under subsection 27(8) of the *Patent Act* and falls outside the definition of "invention" in section 2 of the *Patent Act.*

Optional embodiment involving a computer system

[85] The PR letter at pages 17-19 also set out its preliminary analysis with respect to patentable subject matter for the optional embodiment involving a computer system:

> We previously identified a second optional embodiment for claim 1 in which a computer system determines segmentation parameters and partition levels that determine segments of a parametric set for which a number of side effects is calculated based on the results of clinical trials of a treatment, wherein segments with minimal rate of side effects are selected that define a category of patients for which the treatment has minimal rate of side effects. This second optional embodiment of claim is also equivalent to claim 5. Dependent claims 2-4 select segments with different criteria instead of segments with minimal rate of side effects.
>
> For this optional embodiment involving a computer, the essential elements comprise determining segments based on segmentation parameters and partition levels, calculating a number of side effects based on the results of clinical trials of a treatment, and selecting segments with minimal rate of side effects. Together, these steps represent the computer implementation of an abstract idea or scheme to define a category of patients for which the treatment has minimal side effects. All the computerized steps represent well-known computer-implemented steps of data input, output, and processing.
>
> According to *PN2020-04*, "[i]f a computer is merely used in a well-known manner, the use of the computer will not be sufficient to render the disembodied idea, scientific principle or abstract theorem patentable subject matter and outside the prohibition under subsection 27(8) of the *Patent Act*."
>
> As explained in *Amazon* (paras 61–63, 66, 69), a computer cannot be used to give an abstract idea a practical application satisfying the physicality requirement implicit in the definition of invention in section 2 of the Patent Act simply by programming the idea into the computer by means of an algorithm. This is the situation in [*Schlumberger*] at 205–206, where the computer was merely being used to make the kind of calculations it was invented to make.

> This is the situation for the second optional embodiment involving computers for claims 1-5, wherein the abstract scheme is implemented on the computer, but the computer is merely used in a well-known manner, does not form a single actual invention with the abstract scheme and thus does not render the scheme patentable subject matter.
>
> Accordingly, the abstract scheme to define a category of patients for which the treatment has minimal side effects has no physical existence itself and does not manifest a physical effect or change. Nor does the use of the computer in this case cause it to meet the physicality requirement. Thus, in our preliminary view, the actual invention of claims 1-5 is prohibited under subsection 27(8) of the *Patent Act* and the subject matter of claims 1-5 is not patentable subject matter and falls outside the definition of "invention" in section 2 of the *Patent Act*.

[86] The PR letter at page 19 expressed the preliminary view that considering either optional embodiment, claims 1-5 on file at the time of the FA are directed to non-patentable subject matter prohibited under subsection 27(8) of the *Patent Act* and falls outside the definition of "invention" in section 2 of the *Patent Act*.

[87] Without reference to either optional embodiment specifically, the Applicant asserted in the RPR at page 3 that the analysis does not consider the result of applying the method (emphasis in the original):

> The PAB's analysis on this issue is concentrated on **steps** of the method and **completely ignores the result of applications** of this method. The result is the reduction on X% (from 50% up to 100%) of cases with side effects and related to them death of patients. This is not a mental process, but a real physical result affecting our reality and human lives.
> …
> In the first method also some calculations are performed on steps, but once the optimal mapping of the segments to treatments, which minimize a number of side effects is determined, it allows to reduce a number of side effects and related deaths by administering optimized treatments to each category of patients in accordance with the parameters determined on the steps of the method.
> …
> The PAB erred by failing to consider results of applications of the method and instead concentrated on steps of the method.

[88] With respect, our preliminary analysis did not consider the application of the method results as the claims on file do not include any step of applying the method results. Claim 1 step e recites "segments with minimal rate of side effects are selected, which define category of patients for which this treatment has minimal rate of side effects" (emphasis added) but the claim does not recite the application of such segments. Similarly, claims 2-

4, dependent on claim 1, define and select segments with other defined criteria instead of segments with minimal rate of side effects. Claim 5, also dependent on claim 1, is directed to selecting segmentation parameters and partitions by a computer. None of these claims recite a step of applying such defined segments.

[89] The Applicant at page 3 appears to provide an attempt to remedy this deficiency by proposing a new claim 6: "If the PAB would not mind, it is possible to add the 6-th claim to directly reflect on the fact of applications of the method to solve the problem stated." Proposed claim 6 is as follows:

> 6. A method of claims 1-5, where the determined medical treatments, corresponding to segments with minimal numbers of side effects, are administered to each group of patients, defined by the determined segments of the parametric set, which results in the minimization of side effects or optimization of criteria defined in the claims 2-5.

[90] Notwithstanding any claim clarity defects (for example, proposed claim 6 may be viewed as ambiguous for its circular claim dependency references), we understand the claim is directed to applying the method results of claims 1-5 to a group of patients. Such a step as embodied in proposed claim 6 reciting "the determined medical treatments … are administered to each group of patients" is viewed as a method of medical treatment and not patentable according to *MOPOP* section 23.03.01 (CIPO, January 2009).

[91] This assessment of the purpose of claim 6 appears to be supported by the Applicant. In the RPR at page 4 it states:

> Fourthly, the PAB had missed from the consideration the practical problem which this invention solves and concentrated only on the analysis stage. <u>The analysis stage gives us information we need to optimize medical treatments</u> in such way as to reduce in a maximal possible way side effects for different groups (identified by similar parameters, which include physical and physiological parameters, as shown in examples of the description) of patients. (original emphasis removed and new emphasis added)

[92] Thus, even if the proposed claim provides a required application of the method steps of claims 1-5, it would still not be patentable as it is directed to a method of medical treatment, confirmed by the Applicant's response in the RPR.

[93] In light of the above, we view that considering either optional embodiment, claims 1-5 on file at the time of the FA are directed to non-patentable subject matter prohibited under

subsection 27(8) of the *Patent Act* and falls outside the definition of "invention" in section 2 of the *Patent Act*.

Lack of utility

[94] During the Panel's preliminary review, a question arose as to whether there was a further contravention of section 2 of the *Patent Act* related to a lack of utility. 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.

[95] The PR letter at pages 19-21 assessed the lack of unity defect and informed the Applicant of our preliminary view that the claims on file encompass subject matter that lacks utility:

> Two optional embodiments of claim 1 were identified above in the section "The essential elements of the claims". If either embodiment is considered to encompass unpatentable subject matter that lacks utility, then the claim does not comply with the *Patent Act*.
>
> In the optional embodiments, the claimed method steps include the determination of segmentation parameters and partition levels either by an expert or a computer system (the programming of such system approved by experts, as indicated by the Applicant in the response dated April 25, 2013, referenced previously). With regards to both embodiments, the process by which the expert determines these parameters, either directly or through the approval of a computer system programming, must be assessed in order to whether the invention is "controllable and be reliably reproducible".
>
> Although a lack of utility defect was not identified in the FA, the Examiner had identified this defect in several Office Actions during the examination of this application (see for example, April 10, 2013, November 26, 2014, July 13, 2015, and March 1, 2016). The Examiner's position is best summarized in the Office Action dated March 1, 2016 at pages 2-3:
>
> > Claim 1 outlines method steps pertaining to medical determinations to be made by "experts". If an expert is required to make a medical determination, then a professional skill is required in the claimed method Patentable art, however, cannot rely on professional skill for its performance.
> >
> > Claims 2 to 5 are dependent on claim 1 and are also object to for the same reason.

The corresponding Applicant's response dated March 9, 2016 also summarizes the Applicant's position maintained throughout the examination process with regards to this defect:

> The Examiner is using an assumption that if some information from an expert is used in a procedure, the result of this procedure will depend on the expert's skills. But this assumption is not always true. From the fact that we ask an expert about some information, which will be used in some procedure **DOES NOT** follow in any way that results of this procedure always will depends on the expert skills.
> …
> The [previous section on utility] of the Manual of Patent Office Practice requires that invention must be controllable and reproducible. Any person skilled in the art by following the steps of the proposed method (see claim 1) will arrive in a controllable way to the same reproducible result - reduction of side effects/maximization of efficiency, etc. [emphasis in the original]

The Panel understands the Applicant to be asserting that since the claimed invention only uses the data provided by the experts, then the use of that data in the remaining method steps is controllable and reproducible.

However, the claimed invention recites steps where the segmentation parameters and partition levels are "determined" by an expert or a computer system, not merely "used", according to the recited claim 1 steps a and b (emphasis added):

a. segmentation parameters … are <u>determined</u> by experts or a computer system;
b. partition levels … are <u>determined</u> by the experts or a computer system;

There is no disclosure of how these particular steps are performed, as assessed above in the section on "Insufficient specification". Further, there is no evidence on file to suggest that the claimed methods steps of determining segmentation parameters and partition levels by an expert does not include "factors such as intuition, creativity, conjecture and approximation". Thus, the resulting data produced by the "determination" steps performed by an expert may not be objectively controllable or reproducible and thus lacks utility.

[96] In the RPR at pages 3-5, the Applicant correctly summarized that the main basis of our assessment is the lack of objectively controllable or reproducible results in determining the segmentation parameters and partition levels by experts or a computer system. The Applicant responded by asserting that the claims are controllable and reproducible (emphasis in the original):

> First of all, the PAB confuses opinions of experts with opinions of non-experts. Experts have knowledge, they **know the answers**, therefore their answers will be

> highly correlated. For example, if we ask experts to give us 6 digits of the number PI, they give us the **same answer**, because they **know the answer**. This answer is **controllable and reproducible** by any person who asks the experts.
>
> Secondly, even if we consider non-experts, but take a statistical average of their estimations we still receive a **controllable and reproducible** result (with a specified degree of accuracy), according to the **Central Limit Theorem**.
>
> The PAB's argument is a **fallacy**, because it contradicts not only to the facts that opinions of experts are highly correlated, therefore are **controllable and reproducible**; computer implemented methods, which solve problems in the real world are patentable; but also to the **Central Limit Theorem** on which many modern industries and fields of sciences are based.
>
> Thirdly, if we give the same data to a computer for performing the same set of instructions on the data, we **always** will receive the **same result**, which is **controllable and reproducible** by any person. Therefore, if we give to a computer, data of results of medical treatments and this computer performs a segmentation analysis according to a set of instructions, we always receive the same controllable and reproducible result.
>
> Fourthly, the PAB had missed from the consideration the **practical problem** which this invention **solves** and concentrated only on the analysis stage. The analysis stage gives us information we need to **optimize** medical treatments in such way as to reduce in a **maximal possible way side effects** for different groups (identified by similar parameters, which include physical and physiological parameters, as shown in examples of the description) of patients. To reach this goal, the method determines groups of patients (based on the parameters) for which particular treatments will be optimal (results in the minimal number of side effects and/or maximal efficiency). As the result of this we get a significant reduction of side effects and deaths of real persons (which is a physical process in the real physical world, not in our imagination).
>
> Fifthly, MPOP's section 14.03 (modified in October 2019) states: "Being a **solution to a practical problem** is what provides to the invention the **practical utility** necessary for patentability". The present invention solves very important and practical problems and in addition to this, solves them in a highly efficient and cost effective way. Therefore, the proposed invention has the practical utility necessary for patentability.

[97] With respect, we are not persuaded by the Applicant's arguments.

[98] With respect to the Applicant's first argument, the Applicant made clear in oral submissions at the hearing that if one asked any expert, one would always receive the same answer. Since the experts provide the same answers, experts' data will be controllable and

reproducible. With respect, we do not agree. Experts are subject to their own experiences, biases, education, focus areas and thus will often disagree or at least provide varying degrees of agreement. One need only search patent databases to realize that those skilled in the art, or "experts" can realize multiple, sometimes even conflicting, devices, methods or systems to solve a similar problem. There would be no scientific or technological advancements if the same answer were always received by "experts".

[99] With respect to the Applicant's second argument, as discussed above in the section "Insufficient specification", such an argument exceeds the scope of the claim that recites segmentation parameters or partition levels are determined by experts. Such an argument puts the onus for determining these parameters onto the person skilled in the art which does not comport with the claim as recited.

[100] With respect to the Applicant's third argument, we agree that a computer, once programmed, will give controllable and reproducible results. However, the Applicant has made clear previously that the computer has been programmed by an expert (see the Applicant's response dated April 25, 2013 at pages 1-2) and the fallibilities of the expert will be inherited in the computer algorithm. Thus, data produced by computers programmed by different experts may not agree with each other.

[101] With respect to the Applicant's fourth and fifth arguments, there is no claimed method step that provides a practical implementation, as we assessed above in the section on "Patentable subject matter". The claims are directed only to data analysis steps that ends with the selection of segments with minimal rate of side effects.

[102] In our view then, as stated in the PR letter, there is no evidence on file to suggest that the claimed methods steps of determining segmentation parameters and partition levels by an expert does not include "factors such as intuition, creativity, conjecture and approximation" as discussed in *MOPOP* section 19.01.01 (CIPO, November 2017). Thus, the resulting data produced by the "determination" steps performed by an expert, a computer or both may not be objectively controllable or reproducible and thus lacks utility.

[103] In light of the above, in our view, the claims on file encompass subject matter that lacks utility, contrary to section 2 of the *Patent Act*.

Obviousness

[104] During the Panel's preliminary review, a second question arose as to whether there was a further contravention of section 28.3 of the *Patent Act* related to obviousness. According to subsection 86(9) of the *Patent Rules*, we also informed the Applicant of this defect in the PR letter and invited the Applicant to submit arguments.

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

[106] As a preliminary matter, the Applicant argues in the RPR at page 5 that our position on obviousness is contradictory to our position on previous issues:

> The PAB's position on this issue **contradicts** to the PAB's position on the previous issues. In the previous issues, the PAB argued, that claim 1 steps a and b, make the proposed invention unpatentable. This means that the PAB admits that claim 1 steps a and b, constitute an essential difference, which distinguish the proposed invention from the prior arts D1-D4. But, the PAB's position on the issue of obviousness is the opposite, it states that a combination of D1-D4 would result in the proposed invention (so there is no any difference). Two contradictory positions can not be true at the same time, one of them is false. This contradiction shows that the PAB was biased and had a hidden intent to reject the patent application, in any way and by all means. (emphasis in the original)

[107] We readily admit that all steps of the claims are essential as we indicated in the PR letter and as we concluded above in the section "Purposive construction: Construing the claims on file", under the sub-heading "The essential elements of the claims". We also concluded above that the claims are not directed to patentable subject matter. However, this does not mean that that essential claim 1 steps a and b distinguish the claims over the prior art. Indeed, in our detailed analysis below, we assess that these claims steps are disclosed by the prior art. With respect, there is no contradictory position here.

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

[108] 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

[109] The PR letter at page 22 stated that the obvious analysis would proceed by considering all

recited claim elements:

> The Panel will analyse the claims on file taking into account all the elements of the claims as recited, as identified above in the section "The claims". By taking into account all the elements of the claims on file, as set out below, it is possible to reach a conclusion regarding obviousness of these claims that would not be affected by any error in claim construction.

[110] In the RPR at page 8, the Applicant responded as follows:

> On step 2 it is required to identify an inventive concept. The PAB did not identified an inventive concept of the proposed invention. Without an inventive concept, all other steps have no sense, because there is nothing to compare with.

[111] The *Sanofi* test at this step requires an inventive concept to be identified or the claim must be construed, either will suffice. In the analysis presented in the PR letter and below, we have assessed all the claim elements as construed, based on a reading of the claims informed by the specification (*Apotex Inc v Shire LLC*, 2021 FCA 52 paras 67 [citing *Ciba Specialty Chemicals Water Treatments Limited v SNF Inc*, 2017 FCA 225, paras 76-77] and 70).

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

[112] The PR letter at pages 22-23 describes the general relevance of D1 as follows:

> D1 appears to be most relevant to our obviousness analysis as it relates to the same art as the application under review. In particular, similar to the stated objective of the claimed invention in the application under review, D1 at column 4, line 65 to column 5, line 4 states that:
>
> > Further, with efficient and effective analysis of adverse drug effects, pharmaceutical research and development professionals can learn more details of the reaction profiles of drugs and the at-risk populations who may be prescribed those drugs. This information would allow a more effective selection of lead compounds and would produce drugs with less risk of adverse effects.
>
> The invention in D1 "relates to a system and method for assessing and analyzing the risks of adverse effects resulting from the use of a particular drug, either alone or in combination with other drugs, nutrients, supplements, and other substances" (D1, column 1, lines 7-11; column 3, lines 25-33; column 4, lines 9-22; column 4, lines 30-35; and column 4, lines 52-64) and addresses "a need for a more

> efficient and effective system and method for analyzing the risks of adverse effects resulting from the use of a particular drug on particular segments of the population" (D1, column 3, lines 25-33).
>
> Data used in the computerized system of D1 includes clinical trial data (D1, column 8, lines 4-7). The computerized system (D1, Figure 2) allows a user to select a particular drug to be analyzed (D1, Figure 2, reference 201; column 7, lines 36-42). The user proceeds to a profiler (D1, Figure 2, reference 202) which "displays statistics that describe the behavior of the drug of interest" (D1, column 7, lines 42-45). The user can employ one or more filters "which permit recalculation of the statistics by selecting among the available variables" (D1, column 7, lines 45-48). The filters are directed to multiple dimensions, including reactions and demographics (D1, column 9, lines 51-55; figure 4; column 10, lines 7-14). D1 describes the reactions dimension (D1, Figure 7, column 13, lines 4-39) and the demographics dimension (D1, Figure 9, column 14, lines 17-26). Once a set of cases has been established through the use of the filters, the cases may be submitted to data mining engines for further analysis (D1, Figure 2, reference 205; column 7, lines 48-56).

[113] The Applicant in the RPR at page 5 asserted that "D1 is 'a system and method for assessing and **analyzing the risks** of adverse effects....'. Therefore, it is a method of analysis, not a method to reduce side effects." (emphasis in the original)

[114] We agree insomuch as the invention in D1 is directed to a system and method for assessing and analyzing the risks of adverse effects resulting from the use of a particular drug. D1 explicitly recognizes that such systems and methods "allow a more effective selection of lead compounds and would produce drugs with less risk of adverse effects" (D1 at column 4, line 65 to column 5, line 4, as quoted above in the PR letter), similar to stated goals in the instant application. However, contrary to the Applicant's assertions in the RPR, there is no claimed method step that provides a practical implementation, as we assessed above in the section on "Patentable subject matter". The claims on file are directed to data analysis steps that ends with the selection of segments with minimal rate of side effects. In that sense, both D1 and the instant invention are directed to methods of data analysis.

[115] The Applicant in the RPR at page 5 further asserted that "D1 provides examples of analysis based on **reactions** and **demographics** dimensions" (emphasis in the original) and contrasted that to the proposed method that "includes **physical** and **physiological** parameters (which are not included in D1)." (emphasis in the original)

[116] With respect, there is nothing in the instant application that indicates segmentation parameters are limited to a patient's physical and physiological attributes. The examples in

the description only illustrate two segmentation parameters, namely, blood type and glycemic index. In the PR letter and above in the section "Purposive construction: Construing the claims on file", under the sub-heading "Meaning of claim terms" we construed the term "segmentation parameter" as any suitable patient attribute. The Applicant did not contest this construction. Thus, in our view, D1's gender and age dimensions fall within the meaning of the recited claim element "segmentation parameters" as construed.

[117] The Applicant in the RPR at page 5 further asserted that "pharmaceutical companies have being doing analyses based on **reactions** and **demographics** dimensions for over a century, but were not able to came to the proposed method before the method was published, which is a proof that the method is not obvious" (emphasis in the original). With respect, we disagree, as the detailed analysis below shows that the claims would have been obvious in view of the prior art.

[118] The Applicant in the RPR at page 6 further asserted that if the claimed invention is obvious, then it would have been used to reduce side effects from the COVID-19 vaccines. Since it is not being used, argued the Applicant, the claimed method must be inventive. We are not persuaded that this particular example of non-use demonstrates the claimed invention to be non-obvious, as there may be many other factors on why the claimed invention is not being used.

[119] The Applicant in the RPR at page 6 further asserts that "neither D1 or D4 sets an objective of the **optimal** goal (minimize a number of side effects in all treated patients by means of matching segments based on parameters, which include physical and physiological parameters, with treatments)" (emphasis in the original) which is further reflected in the RPR under the heading "6. Different concepts" spanning pages 6-7 and under the heading "7. Different solutions to different problems" on page 7. Again, with respect, we disagree. There is no mention of identifying "optimal" segments in the recited claims, rather segments are selected with minimal side effects, maximal efficiencies, or a combination of criteria. And, as discussed above, both D1 and the instant invention are directed to methods of data analysis. In any event, the detailed analysis below shows that the claims would have been obvious in view of the prior art.

[120] In view of the above, having considered all the Applicant's general arguments, we consider D1 to be most relevant to our obviousness analysis as it relates to the same art as the

application under review. We now assess the differences between D1 and each claim as assessed in the PR letter at pages 23-24:

> *Claim 1. A low-cost method for reducing rates of side effects from using drugs, healing substances, and medical procedures for medical treatments of humans or animals*
>
> The invention of D1 relates to a method for assessing and analyzing the risks of adverse effects resulting from the use of a particular drug on particular segments of the population. See for example: column 1, lines 7-11; column 3, lines 25-33; column 4, lines 9-22; column 4, lines 30-35; and column 4, lines 52-64.
>
> *comprising the following steps:*
>
> > *a. segmentation parameters affecting efficiency of the medical treatment are determined by experts or a computer system;*
> >
> > D1 discloses a demographics filter (D1, Figure 9, column 14, lines 17-26), based on gender and age. Gender and age are equivalent to the recited segmentation parameters, construed above as "any suitable patient attribute".
> >
> > *b. a partition levels of a parametric set, defined by the segmentation parameters, are determined by the experts or a computer system;*
> >
> > D1 discloses that "[t]he demographics filter allows selections of generational or individual age brackets, and male/female selections as well. Generational filters are preferably user definable." (D1, column 15, lines 52-54). Age brackets and male/female are equivalent to partition levels construed above.
> >
> > *c. the boundaries of the partition levels determine segments of the parametric set;*
> >
> > D1 discloses that data associated with a drug can be filtered based on demographics (D1, Figure 4, reference 402, column 9, lines 51-55).
> >
> > *d. for each segment defined by the partition levels, a number of side effects is calculated based on the results of clinical trials;*
> >
> > D1 discloses that the profiler displays the reactions dimension including the "reaction count" for the filtered data (D1, Figure 7, column 13, lines 17-31).
> >
> > *e. segments with minimal rate of side effects are selected, which define category of patients for which this treatment has minimal rate of side effects.*
> >
> > D1 does not explicitly disclose the "segments with minimal rate of side effects are selected".

> *Claim 2. A method as in claim 1, where instead of segments with minimal rate of side effects, segments with minimal rate of side effects and maximal efficiency are selected.*
> *Claim 3. A method as in claim 1, where instead of segments with minimal rate of side effects, segments with maximal efficiency and limited rate of side effects are selected.*
> *Claim 4. A method as in claim 1, where instead of segments with minimal rate of side effects segments with defined by the experts criteria are selected.*
>
> D1 does not explicitly disclose the embodiments of claims 2-4.
>
> *Claim 5. A method as in claim 1, where segmentation parameters and partitions are selected by a computer program, based on a supplied set of variables.*
>
> D1 discloses a computerized system (see for example, D1 claims directed to a "computer system" and "computer-implemented method").

[121] As the Applicant did not contest any of these detailed assessments, and consistent with our summary in the PR letter at page 24, we view that with respect to the *Sanofi* step 3 analysis, D1 does not explicitly disclose:

- Claim 1, step e "segments with minimal rate of side effects are selected"; and
- Claims 2-4, where instead of segments with minimal rate of side effects, segments with other defined criteria are selected.

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?

[122] The PR letter at pages 24-27 looked to the CGK and D4 to bridge the differences identified between the claimed invention and the prior art document D1:

> Regarding the first identified difference (claim 1, step e), the person skilled in the art would understand that although D1 does not explicitly disclose the "segments with minimal rate of side effects are selected", the system of D1 identifies at-risk populations based on the reactions to drugs that assist in, for example, drug development and medical providers in delivering medical services (see for example, D1 column 4, line 65 to column 5, line 36):
>
> > Further, with efficient and effective analysis of adverse drug effects, pharmaceutical research and development professionals can learn more details of the reaction profiles of drugs and the at-risk populations who may

> be prescribed those drugs. This information would allow a more effective selection of lead compounds and would produce drugs with less risk of adverse effects.
>
> Thus, the present invention allows for analysis of adverse drug effects with enhanced speed and flexibility. The present invention also offers new insights with regard to adverse drug effects and augments the existing processes of drug development.
>
> …
>
> It is an object of the present invention to provide a more efficient and effective system and method for analyzing the risks of adverse effects resulting from the use of a drug.
>
> …
>
> Yet another object of the present invention is to provide a more efficient and effective system and method useful for analyzing the risks of adverse effects resulting from the use of a drug, alone or in combination with another substance, wherein the substance is a nutrient, vitamin, hormone, or drug, further wherein the system and method can be used by providers of medical or veterinary care services.

Further, the person skilled in the art would understand that D1 may be used to assess correlations between outcomes and multiple dimensions of a individual or group (see for example, D1 column 20, lines 17-27) :

> It will further be appreciated that the system and method of the present invention has applications in risk assessment in the fields of demographics, phenotype, genotype, genomics, and proteomics. Specifically, the system and method of the present invention can be used assess the risk/susceptibility of an individual or a group of a possible outcome (for example, lung cancer, leukemia, Jacob-Kreutzfeld syndrome) based on phenotype, genotype, or environmental exposure. The system and method of the present invention permits a user to assess the correlation between a possible outcome and multiple dimensions of an individual or a group.

Based on these passages in D1, the person skilled in the art with their CGK would understand that, at least one purpose of the invention as disclosed by D1 is for medical providers to apply the results determined by the system of D1 (for example, correlations between population segments and reactions) in delivering medical services to at-risk populations. Thus, the difference between the claimed invention step of selecting segments with minimal side effects and the disclosure of D1 constitutes a step which would have been obvious to the person skilled in the art.

Regarding the second identified difference, (claims 2-4), the prior art document D4 is applicable in our analysis.

In the same art as the claimed invention in the application under review, the invention in D4 relates to:

> A system is provided for facilitating the development of an individualised treatment regimen for a patient based on an evaluation of the risk(s) associated with a disease and/or associated with known treatment options. In order to evaluate these risk(s), the system utilises clinical data from a plurality of patients having the disease in question. The clinical data includes information for each of the plurality of patients relating to the presence, absence and/or severity of one or more negative events. The negative event(s) can be disease-related, for example, a complication such as metastasis of a cancer to bone or the brain, or the negative event(s) can be treatment-related, for example a toxicity associated with the treatment. [D4, abstract]

The system of D4 uses clinical data, defined as follows (D4, page 14, lines 7-13):

> The clinical data for the system of the present invention is assembled from patients having the disease of interest, i.e. the "patient population," and includes information relating to the presence, absence and/or severity of one or more negative events, such as complications or toxicities, for each of the patients. The clinical data can be obtained from the scientific literature, from existing databases, from clinical trials and/or directed chart review.

The invention of D4 defines negative events as either disease related or treatment-related (D4, page 16, lines 26-29). Most relevant to the analysis of the claimed invention is treatment-related negative events defined as "negative events are generally toxicities (or 'toxic events') associated with the treatment the patient is undergoing" (D4, page 17, lines 5-6). D4 also provides a list of example toxic events with reference to cancer (D4, page 17, lines 6-11), including anaemia. D4 discloses the presence or absence of a treatment-related toxicities are determined by:

> For treatment-related negative events, such as treatment-related toxicities, in general a yes/no (i.e. present/absent) designation is assigned based on a "quantifiable characteristic" of the negative event and a pre-set cut-off value. The "quantifiable characteristic" can be evaluated through measurement, or it can be evaluated by comparing the severity of a characteristic with a standard scale and then according a "grade" to the negative event. For example, when the treatment-related toxic event is anaemia, haemoglobin levels can be measured; when the toxic event is neutropenia, neutrophil cell counts can be evaluated; for the toxic event thrombocytopenia, platelet counts can be evaluated. For other chemotherapy related toxic events, such as nausea, fever and the like, the severity of the event can be graded. Establishing grades for such toxic events is common clinical practice and is frequently used as an

> evaluation of the severity of side effects during clinical trials. Quantifiable characteristics that provide an indication of the presence or absence of other toxic events are known in the art.
>
> In our preliminary view, the D4 disclosure of "treatment-related negative events" determined through the evaluation of a "quantifiable characteristic" is equivalent to the claimed elements of a "side effect" that is related to "segments" defined by segmentation parameters and partition levels. For example, the D4 disclosure of the presence of a toxic event anaemia determined by haemoglobin levels is equivalent to the disclosure in the application Example 1 of a side effect recorded and segmented by blood type and glycemic index.
>
> D4 also discloses that the clinical data further comprises benefit data that patients derived from a treatment option including overall survival, disease control rates, restoration of functionality, etc. (D4, page 17, lines 5-16). As part of the D4 system's output, the analysis may include for example, "cumulative toxicity associated with each treatment regimen and plotting this against the average benefit (for example, overall survival) associated with the treatment option" (D4, page 18, lines 31-33) that may be graphically represented (see for example D4 Figure 1). Thus the system of D4 "provides for analysis of the clinical data to provide an indication of the risk/benefit ratio (or 'therapeutic index') associated with each treatment option and/or an indication of the probability that the individual patient under assessment will experience one or more of the negative events associated with a treatment option and/or disease." (D4, page 10, lines 18-22). D4 Example 3 (page 61, line 14 to page 70, line 7) describes an analysis of a benefit to toxicity ratio for a given treatment regime.
>
> In our preliminary view, the person skilled in the art would view such "benefit data" and the assessment of a benefit to toxicity ratio as disclosed in D4 as equivalent to the elements of claims 2-4 of "minimal rate of side effects", "maximal efficiency", or any other characteristics assessed in combination to identify population segments of interest.
>
> In light of the above, with regards to claims 2-4, it is our preliminary view that the assessment of both benefits and toxicities as disclosed in D4 constitutes a step that would have been obvious to the person skilled in the art starting with the system as disclosed in D1, In other words, instead of only assessing reactions of a treatment as disclosed in D1, the person skilled in the art would view the assessment of both benefits and toxicities as disclosed in D4 as an obvious extension to the invention of D1.

[123] Beyond the general arguments against the validity of D1 in our obviousness argument, as addressed above, the Applicant did not specifically contest our preliminary view regarding the first difference between the disclosure of D1 and the claimed invention, Specifically, we considered that difference – the claimed step of selecting segments with minimal side

effects – to constitute an obvious step.

[124] With respect to our assessment of the second difference, the Applicant submits in the RPR at page 6 that D4 cannot be combined with D1:

> Fifthly, the system in D4 "provides for **analysis** of the clinical data **to provide an indication** of the risk/benefit ratio (or '**therapeutic index**') associated with each **treatment** option and/or an **indication of the probability** that the individual patient under assessment will experience **one or more** of negative events associated with a treatment option and/or disease." As we can see this is a **rating system** for **analysis** of different treatments based on the **therapeutic index** and/or **probability** that the **individual patient** under assessment will experience **one or more** of negative events associated with a treatment option and/or disease. This system **has no any connections** to D1 or to the proposed invention. It is **not possible** to apply a rating system which is based on the **therapeutic index** and/or **probability** of an individual person (D4) to an analysis system which is based on reactions and demographics dimensions of groups of people (D1). They are not compatible. (emphasis in the original)

[125] We are not persuaded by this argument. As assessed in detail in the PR letter and quoted above, D4 discloses the assessment of both benefits and toxicities. Starting with a system as disclosed in D1, which assesses reactions of a treatment, D4's assessment constitutes an obvious step towards disclosing segments representing other criteria as claimed. We also consider D1, D4 and the instant application to all relate to the same art.

Conclusion on obviousness

[126] In light of the above, we view that claims 1 and 5 would have been obvious having regard to D1. Furthermore, we view that claims 2-4 would have been obvious to a person skilled in the art having regard to D1 in light of D4. Thus, the subject matter of the claims on file do not comply with section 28.3 of the *Patent Act*.

Proposed claims

[127] As discussed above under the section "Indefiniteness", the Applicant proposed to amend claims 1 and 4 as suggested in the PR letter. We agree that the editorial corrections proposed overcome the identified indefiniteness defect.

[128] However, as discussed above under the section "Patentable subject matter", the step embodied in proposed claim 6 reciting "the determined medical treatments … are administered to each group of patients" is considered to be a method of medical treatment

and is therefore not patentable according to *MOPOP* and case law.

[129] As the proposed claims do not address any other defects of the claims on file, the proposed claims suffer from the same defects of the claims on file with the same reasoning as above, namely, the proposed claims are not directed to patentable subject matter, the proposed claims lack utility, and the proposed claims are directed to subject matter that would have been obvious.

[130] In light of the above, it is our view that proposed claims 1-6 are not considered a necessary amendment under subsection 86(11) of the *Patent Rules*.

CONCLUSIONS AND RECOMMENDATION OF THE PATENT APPEAL BOARD

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

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

- Claims 1 and 4 on file are indefinite and do not comply with subsection 27(4) of the *Patent Act*;
- The specification is insufficient and does not comply with subsection 27(3) of the *Patent Act*;
- The claims on file are directed to non-patentable subject matter prohibited under subsection 27(8) of the *Patent Act* and that falls outside the definition of "invention" in section 2 of the *Patent Act*;
- The claims on file are directed to subject matter that lacks utility and do not comply with section 2 of the *Patent Act*; and
- The claims on file are directed to subject matter that would have been obvious and do not comply with section 28.3 of the *Patent Act*.

[133] We also conclude that the proposed claims 1-6 are not considered a necessary amendment under subsection 86(11) of the *Patent Rules*.

Lewis Robart	Blair Kendall	Leigh Matheson
Member	Member	Member

DECISION OF THE COMMISSIONER

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

- Claims 1 and 4 on file are indefinite and do not comply with subsection 27(4) of the *Patent Act*;
- The specification is insufficient and does not comply with subsection 27(3) of the *Patent Act*;
- The claims on file are directed to non-patentable subject matter prohibited under subsection 27(8) of the *Patent Act* and that falls outside the definition of "invention" in section 2 of the *Patent Act*;
- The claims on file are directed to subject matter that lacks utility and do not comply with section 2 of the *Patent Act*; and
- The claims on file are directed to subject matter that would have been obvious and do not comply with section 28.3 of the *Patent Act*.

[135] 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 22nd day of October, 2021