Commissioner’s Decision #1459

Décision du commissaire n^{o} 1459

TOPIC:	F-00 (Novelty) O-00 (Obviousness) A-20 (Double Patenting)
SUJET :	F-00 (Nouveauté) O-00 (Évidence) A-20 (Double brevet)

Application No.: 2,496,581

Demande n° : 2 496 581

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,496,581, having been rejected under subsection 30(3) of the *Patent Rules*, has subsequently been reviewed in accordance with paragraph 30(6)(*c*) of the *Patent Rules*. The recommendation of the Patent Appeal Board and the decision of the Commissioner are to refuse the application if the necessary amendments are not made.

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INTRODUCTION

[1] This recommendation concerns the review of rejected patent application number 2,496,581 entitled "The use of erythropoietin in the treatment of disturbances of iron distribution in diabetes" and owned by F. Hoffmann-La Roche AG. The outstanding defects to be addressed are whether the subject-matter of claims 1-5 and 14 on file lacks novelty, whether the subject-matter of claims 1-53 on file would have been obvious and whether claims 1-53 on file are unpatentable on the grounds of double-patenting in view of the claims of issued patents 2,505,524 and 2,549,486, also owned by F. Hoffmann-La Roche AG. Paul Lehmann, Ralf Roeddiger and Ruth Walter-Matsui are named inventors in the instant application and the issued patents 2,505,524 and 2,549,486. A review of the rejected application has been conducted by the Patent Appeal Board pursuant to paragraph 30(6)(*c*) of the *Patent Rules*. As explained below, our recommendation is that the Applicant be notified that their proposed claim amendments be considered "necessary" amendments under subsection 30(6.3) of the *Patent Rules* for compliance with the *Patent Act* and *Patent Rules* and that the patent application be allowed if amended accordingly.

BACKGROUND

The application

[2] Patent application 2,496,581, based on a previously filed Patent Cooperation Treaty application, was effectively filed in Canada on August 20, 2003 and published on March 11, 2004.

[3] The application relates to the use of a hormone called erythropoietin (EPO) in the treatment of disturbances of bodily iron distribution in patients suffering from diabetes.

Prosecution history

[4] On January 21, 2014, a Final Action ("FA") was written pursuant to subsection 30(4) of the *Patent Rules*. The FA explained that the subject-matter of claims 1-5 and 14 on file lacks novelty, contrary to paragraph 28.2(1)(*b*) of the *Patent Act*; that the subject-matter of claims 1-53 on file would have been obvious, contrary to section 28.3 of the *Patent Act*; and that claims 1-15 and 36-42 on file are unpatentable on the grounds of double-patenting in view of copending application 2,505,524 and copending application 2,549,486 (now issued to patent).

[5] In a response to the FA ("R-FA") dated June 2, 2015, the Applicant expressed his disagreement with respect to the defects identified in the FA but nonetheless submitted a set of 51 amended claims (the "proposed claims set-1") and provided arguments as to why the subject-matter of the proposed claims was patentable and not open to objection for the reasons outlined in the FA.

[6] As the Examiner was not persuaded by the Applicant's arguments with regard to the claims on file and considered that the proposed claim set-1 would not overcome the double-patenting defect, the rejected application was forwarded to the Patent Appeal Board ("the Board") for review, along with a Summary of Reasons ("SOR"). Although the SOR stated that the amendments found in proposed claims set-1 overcome the lack of novelty and obviousness defects, the SOR also stated that the double-patenting defect was maintained for the reasons indicated in the FA. The SOR further invited the Board to consider whether claims 16-35 and 43-53 on file are also the subject of double patenting in view of (then) copending application 2,505,524 and issued patent 2,549,486.

[7] In a letter dated February 25, 2016, the Board forwarded the Applicant a copy of the SOR and offered the Applicant an opportunity to make further written submissions and/or attend an oral hearing.

[8] In a letter dated May 25, 2016, the Applicant expressed the wish to not participate in an oral hearing at that time. In the same letter, the Applicant submitted a second set of 51 amended claims (the "proposed claims set-2") that corrected a minor dependency issue found in the proposed claims set-1 and provided written submissions in response to the SOR (the "R-SOR") as to why there is no double-patenting issue between the instant application and (then) copending application 2,505,524 and issued patent 2,549,486.

[9] The present Panel was formed to review the application under paragraph 30(6)(*c*) of the *Patent Rules* and make a recommendation to the Commissioner as to its disposition. In a letter dated November 22, 2017 (the "Panel Letter"), we clarified that the proposed claims set-1 and proposed claims set-2 have not been entered as an amendment and that the claims under review are, in accordance with paragraph 30(6)(*b*) of the *Patent Rules*, claims 1-53 on file at the time of the FA.

[10] In the same letter, we considered whether the instant application does not comply with the *Patent Act* and *Patent Rules* with respect to defects other than those indicated in the FA, pursuant to subsection 30(6.1) of the *Patent Rules*. More specifically, we considered whether claims 16-35 and 43-53 on file are unpatentable on the grounds of double-patenting in view of the claims of issued patents 2,505,524 and 2,549,486 and whether claims 1-53 on file are overly broad, contrary to the judicially created doctrine prohibiting claiming broader than the invention made or described.

[11] Further, we set out our preliminary analysis and rationale as to why, based on the record before us, the subject-matter of claims 1-5 and 14 on file is novel, the subject-matter of claims 43-45 on file would have been obvious in view of the cited prior art, the claims 1-53 on file of the instant application are patentably distinct from those in issued patents 2,505,524 and 2,549,486 and why claims 1-53 on file are broader in scope than the invention disclosed. Finally, we expressed the view that the claims of

the proposed claims set-2 constitute a "necessary" amendment under subsection 30(6.3) of the *Patent Rules*.

[12] In a response to the Panel Letter dated December 21, 2017, the Applicant declined the opportunity to make further written and/or oral submissions and informed the Board of its wish to obtain allowance of the claims of the proposed claims set-2.

ISSUES

[13] In view of the above, four issues are addressed in this review:

i) whether the subject-matter of claims 1-5 and 14 on file lacks novelty, contrary to paragraph 28.2(1)(*b*) of the *Patent Act*;

ii) whether the subject-matter of claims 1-53 on file would have been obvious, contrary to section 28.3 of the *Patent Act*;

iii) whether claims 1-53 on file are unpatentable on the grounds of double-patenting in view of the claims of issued patents 2,505,524 and 2,549,486; and

iv) whether claims 1-53 on file are overly broad, contrary to the judicially created doctrine prohibiting claiming broader than the invention made or described.

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICES

Purposive construction

[14] In accordance with *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, essential elements are identified through a purposive construction of the claims done by considering the whole of the disclosure, including the specification and drawings

(see also *Whirlpool Corp v. Camco Inc.*, 2000 SCC 67 at paras 49(f) and (g) and 52 (*Whirlpool*)). In accordance with the *Manual of Patent Office Practice*, revised June 2015 (CIPO) at §13.05 (*MOPOP*), the first step of purposive claim construction is to identify the person of ordinary skill in the art (POSITA) and their relevant common general knowledge (CGK). The next step is to identify the problem addressed by the inventors and the solution disclosed in the application. Essential elements can then be identified as those elements of the claims that are required to achieve the disclosed solution.

Novelty

[15] Paragraph 28.2(1)(*b*) of the *Patent Act* sets out the conditions under which a claim may be found to lack novelty in view of a disclosure by a third party:

> 28.2 (1) The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
>
> …
>
> (b) before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in Canada or elsewhere.

[16] There are two separate requirements in order to show that a prior art document anticipates a claimed invention: a prior disclosure of the claimed subject-matter; and the prior disclosure must enable the claimed subject-matter to be practised by the POSITA (*Apotex Inc v Sanofi Synthelabo Canada Inc*, 2008 SCC 61 (*Sanofi*) at paragraphs 24-29).

[17] "Prior disclosure" means that the prior art must disclose subject-matter which, if performed, would necessarily result in infringement of the patent. The POSITA looking at the disclosure is "taken to be trying to understand what the author of the description [in the prior patent] meant" (para 32). At this stage, there is no room for trial and error or experimentation by the POSITA. The prior art is simply read "for

the purposes of understanding it": see *Sanofi*, at para 25, citing *Synthon B.V. v SmithKline Beecham plc*, [2006] 1 All ER 685, [2005] UKHL 59.

[18] "Enablement" means that the POSITA would have been able to perform the invention without undue burden. The POSITA is assumed to be willing to make trial and error experiments to get it to work: *Sanofi*, at paras 26-27).

Obviousness

[19] Section 28.3 of the *Patent Act* sets out the statutory requirement that the claimed subject-matter must not have been obvious to the POSITA:

> 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.

[20] In *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?

Double-patenting

[21] Put simply, double patenting involves the concept that a person cannot get a second patent for the same thing for which they already have received a patent or for an obvious equivalent.

[22] There are no expressed provisions in the *Patent Act* dealing with double-patenting. However, the Supreme Court of Canada has indicated that the statutory basis for double-patenting is subsection 36(1) of the *Patent Act*, which indicates, in the singular, that "a patent shall be granted for one invention only" (see *Whirlpool* at para 63). The courts have also considered double-patenting to be a proper basis for the Commissioner of Patents to refuse an application: *Bayer Schering Pharma Aktiengesellschaft v. Canada* (Attorney General), 2010 FCA 275, aff'g 2009 FC 1249.

[23] In *Whirlpool*, the Supreme Court noted that there are two branches to the test for double patenting. The first is "same-invention" double-patenting, which occurs when the claims of a first and second patent, both of which are owned by the same party, are "identical" or "conterminous" to one another. In the present case, the application has been rejected under the second branch of the test for double-patenting, known as "obviousness double-patenting". This is a "more flexible and less literal test" than same-invention double-patenting as it prohibits the issuance of the second patent unless its claims are "patentably distinct" and exhibit "novelty or ingenuity" over those of the first patent (*Whirlpool*, paras 66-67).

[24] Obviousness double-patenting and obviousness under section 28.3 of the *Patent Act* are both assessed from the perspective of the POSITA, taking into account that person's CGK. However, an obviousness double-patenting analysis compares the

claims in the subject application to the claims of the issued patent. By contrast, particular pieces of prior art are compared to a claimed invention when doing an obviousness analysis under section 28.3 of the *Patent Act* (*Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc.*, 2016 FCA 119 at paras 28-29).

Overbreadth of claims

[25] Excessive claim scope can give rise to an allegation that an Applicant is "claiming broader than the invention made or disclosed". As stated by Thurlow J. (as he then was) in *Farbewerke Hoechst A/G v. Canada Commissioner of Patents*), [1966] Ex CR 91, aff'd, [1966] SCR 604 at para 20:

> Here are two fundamental limitations on the extent of the monopoly which an inventor may validly claim. One is that it must not exceed the invention which he has made, the other is that it must not exceed the invention which he has described in his specification.

[26] In *Amfac Foods Inc. v. Irving Pulp & Paper, Ltd.* (1986), 12 CPR (3d) 193, aff'g 80 CPR (2d) 59, the Federal Court of Appeal, after reviewing a line of previous decisions, similarly indicated that the claimed invention must not be broader than the one made or disclosed.

ANALYSIS OF THE CLAIMS ON FILE

Purposive construction

The POSITA and the relevant CGK

[27] In the Panel Letter, we agreed with the FA that the POSITA is a clinician with experience treating disorders related to iron metabolism and that said clinician would have significant and extensive knowledge in experimental medicine and would be well versed in treatment options for said disorders.

[28] With respect to the CGK possessed by the POSITA, we noted that the FA did not identify any specific CGK elements with regard to commonly known treatment

options for disorders related to iron metabolism in general or related to disturbances of iron distribution in particular.

[29] After review of the instant specification and prior art documents cited in the FA, notably Peeters et al., *Ann Rheum Dis*, vol. 55, pp. 739-744, 1996 (*Peeters*), we expressed the view that it is CGK for the POSITA defined above that anemia often occurs in patients with rheumatoid arthritis and that anaemia of chronic disease (ACD), a type of disturbance in iron distribution wherein the overall concentration of iron in the body is normal, is the most important cause of anemia in this condition.

[30] With regard to what appears to not be part of the CGK, we expressed the view that:

- EPO was not commonly known to the POSITA as a treatment option for disorders related to the distribution of iron in the body; and

- ACD and disturbances of iron distribution were not commonly known to occur in patients with diabetes, heart diseases or chronic inflammatory intestinal diseases.

Meaning of specific terms

[31] In the Panel Letter, we construed that the phrases "treatment of a disturbance of iron distribution in a patient suffering from diabetes" (claim 1), "treating disturbances of iron distribution in a patient suffering from diabetes" (claim 14), and "treating disturbances in iron distribution in a patient suffering from non-insulin dependent diabetes mellitus" (claims 16, 36, 38, 41, 46, 47, 49 and 52) to mean a treatment that would ameliorate the diagnosed disturbances of iron distribution in a patient suffering from diabetes, disturbances that are characterized in that the concentration of soluble transferrin receptor [mg/L] divided by log(concentration of ferritin [μg/L]) is smaller than 3.5 and that the concentration of C-reactive protein (CRP) is above 5 mg/L.

[32] With respect to claim 43 and claims depending thereon, we construed the phrase "treatment of disturbances in iron distribution" as relating to a treatment that would ameliorate disturbances in iron distribution that are not limited to the ones affecting patients suffering from diabetes.

The problem to be solved and the proposed solution

[33] In the Panel Letter, we identified that the problem to be solved is "a need for the treatment of disturbances of iron distribution that specifically occur in patients suffering from diabetes and that the solution is the use of EPO."

The essential elements that solve the identified problem

[34] In the Panel Letter, we considered that the use of EPO ("element A") to treat disturbances of iron distribution ("element B") in a patient suffering from diabetes ("element C") are essential elements of claims 1-42 and 46-53 on file to solving the identified problem.

[35] We also expressed the view that claims 43-45 on file lack the essential elements B and C with regard to the problem to be solved because these claims are not limited to the treatment of a particular type of disturbances of iron distribution found in a particular group of patients affected by diabetes.

[36] Claims 2-13 and 15-53 on file further characterize the EPO protein as being part of a conjugate, as comprising a particular amino acid sequence, as being a modified form of EPO, as being an analog of EPO and/or further define the pH, components and acceptable excipients present in a composition comprising EPO. Accordingly, we consider that these claims further characterize or limit the essential element A or define non-essential elements of a composition comprising EPO.

[37] Independent claim 1 is a "Swiss" style use claim. The form of this type of claims is typically *the use of compound X in the manufacture of a medicament for the*

treatment of Y. A literal interpretation may suggest that the contemplated use is simply for the manufacture of a medicament but the format also permits an interpretation of the claim as relating to a therapeutic use for the compound, the latter interpretation being in line with the jurisprudence (for example, see *GD Searle & Co v Canada (Minister of Health)*, 2008 FC 437, aff'd 2009 FCA 35; *Eli Lilly Canada Inc v Apotex Inc*, 2008 FC 142; and *Pfizer Canada Inc v Apotex Inc*, 2007 FC 971, aff'd 2009 FCA 8). Although the use recited in the preamble of claim 1 is focused on the manufacture of a medicament, the claim specifies a therapeutic use. In our view, the claimed use goes beyond utilizing EPO or a derivative thereof to make a medicament; it further requires the actual delivery of that medicament to ameliorate a disturbance of iron distribution in a patient suffering from diabetes. Accordingly, we consider that although claim 1 is worded in the "Swiss" format, it essentially claims the same subject-matter as claim 14.

[38] As there has been no disagreement expressed by the Applicant, we therefore adopt for the purpose of this review the above identifications of the POSITA and the relevant CGK as well as the characterization of the problem to be solved, the solution and the essential elements.

Novelty of claims 1-5 and 14

[39] The FA referred to the disclosure of *Peeters* in assessing the novelty of claims 1-5 and 14 on file.

[40] Claim 1 on file, which we take as representative of the claims identified as lacking novelty in view of *Peeters*, reads as follows:

> 1. Use of erythropoietin protein in the manufacture of a medicament for the treatment of a disturbance of iron distribution in a patient suffering from diabetes, wherein the overall concentration of iron in the patient is normal.

[41] In the Panel Letter, we stated that having expressed the view that the recited diabetes patient group is an essential element of the claims on file, we considered that the claims on file are not broadly directed to the use of EPO in the treatment of any disturbance in iron distribution, contrary to the position taken in the FA.

[42] With regard to the disclosure of *Peeters*, we noted in the Panel Letter that the patient group in *Peeters* consists of rheumatoid arthritis patients, a group that is not encompassed by the scope of claims 1-5 and 14 on file. We also considered that *Peeters* does not disclose that EPO is useful for the treatment of disturbances of iron distribution in general and does not disclose the use of EPO for the treatment of disturbances of iron in a diabetic patient diagnosed with disturbances of iron distribution. Accordingly, we expressed the view that *Peeters* does not disclose subject-matter which, if performed, would necessarily result in infringement of the instant claims 1 to 5 and 14.

[43] Further, we considered that there are indications that a disturbance of iron distribution in the context of diabetes is different than the one observed in the context of rheumatoid arthritis because we understood from *Peeters* that, unlike in diabetes patients, CRP levels are not decreased by the use of EPO for the treatment of ACD in rheumatoid arthritis patients.

Conclusion on novelty

[44] In view of the above, we are of the view that the subject-matter of claims 1-5 and 14 is novel in view of *Peeters* and complies with paragraph 28.2(1)(*b*) of the *Patent Act*.

Obviousness

[45] In accordance with the four-step approach to performing an obviousness assessment put forward in *Sanofi*, we present the following analysis with respect to the claims on file.

Identify the POSITA and the relevant CGK

[46] The POSITA and the relevant CGK have been set out above as part of the purposive construction of the claims.

Identify the inventive concept

[47] In the Panel Letter, we expressed the view that the POSITA would consider that the characterization of the inventive concept found in the FA is too broad with respect to the type of disturbance in iron distribution to be treated, at least for claims 1-42 and 46-53 on file. We were of the view that the POSITA would consider that the inventive concept of claims 1-42 and 46-53 on file is the use of an EPO protein, an EPO protein derivative or conjugate thereof to treat a disturbance in iron distribution in a patient suffering from diabetes, wherein the overall concentration of iron in the patient is normal. With respect of claims 43-45, we agreed with the characterization found in the FA and considered that their inventive concept is the use of a composition comprising an EPO protein to treat disturbances in iron distribution. We apply these inventive concepts in the analysis below.

Differences between the matter cited as forming part of the "state of the art" and the inventive concept

[48] The following three prior art references are cited in the obviousness analysis presented in the FA:

- *Peeters*, introduced above;
- WIPO international patent application WO 01/87329 A1, published in 2001; inventor: Papadimitriou (*Papadimitriou*); and
- European patent application EP 1064951 A2, 2001; inventor: Bailon (*Bailon*).

[49] With respect to their respective disclosure, we consider that:

- *Peeters* teaches that anemia often occurs in patients with rheumatoid arthritis and ACD is the most important cause of anemia in this condition. Further, *Peeters* discloses the use of recombinant EPO for the treatment of ACD in rheumatoid arthritis patients and discloses that CRP levels are not decreased by the use of EPO in rheumatoid arthritis patients;

- *Papadimitriou* discloses conjugates of EPO with poly(ethylene glycol) comprising an EPO glycoprotein having at least one free amino group and having the in vivo biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells. *Papadimitriou* further discloses EPO proteins encompassed by claims 1-15 on file, EPO protein modifications encompassed by claims 16-36 on file as well as EPO protein compositions encompassed by claims 43-53 on file.

- *Bailon* discloses pegylated derivatives of EPO proteins having the *in vivo* biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells.

[50] We expressed the view in the Panel Letter that *Peeters* is the most pertinent and closest cited prior art document with regard to the use of EPO for the treatment of a disturbance in iron distribution. We considered that the main difference between the teachings of *Peeters* and the inventive concept of claims 1-42 and 46-53 on file identified above is that *Peeters* does not teach or suggest treating a disturbance in iron distribution in a patient suffering from diabetes with EPO. Further, *Peeters* does not teach the use of EPO protein derivatives or EPO protein conjugates. With respect to claims 43-45 on file, we considered that the differences are limited to the exact constituents and pH of the EPO compositions recited in the claims.

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?

[51] In the Panel Letter, we expressed the view that the POSITA, following the teachings of *Peeters*, would not consider EPO as a potential treatment for any type of disturbances in iron distribution other than ACD. As mentioned above, there is no indication in the record that ACD was commonly known to occur in patients with diabetes and no indication that it was commonly known that patients suffering from diabetes have a high probability to be affected by disturbances of iron distribution. Accordingly, we expressed the preliminary view that it would not have been obvious to the POSITA to use an EPO protein, an EPO protein derivative or conjugate thereof to treat a disturbance in iron distribution in a patient suffering from diabetes, wherein the overall concentration of iron in the patient is normal.

[52] With respect to claims 43-45 on file, which are not limited to patients with diabetes, we were of the view that it would not have required any degree of invention from the POSITA taught by *Peeters* and aware of the compositions disclosed by *Papadimitriou*, to use EPO compositions having the recited constituents and pH to treat ACD in a patient suffering from rheumatoid arthritis. Accordingly, in the Panel Letter we expressed the preliminary view that it would have been obvious to the POSITA to use the composition recited in claims 43-45 to treat a disturbance in iron distribution.

Conclusion on obviousness

[53] In view of the above, we consider that the subject-matter of claims 1-42 and 46-53 on file would not have been obvious at the claim date to the POSITA in view of the cited prior art and the relevant CGK.

[54] Further, and in absence of submissions from the Applicant with regard to the claims on file, we consider that the subject-matter of claims 43-45 on file would have been

obvious at the claim date to the POSITA in view of the teachings of *Peeters*, *Papadimitriou* and the relevant CGK.

Double-patenting

[55] In the Panel Letter we noted that a double-patenting analysis is conducted by comparing the claims of each patent document and considering whether they are patentably distinct from one another. However, claims are to be given a purposive construction. The analysis in the Panel Letter was performed taken into account the POSITA and the CGK identified above.

[56] In the Panel Letter, we considered that claim 1 on file of the instant application, claim 1 of issued patent 2,505,524 and claim 1 of issued patent 2,549,486 are representative claims of the invention claimed in each patent document (see Table 1 below). If claim 1 of the subject application is found to be patentably distinct from claim 1 of the issued patents, claims 1-42 and 46-53 on file in the instant application can also be considered patentably distinct because they are either similar in scope or include further claim limitations.

Table 1

On file	Issued patent 2,505,524	Issued patent 2,549,486
1. Use of erythropoietin protein in the manufacture of a medicament for the treatment of a disturbance of iron distribution in a patient suffering from diabetes, wherein the overall concentration of iron in the patient is normal.	1. A use of erythropoietin protein in the manufacture of a medicament for the treatment of a disturbance of iron distribution in a patient suffering from a heart disease, wherein the disturbance of iron distribution is characterized in that the concentration of soluble transferrin receptor [mg/L]: (log concentration of ferritin	1. The use of erythropoietin protein in the manufacture of a medicament for the treatment of disturbances of iron distribution in chronic inflammatory intestinal diseases, wherein the disturbance of iron distribution is characterized in that the concentration of soluble transferrin receptor [mg/L]: (log concentration of ferritin

	[μg/L]) is smaller than 3.5 and that the concentration of C-reactive protein is above 5 mg/L.	[μg/L]) is smaller than 3.5 and that the concentration of C-reactive protein is above 5 mg/L.

[57] Claims 43-45 on file were the subject of a separate analysis in the Panel Letter. We considered that claim 15 of issued patent 2,505,524 is the closest and most relevant claim (see Table 2 below).

Table 2

On file	Issued patent 2,505,524
43. A composition for the treatment of disturbances in iron distribution comprising from 25 to 2,500 μg/ml of erythropoietin protein, from 10 to 200 mmol/1 sulfate, a pharmaceutically acceptable carrier, wherein said composition has a pH of from 6.0 to 7.0.	15. A pharmaceutical composition for treating a disturbance of iron distribution in a patient with heart disease, wherein the disturbance of iron distribution is characterized in that the concentration of soluble transferrin receptor [mg/L]: (log concentration of ferritin [μg/L]) is smaller than 3.5 and that the concentration of C-reactive protein is above 5 mg/L, and wherein the composition comprises an effective amount of erythropoietin protein, and a pharmaceutically acceptable diluent or carrier.
44. The composition of claim 43 comprising from 50 to 2,500 μg/ml of erythropoietin protein, 10 mm sodium phosphate, 40 mM sodium sulfate, 3% mannitol (w/v), 10 mM methionine and 0.01% poloxamer 188 (w/v) and has a pH of about 6.2.	
45. The composition of claim 43 comprising from 50 to 2,500 μg/ml of erythropoietin protein, 40 mM arginine, 30 mM sodium sulfate,	

3% mannitol (w/v), 10 mM methionine, 0.01% poloxamer 188 (w/v) and having a pH of about 6.2.	

[58] In the Panel Letter, we stated that main difference between claim 1 of the instant application and those issued in patents 2,505,524 and 2,549,486 is with respect to the disease associated with the disturbance of iron distribution: the instant application refers to patients suffering from diabetes whereas the issued patents refers to patients suffering from a heart disease (issued patent 2,505,524) or chronic inflammatory intestinal diseases (issued patent 2,549,486).

[59] With respect to claims 43-45 on file and claim 15 of issued patent 2,505,524, we were of the view that the differences essentially lie in the characterization of the disturbance of iron distribution in terms of the levels of three biochemical markers that can be measured in a sample of a patient's blood, the disease associated with said disturbance of iron distribution (claim 15 of issued patent 2,505,524) and the explicit recitation of the constituents and pH of the EPO compositions of claims 43-45.

[60] In the Panel Letter, we noted that claims 1-42 and 46-53 of the instant application and the claims of the issued patents do not broadly refer to disturbances of iron distribution, nor mention other diseases that may be associated with them. Although the POSITA is a clinician with experience treating disorders related to iron metabolism (see the identification of the POSITA above), we expressed the view that EPO was not commonly known to the POSITA as a treatment option for disorders related to the distribution of iron in the body and that it was not commonly known that patients suffering from diabetes, heart diseases or chronic inflammatory intestinal diseases would have a high probability to be affected by disturbances in iron distribution.

[61] Therefore, we considered that the patients of claim 1 of the instant application, being limited to those who suffer from diabetes, would not be regarded by the POSITA as

obviously suitable for treatment with EPO in view of any of the corresponding claims of the issued patents which both define a group of patients suffering from a different disease. We further expressed the view that the POSITA would consider that the non-overlapping patient groups defined in the claims of each patent application or issued patent are distinct and non-obvious in view of one another.

[62] Finally, we considered the subject-matter of claim 15 of issued patent 2,505,524 to be patentably distinct from instant claims 43-45 on file as it would not have been obvious for the POSITA, solely aware of the subject-matter of claims 43-45, to measure the recited specific biochemical parameters before using EPO to treat patients with heart disease.

Conclusion on double-patenting

[63] In view of the above, we are of the view that claims 1-53 on file of the instant application and the claims of the issued patents 2,549,486 and 2,505,524 are patentably distinct. As such, no potential for double-patenting exists should the subject application issue to patent.

Overbreadth of the claims on file

[64] In the Panel Letter, we expressed the view that the phrases "treatment of a disturbance of iron distribution in a patient suffering from diabetes" (claim 1), "treating disturbances of iron distribution in a patient suffering from diabetes" (claim 14), "treating disturbances in iron distribution in a patient suffering from non-insulin dependent diabetes mellitus" (claims 16, 36, 38, 41, 46, 47, 49 and 52) and "treatment of disturbances in iron distribution" (claim 43) encompass a treatment that would ameliorate disturbances of iron distribution that are not limited to the ones affecting patients suffering of diabetes (claim 43) or that would ameliorate disturbances of iron distribution in a patient suffering from diabetes but not necessarily diagnosed on the basis that the overall concentration of iron in the

diabetic patient is normal and a concentration of CRP is equal to or above 5 mg/L (claims 1, 14, 16, 36, 38, 41, 46, 47, 49 and 52).

[65] We noted that there is no indication in the description that the inventors broadly address the treatment of all types of disturbances of iron distribution, or that they are concerned with disturbances of iron distribution other than those which occur in patients suffering from diabetes. The description only discloses on detailed method of diagnosing disturbances in iron distribution in a patient suffering from diabetes and it involves the determination of levels of CRP, ferritin and soluble transferrin receptor. The presented example (see the description on page 20) describes favourable clinical outcomes following the administration of EPO to a middle-aged woman suffering from diabetes that showed disturbances of iron distribution characterized by determined levels of CRP, ferritin and soluble transferrin receptor. Accordingly, we expressed the view that the POSITA would understand from the description of the instant application that the disclosed use of EPO to treat a disturbance in iron distribution in a patient suffering from diabetes is not directed to the treatment of any disturbance in iron distribution, but rather is limited to the treatment of a disturbance in iron distribution characterized in that the concentration of soluble transferrin receptor [mg/L] divided by log (concentration of ferritin [µg/L]) is smaller than 3.5 and that the concentration of CRP is above 5 mg/L.

Conclusion on overbreadth

[66] In view of the above, and in absence of submissions from the Applicant with regard to the claims on file, we are of the view that claims 1-53 on file are broader in scope than the invention disclosed.

Summary of the defects identified with respect to the claims on file

[67] For the foregoing reasons and more specifically because the subject-matter of claims 43-45 on file is not limited to patients with diabetes and because the subject-matter of claims 1-53 on file is not limited to the treatment of a disturbance in iron

distribution characterized in that the concentration of soluble transferrin receptor [mg/L] divided by log (concentration of ferritin [µg/L]) is smaller than 3.5 and that the concentration of CRP is above 5 mg/L, we are of the view that the subject-matter of claims 43-45 on file would have been obvious, contrary to section 28.3 of the *Patent Act* and that claims 1-53 on file are broader in scope than the invention disclosed.

ANALYSIS OF THE PROPOSED CLAIMS

[68] In the R-SOR and the letter dated December 2, 2017, the Applicant indicated that it seeks allowance of the claims of proposed claims set-2 as submitted on May 25, 2016. The proposed claims set-2 contains claims 1-51 wherein all independent claims recite "the disturbance of iron distribution is characterized in that the concentration of soluble transferrin receptor [mg/L]: (log concentration of ferritin [µg/L]) is smaller than 3.5 and that the concentration of C-reactive protein is above 5mg/L" and wherein all independent claims recite that patient is suffering from diabetes or non-insulin dependent diabetes mellitus.

[69] In the Panel Letter, we noted that there is a clear correspondence between the proposed claims set-2 and the claims on file, that the proposed claims set-2 do not broaden the scope of the corresponding claims on file and do not necessitate another prior art search. Accordingly, we stated that the proposed claims set-2 could be considered for amendment if it is determined that they overcome the defects noted above with regard to the claims on file and provided our preliminary views on these claims as well.

[70] Given that the scope of the claims of the proposed claims set-2 is limited to a disturbance of iron distribution characterized by specific levels of CRP, ferritin and soluble transferrin receptor and to patient suffering from diabetes, we expressed the preliminary views that:

- the claims of the proposed claims set-2 are novel and comply with paragraph 28.2(1)(*b*) of the *Patent Act* for the reasons provided with respect to the corresponding claims on file at paras [39]-[44];

- that the claims of the proposed claims set-2 are not obvious and comply with section 28.3 of the *Patent Act* for the reasons provided previously with respect to the claims 1-42 and 46-53 on file at paras [45]-[53];

- that claims of the proposed claims set-2 and the claims of the issued patents are patentably distinct for the reasons provided previously with respect to the claims on file at paras [55]-[63] and therefore no potential for double-patenting exists should the subject application issue to patent with proposed claims set-2; and

- that the claims of the proposed claims set-2 are not broader in scope than the invention disclosed.

Conclusion with respect to the proposed claims

[71] In view of the above, we are of the view that the claims of proposed claims set-2 constitute a "necessary" amendment under subsection 30(6.3) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[72] We conclude that the subject-matter of claims 43-45 on file would have been obvious, contrary to section 28.3 of the *Patent Act* and that claims 1-53 on file are broader in scope than the invention disclosed. We also conclude that proposed claims 1-51 as submitted in the letter of May 25, 2016 overcome these defects and do not introduce any new defects. We therefore recommend that the Applicant be notified, in accordance with subsection 30(6.3) of the *Patent Rules*, that the deletion of the claims on file and the insertion of claims 1-51 as proposed in the letter of May 25, 2016 are "necessary" for compliance with the *Patent Act* and *Patent Rules*.

Marcel Brisebois Member	Ed MacLaurin Member	Andrew Strong Member

DECISION

[73] I concur with the findings and the recommendation of the Panel. In accordance with subsection 30(6.3) of the *Patent Rules*, I hereby notify the Applicant that the above amendments must be made within three (3) months of the date of this decision, failing which I intend to refuse the application.

[74] In accordance with paragraph 31(*b*) of the *Patent Rules*, the following amendments, and only these amendments, may be made to the application:

i) delete claims 1-53 on file; and
ii) insert claims 1-51 as proposed in the letter of May 25, 2016.

Johanne Bélisle
Commissioner of Patents
Dated at Gatineau, Quebec,
this 8th day of August, 2018