Commissioner's Decision #1412
Décision du Commissaire #1412

TOPIC: A20 – Double-patenting
SUJET: A20 – Double brevet

Application No. : 2,505,524
Demande n^{o} : 2,505,524

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,505,524 having been rejected under subsection 30(4) of the *Patent Rules*, has consequently been reviewed in accordance with paragraph 30(6)(*c*) of the *Patent Rules* by the Patent Appeal Board. The recommendation of the Patent Appeal Board and the decision of the Commissioner is to allow the application.

Agent for the Applicant:

GOWLINGS WLG (CANADA) LLP
2600 - 160 Elgin Street
Ottawa, Ontario
K1P 1C3

INTRODUCTION

[1] Patent application number 2,505,524, entitled "Novel Use of Erythropoietin in Heart Diseases", is owned by F. Hoffman-La Roche AG and stands rejected on the grounds of double-patenting. 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 As explained below, our recommendation is that the rejection be withdrawn and the application proceed to allowance.

BACKGROUND

The technology

[2] The subject application concerns a novel therapeutic use for a biochemical compound known as "erythropoietin", or "EPO". EPO is a hormone produced in the body that promotes the production of red blood cells. It is typically used as a therapeutic agent to treat iron deficiency or low levels of red blood cells, i.e. anemia.

[3] The subject application is based on the discovery that patients with a heart disease, such as coronary heart disease or congestive heart failure, may be affected by disturbances of iron distribution in their bodies and that such patients may benefit from treatment with EPO. Unlike conditions in which overall levels of iron in the body are too low (anemia), or too high (hemochromatosis), a disturbance of iron distribution does not change the overall concentration of iron in the body. A disturbance of iron distribution may nonetheless lead to localized accumulation of damaging levels of iron in organs.

[4] The application teaches that the overall concentration of iron in a patient with heart disease can be measured, and if found to be normal, disturbances in iron distribution can then be detected by measuring the levels of two biochemical markers: soluble transferrin receptor and "C-reactive protein". If disturbances in iron distribution are detected, EPO can be administered as a corrective measure.

[5] The issued patent that triggered the allegation of double-patenting also relates to the use of

EPO to treat disturbances in iron distribution, but not in a group of patients with heart disease. The patient group in the issued patent is limited to individuals with a chronic inflammatory intestinal disease, such as Crohn's disease or ulcerative colitis.

Prosecution history

[6] The subject application was filed in Canada on November 17, 2003. Examination ensued and culminated with the issuance of a Final Action ("FA") on April 18, 2013 which rejected all the claims then on file for obviousness, lack of novelty and on the grounds of "obviousness-type" double-patenting. The rejection on the latter grounds identified two later filed co-pending applications, owned by the same Applicant, as not being patentably distinct from the subject application:

- application number 2,496,581, filed August 20, 2003 and entitled "The Use of Erythropoietin in the Treatment of Disturbances of Iron Distribution in Diabetes"; and,

- application number 2,549,486, filed December 10, 2004 and entitled "Use of Erythropoietin in the Treatment of Disturbances of Iron Distribution in Chronic Inflammatory Intestinal Disease."[1]

[7] The Applicant replied to the FA on October 3, 2014 and provided amended claims that introduced a limitation which the Examiner considered to be sufficient to overcome the obviousness and novelty defects. The amended claims were also considered patentably distinct from those of application 2,496,581, but not those of application 2,549,486. A Summary of Reasons ("SOR") was therefore prepared and the application was referred to the Patent Appeal Board for review. Upon being informed that the application was pending review, the Applicant provided written submissions on October 26, 2015 in response to the SOR.

1: Application 2,549,486 has since issued to patent

THE ISSUE

[8] The issue is whether the claims on file are unpatentable on the grounds of double-patenting in view of the claims in issued patent number 2,549,486.

LEGAL PRINCIPLES

Claim construction

[9] 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* §13.05 [revised June 2015], the first step of purposive claim construction is to identify the person skilled in the art and their relevant common general knowledge. The next step is to identify the problem addressed by the inventors and the solution put forth in the application. Essential elements can then be identified as those required to achieve the disclosed solution as claimed.

Double-patenting

[10] The Examiner took the position in the Final Action and the SOR that the claims on file could not be granted due to the potential for "obviousness-type" double-patenting should the subject application issue to patent.

[11] 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 Act which indicates, in the singular, that "a patent shall be granted for one invention only" (*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.

[12] 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 "coterminous" 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 which 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).

[13] Obviousness double-patenting and obviousness under 28.3 of the Act are both assessed from the perspective of a person skilled in the art, taking into account that person's common general knowledge. 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 Act (*Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc*, 2016 FCA 119 at paras 28-29).

[14] The decision in *Eli Lilly Canada Inc v Mylan Pharmaceuticals ULC*, 2015 FC 17 at paras 125-128 [*Lilly*] acknowledges that when conducting an obviousness-type double-patenting analysis "[o]ne must be able to ascertain what is alleged to have been invented in each patent to compare them". This can entail considering the disclosure to construe the claims and "ascertain the true nature of the invention." Similarly, in *Re SmithKline Beecham Corp* (2012), 104 CPR (4th) 106, CD 1328 at para 45, reference to the description was considered appropriate "so long as it is to construe the claim in accordance with the principles of purposive construction."

ANALYSIS

[15] The double-patenting analysis is conducted by comparing the claims of each document and considering whether they are patentably distinct from one another (*Whirlpool*, *supra*). The analysis is informed by an identification of the skilled person and their the common general

knowledge, as well as an understanding of what is alleged to have been invented in each case, based on the problems and solutions disclosed in each document.

Person skilled in the art and the common general knowledge

[16] For the purpose of the obviousness objection made in the FA, the person skilled in the art was defined as "a clinician with experience treating disorders related to the distribution of iron in the body." Concerning the common general knowledge, the skilled person was said to have "significant and extensive knowledge in experimental medicine and would be well versed in treatment options for said disorders."

[17] The record does not indicate that EPO was commonly known to the skilled person as a treatment option for disorders related to the distribution of iron in the body.

[18] In our view, these definitions are also appropriate for the obviousness double-patenting analysis.

The problems addressed in the subject application and issued patent are different

[19] With respect to the subject application, there are no indications in the description that the inventors broadly contemplate treatment of all medical problems that may also be associated with disturbances of iron distribution, or that they are concerned with problems other than heart diseases.

[20] Thus, according to the description of the subject application, "The problem underlying the present invention is therefore to provide a treatment for disturbances of iron distribution in heart diseases in order to minimize or suppress the above mentioned disadvantages" (page 1, lines 27-29) – the "above mentioned disadvantages" being damage to the heart.

[21] As regards the issued patent, its description is limited to problems of disturbances of iron distribution only when associated with chronic inflammatory intestinal diseases; associations with heart disease are not mentioned.

[22] The problem underlying the invention in the issued patent is therefore different: it is to "provide a treatment for disturbances of iron distribution in chronic inflammatory intestinal diseases in order to minimize or suppress the above mentioned disadvantages" (page 2, lines 7-10) – the "above mentioned disadvantages" in that case being damage to the intestines.

The solutions presented in the subject application and the issued patent are different

[23] There are no indications in the description of the subject application that EPO is to be used to treat disturbances in iron distribution in general, or that EPO is to be used to treat patients with disorders other than heart diseases.

[24] The description of the issued patent is limited to EPO treatment of patients with disturbances in iron distribution and chronic inflammatory intestinal diseases –heart diseases are not mentioned.

[25] In both the subject application and the issued patent, we note that the two types of diseases associated with disturbances of iron distribution are described as associations that were found, about one year apart, to be novel:

> Until now [i.e., November 17, 2003] it was not known that patients suffering from heart diseases have a high probability to be affected by disturbances of iron distribution. (page 1, subject application)

> Until now [i.e., December 10, 2004] it was not known that patients suffering from chronic inflammatory intestinal diseases have a high probability to be affected by disturbances of iron distribution. (page 1, issued patent)

[26] The use of EPO to treat patients with either heart disease or chronic inflammatory intestinal diseases and suffering from disturbances in iron distribution is also described as novel in the subject application and the issued patent, respectively, and is based in each case on an example describing favourable clinical outcomes.

[27] Thus, the description of the subject application indicates that the solution to the problem in

that case is based on the discovery that EPO "[h]as a beneficial effect on disturbances of iron distribution in heart diseases" (page 2, lines 1-2). Accordingly, "The problem is therefore solved, according to the present invention, by providing erythropoietin for the use in the treatment of disturbances of iron distribution in heart diseases" (page 2, lines 2-4).

[28] The issued patent solves its problem in a different patient group, i.e., by "providing erythropoietin for the use in the treatment of disturbances of iron distribution in chronic inflammatory intestinal diseases" (page 2, lines 12-13).

Claims comparison

[29] Claim 2 of the subject application and claim 2 of issued patent 2,549,486 are representative claims of the invention claimed in each document[2]. If claim 2 of the subject application is found to be patentably distinct from claim 2 of the issued patent, the other claims on file in the subject application can also be considered patentably distinct because they are either similar in scope or include further claim limitations.

Claim 2 of the subject application	Claim 2 of issued patent 2,549,486
A use of erythropoietin protein for treating 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 [ug/L] is smaller than 3.5 and that the concentration of C-reactive protein is above 5 mg/L.	The use of erythropoietin protein 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 [ug/L] is smaller than 3.5 and that the concentration of C-reactive protein is above 5 mg/L.

2: Claim 1 of the subject application and claim 1 of the issued patent may also be considered representative of the invention claimed in each document, but have not been compared because they are phrased in the "Swiss format" of medical use claim. The analysis would be the same regardless.

Claim similarities

[30] There are two similarities between the claims: both claim the use of EPO for treating a disturbance of iron distribution; and both claims characterize the disturbance of iron distribution in terms of the same levels of two biochemical markers (transferrin receptor and C-reactive protein) that can be measured in a sample of a patient's blood.

Claim difference

[31] The difference between the claims of the subject application and the issued patent is the disease associated with the disturbance of iron distribution: the subject application refers to patients suffering from heart diseases whereas the issued patent refers to treatment in chronic inflammatory intestinal diseases.

[32] The FA and the SOR express the view that this is not a difference that renders the claims patentably distinct from one another because both claims are directed to the treatment of disturbances of iron distribution characterized in terms of the same levels of biochemical markers and using the same drug (EPO):

> Regardless of any other disease a patient may also suffer from (i.e., a heart disease, diabetes, or a chronic inflammatory intestinal disease) a disturbance in iron distribution in said patient is not considered a distinct medical condition between said patient populations. (page 6, FA; emphasis in original)
>
> . . .
>
> [t]he EPO protein defined in the claims of the present application or in [the issued patent] is not contemplated to treat heart disease or chronic inflammatory intestinal disease, but is contemplated to treat a disturbance of iron distribution in patients who also happen to have said diseases. (page 2, SOR)

[33] In response to the FA, the Applicant submitted that the "inventive concept of the present application is based on use of EPO in treating a particular group of patients. In the present

claims this is a group of patients suffering from heart disease and iron distribution disorder."

[34] In its written submissions provided in response to the SOR, the Applicant pointed out that the second disease of the patient population, be it heart disease or chronic inflammatory intestinal disease, "has a major impact on the clinical pictures of the patients of the patient populations and should not be discounted" and "heart disease is a medical condition which is distinct from chronic inflammatory intestinal disease" (pages 2-3, written submissions).

The claims are patentably distinct

[35] Having compared the claims in the subject application and the issued patent, reviewed the record, and ascertained what has allegedly been invented in each document, it is our view that the skilled person would regard their claimed subject matter as patentably distinct. Although the claims share common features, the skilled person would understand that the patient groups defined in the claims of each document are distinct and non-obvious in view of one another.

[36] The claims of either the subject application or the issued patent neither broadly refer to disturbances of iron distribution, nor mention other diseases that may be associated with them. Although the skilled person is "a clinician with experience treating disorders related to the distribution of iron in the body", the record does not establish that patients having such disturbances would be considered by the skilled person as a uniform group in which all patients are suitable for the same types of treatments, regardless of the presence of other diseases that may be associated with disturbances in iron distribution. Moreover, the record does not establish that the skilled person would commonly know that EPO could be used to treat disturbances of iron distribution, or that patients suffering from heart diseases or chronic inflammatory intestinal diseases would have a high probability to be affected by disturbances in iron distribution.

[37] As such, the patients of claim 2 of the subject application, being limited to those who have a heart disease, would not be regarded by the skilled person as obviously suitable for treatment

with EPO in view of claim 2 of the issued patent which defines a group of patients suffering from a different disease, i.e., a chronic inflammatory intestinal disease. In each case, the disease associated with the disturbance in iron distribution, be it a heart disease or a chronic inflammatory intestinal disease, was apparently only discovered, in an empirical manner, through favourable clinical outcomes achieved for each group of patients. In our view, this indicates that an inventive step would be required of the skilled person before EPO would be used to treat patients defined in the claims of the subject application.

Conclusion

[38] In our view, claim 2 of the subject application and claim 2 of the issued patent are patentably distinct. Because the other claims on file in the subject application are either of similar scope or include further claim limitations, they too are patentably distinct. As such, no potential for double-patenting exists should the subject application issue to patent.

RECOMMENDATION

[39] For the reasons set out above, we are of the view that the rejection is not justified on the basis of the defect indicated in the FA and have reasonable grounds to believe that the application complies with the *Patent Act* and the *Patent Rules*. We recommend that the Applicant be notified in accordance with subsection 30(6.2) of the *Patent Rules* that the rejection of the application is withdrawn and that the application has been found allowable.

Ed MacLaurin	Andrew Strong	Marcel Brisebois
Member	Member	Member

DECISION

[40] I concur with the findings and the recommendation of the Board. In accordance with subsection 30(6.2) of the *Patent Rules*, I hereby notify the Applicant that the rejection of the application is withdrawn, the application has been found allowable and I will direct my officials to issue a Notice of Allowance in due course.

Johanne Bélisle,
Commissioner of Patents
Dated at Gatineau, Quebec,
this 20th day of October, 2016