Commissioner’s Decision #1415

Décision du Commissaire n^{o} 1415

TOPIC: O00 (Obviousness); A20 (Double Patenting)

SUJET: O00 (Évidence); A20 (Double brevet)

Application No.: 2,555,050

Demande n°.: 2,555,050

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,555,050 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 is to refuse if the application if necessary amendments are not made.

Agent for the Applicant:

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INTRODUCTION

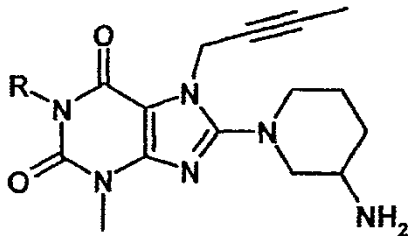
[1] This recommendation concerns the review of rejected patent application number 2,555,050, which is entitled "8-[3-amino-piperidin-1-yl]-xanthine derivatives, the production thereof and the use in the form of a DPP-IV inhibitor" and owned by Boehringer Ingelheim International GMBH. The outstanding defects to be addressed are whether the claimed invention is obvious and whether the claimed invention is unpatentable 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 in more detail below, our recommendation is that the Applicant be notified that the claims 1-8 as proposed in the letter of November 21, 2016 are "necessary" amendments under subsection 30 (6.3) of the *Patent Rules* for compliance with the *Patent Act* and *Patent Rules*.

BACKGROUND

The application

[2] Patent application 2,555,050 was filed in Canada on February 12, 2005 and published on September 15, 2005.

[3] The application relates to substituted xanthine compounds of general formula



(I),

and their use as inhibitors of the enzyme dipeptidylpeptidase-IV (DPP-IV). Increased activity of the enzyme DPP-IV promotes higher glucose blood levels through inactivation of glucagon-like peptide 1 whereas a decrease in DPP-IV activity promotes the release of insulin and reduces glucagon secretion, thereby lowering blood glucose levels. Given the effect the enzyme DPP-IV has on glucose levels, DPP-IV inhibitors have been indicated to be particularly useful in the treatment of type-2 diabetes.

[4] The present patent application exemplifies the preparation of various compounds of the general formula above showing DPP-IV inhibiting activity.

[5] The scope of the claims on file is limited to the specific compound 1-[(3-cyano-pyridin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8((R)-3-amino-piperidin-1-yl)-xanthine ("the Compound") and related subject matter.

History

[6] On January 9, 2015, a Final Action ("FA") was written pursuant to subsection 30(4) of the *Patent Rules*. The FA states that the claims on file are obvious, contrary to section 28.3 of the *Patent Act* and that the claims on file are unpatentable on the grounds of double-patenting in view of the claims in issued patent number 2,617,090.

[7] In a response to the FA ("R-FA") dated March 3, 2015, the Applicant submitted an amended claim set (the "Proposed Claims") and argued that the claimed invention was not obvious and that the proposed claims overcome the double-patenting defect.

[8] As the Examiner considered that the application did not to comply with the *Patent Act* and was not convinced that the Proposed Claims submitted by the Applicant in the R-FA would render the application allowable, the application was forwarded to the Patent Appeal Board ("the Board") for review, along with a Summary of Reasons

("SOR") that maintains the defects for the claims on file at the time of the FA. With regard to the proposed amendments made in the R-FA, the SOR explains that the double-patenting defect would have been withdrawn in light of the proposed amendments had the Proposed Claims been found non-obvious in view of the cited prior art and otherwise compliant with the *Patent Act* and *Patent Rules*. However, the SOR states that the Proposed Claims are obvious in view of the cited prior art and identifies a new defect with respect to one of the proposed claims.

[9] In a letter dated October 6, 2015 (the "Acknowledgement Letter") 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. On April 4, 2016 the Applicant expressed the wish to provide written submissions in response to the SOR and to participate in an oral hearing.

[10] 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 October 21, 2016 (the "Panel Letter"), we set out our preliminary analysis and rationale as to why, based on the record before us, the subject matter of the claims on file at the time of the FA complies with section 28.3 of the *Patent Act* but is unpatentable on the grounds of double-patenting in view of the claims in issued patent number 2,617,090.

[11] In the same letter, we also provided our preliminary views on the Proposed Claims submitted in response to the FA. After review, we considered that the subject matter of the Proposed Claims complies with section 28.3 of the *Patent Act* for the same reasons given for the claims on file, acknowledged the statement in the SOR that the Proposed Claims would overcome the double-patenting defect with regard to the claims on file and also agreed that the Proposed Claims would introduce a new minor defect.

[12] On November 21, 2016 the Applicant replied to the Panel Letter (the "Reply to the Panel Letter"). In this letter, the Applicant acknowledged the preliminary views of

the Board and submitted "New Proposed Claims" that are identical to the Proposed Claims submitted in response to the FA except for the absence of the minor defect identified in the SOR.

[13] In view of the Reply to the Panel Letter and the New Proposed Claims, we consider that an oral hearing is not required at this time because, based on our review of the application and record as it presently stands, our recommendation is to notify the Applicant that the New Proposed Claims constitute amendments that are "necessary" for compliance with the *Patent Act* and *Patent Rules*.

ISSUE

[14] There are two issues to address in this review:

1. whether the subject matter defined by the claims on file is obvious, contrary to subsection 28.3 of the *Patent Act*; and

2. whether the claims on file are unpatentable on the grounds of double-patenting in view of the claims in issued patent number 2,617,090.

LEGISLATION AND LEGAL PRINCIPLES

Purposive construction

[15] 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). In accordance with the *Manual of Patent Office Practice* §13.05 [revised June 2015; 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.

[16] In the Panel Letter, we expressed our view that the construction of the claims did not appear to be at issue and that the claim terminology was clear. The Applicant did not comment on the construction of the claims or their terminology in the Reply to the Panel Letter.

Selection patents

[17] Because the Compound recited in the claims on file appears to be a member of a previously disclosed genus of similar compounds, we noted in the Panel Letter that there was debate during the prosecution as to whether the claimed invention met the criteria for a "selection patent".

[18] In *Apotex Inc v Sanofi-Synthelabo Inc*, 2008 SCC 61 at paras 9-11 ("*Sanofi*"), the Supreme Court of Canada described selection patents as "patents based on a selection of compounds from those described in general terms and claimed in the originating patent" and considered the three part test set out in *In re I. G. Farbenindustrie A. G.'s Patents* (1930), 47 R.P.C. 289 (Ch. D.) to be a useful starting point for the validity analysis:

1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members.

2. The whole of the selected members (subject to "a few exceptions here and there") possess the advantage in question.

> 3. The selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a larger number of unselected compounds possessed the same advantage, the quality of the compound claimed in the selection patent would not be of a special character.

[19] A determination that the conditions for a selection patent have not been met does not constitute an independent basis upon which to attack the validity of a patent (see *Eli Lilly Canada Inc v Novopharm Limited*, 2010 FCA 197 at para 27). A selection patent is like any other patent and must satisfy the requirements of the *Patent Act* and *Patent Rules*, including the requirements that the invention be patentable subject matter, new, non-obvious, useful, adequately disclosed and enabled. In *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 236 at paras 44-45, the Federal Court of Appeal stated:

> In *Plavix*, cited above, the Supreme Court, at paragraph 11, accepted that a selection patent is like any other patent. As a result, it must satisfy the requirements of the *Act*, including the requirement that the invention be new and useful. The element of novelty is satisfied by the fact that the selected compounds have not previously been made. The element of utility is usually satisfied by the presence of a special property of an unexpected character, consisting in the advantage secured or the disadvantage avoided by the selection and which is at the heart of the inventive steps (*Plavix* above at paragraphs 9-10). Were it not so, no selection would meet the statutory criteria for patentability.
>
> A selection patent must also satisfy the disclosure requirements found in s. 34 of the *Old Act*. It does so by setting out in the specification "in clear terms the nature of the characteristic which the patentee alleges to be possessed by the selection for which he claims a monopoly": see *Plavix*, at paragraph 114. See also *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197, [2012] 1 F.C.R. 349 (*Olanzapine*) at paragraph 78.

[20] In view of the above passage, the advantage of a selection must be properly disclosed for there to be an invention (see also *Pfizer Canada Inc. v. Ranbaxy Laboratories Limited*, 2008 FCA 108 at para 59 and *Eli Lilly Canada Inc. v. Apotex Inc.*, 2007 FC 455 at para 89).

[21] Accordingly and as noted in the Panel Letter, we consider it unnecessary to independently assess the selection criteria listed above as they are subsumed within the obviousness inquiry.

Obviousness

[22] The *Patent Act* requires that the subject matter of a claim not be obvious to the POSITA. Section 28.3 of the *Patent Act* provides:

> 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.

[23] In *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at para. 67 (*Sanofi*), 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?

[24] With respect to the second step of this obviousness analysis framework, *Sanofi* recognized that: i) the inventive concept of a patent can differ from the construction of its claims (paras 76 and 78) and ii) where the inventive concept of a patent is not readily discernable from the claims themselves (as may be the case with a bare chemical formula), it is acceptable to read the specification in the patent to determine the inventive concept of the claims (para 77):

> [76] The construction of the claims in the '777 patent is not an issue. It is agreed that they constitute the dextro-rotatory isomer of the racemate and its pharmaceutically acceptable salts and processes for obtaining them.
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> [77] The inventive concept of the claims is not readily discernable from the claims themselves. A bare chemical formula in a patent claim may not be sufficient to determine its inventiveness. In such cases, I think it must be acceptable to read the specification in the patent to determine the inventive concept of the claims. Of course, it is not permissible to read the specification in order to construe the claims more narrowly or widely than the text will allow.
>
> [78] In the present case, it is apparent that the inventive concept of the claims in the '777 patent is a compound useful in inhibiting platelet aggregation which has greater therapeutic effect and less toxicity than the other compounds of the '875 patent and the methods for obtaining that compound.

[25] Based on the passage above, where the inventive concept is not discernable from the claim itself, a purposive reading of the specification permits the inventive concept of a claim to a bare chemical formula to include an indication of the utility of the

compound (i.e., what the compound is useful for) and advantageous properties of the compound, if any.

Double-patenting

[26] 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 that "a patent shall be granted for one invention only" (*Whirlpool* at para 63). The courts have 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.

[27] 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)).

[28] 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).

ANALYSIS

1. Obviousness of the claims on file (section 28.3 of the *Patent Act*)

Identify the POSITA and the relevant CGK

[29] In the Panel Letter, we noted that the identity of the POSITA and the relevant CGK are not explicitly defined in the FA or the SOR and did not appear to be at issue. In the same letter, we identified the POSITA as a team of persons practising in the fields of medical chemistry, clinical pharmacology and drug formulations.

[30] With respect to CGK possessed by the POSITA, we stated that the POSITA has CGK in the fields identified above and CGK with respect to organic synthesis, pharmacokinetics, pharmaceutical compositions comprising known DPP-IV inhibitors and potential therapeutic uses for DPP-IV inhibitors.

[31] The Applicant's Reply to the Panel Letter did not dispute these aspects of the analysis.

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

[32] In the Panel Letter, we stated that all the claims on file were considered to relate to the same inventive concept as a review of the prosecution record did not indicate that the issue of obviousness has been separately argued in relation to each claim. We noted that the inventive concept identified in the FA includes the Compound's utility. We also noted the Applicant's suggestion in the R-FA that the inventive concept of the claimed invention further includes an advantage, "distinctly better

activity", of the claimed Compound over the genus of previously disclosed compounds.

[33] In the Panel Letter we noted that claim 1 was directed to a bare chemical formula, expressed the view that the inventive concept of the claim is not readily discernable from the claim itself and expressed the view that it was appropriate to read the specification as a whole to determine the inventive concept.

[34] Based on the disclosure found in the description, we expressed our view in the Panel Letter that the POSITA would understand that the application relates to a subgenus of xanthine compounds all having a relatively high degree of DPP-IV inhibiting activity and having specific substituents (i.e., a 2-butyn-1-yl group at the 7-position and a 3-amino-piperidin-1-yl group at the 8-position), that the Compound recited in the claims is a member of that subgenus and that the Compound would have a relatively high degree of potency, just as any other member of the subgenus, because of its close structural similarity.

[35] Accordingly, in the Panel Letter we expressed the view that the POSITA would understand that the inventive concept of the patent application is not simply a compound of the bare chemical formula (Ia), above, but also includes an indication of its utility as a DPP-IV inhibitor, as well as its advantage of having a relatively high degree of potency in comparison to the genus of known xanthine compounds.

[36] The Applicant's Reply to the Panel Letter did not indicate disagreement with this assessment.

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

[37] A single reference is cited in the FA for obviousness:

- Canadian patent CA 2,435,730 C (D1) having a publication date of September 6, 2002 (06-09-2002)

[38] The international application corresponding to D1 is cited in the background section of the instant application.

[39] With respect to the disclosure of the cited prior art document D1, we noted in the Panel Letter that D1 describes a genus of substituted xanthine compounds having an inhibiting effect on the enzyme DPP-IV. We also noted that, although D1 does not specifically describe the Compound recited in the claims on file, the Compound claimed in the instant application is encompassed by the genus of compounds disclosed in D1.

[40] More importantly, we also expressed the view that the POSITA would understand that D1 discloses compounds having DPP-IV inhibiting activity wherein the potency of the tested compounds varies greatly (i.e., IC50 values from 2nM to 2770nM for an average of 247nM) and wherein no particular substituent could reasonably be associated to compounds having the best DPP-IV inhibiting potencies.

[41] In the Panel Letter, we summarized the differences between the inventive concept of the claims and D1 as "an advantageous and unexpected overall increase in the DPP-IV inhibiting activity" and expressed the view that this difference constitutes a substantial advantage over the vast majority of tested xanthine compounds of D1.

[42] The Applicant's Reply to the Panel Letter did not express disagreement with our assessment of the differences between the matter cited as forming part of the state of the art and the inventive concept.

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?

[43] We expressed the view that identifying the specific substituents shared by the compounds of the instant application as advantageous substituents would not constitute steps which would have been obvious to the POSITA having been taught by D1.

[44] Having noted that the Compound recited in the claims on file bears a very strong structural resemblance to other tested compounds, we expressed the view in the Panel Letter that the POSITA would expect that the Compound has DPP-IV inhibiting activity comparable to the DPP-IV inhibiting activity of the tested compounds.

[45] The Applicant's Reply to the Panel Letter did not express disagreement with our assessment of the differences between the matter cited as forming part of the state of the art and the inventive concept.

Conclusion on obviousness

[46] In our view and for the reasons above, the subject matter defined by the claims on file would not have been obvious to the POSITA in view of D1 and, accordingly, the claims on file comply with section 28.3 of the *Patent Act*.

2. Double-patenting

[47] In the Panel Letter, having compared a representative claim of the claims on file and of issued patent 2,617,090, we agreed with the FA that the claims on file and claims of issued patent 2,617,090 encompass a hydrochloride salt of the Compound and we expressed the preliminary view that the POSITA would not regard the claimed

subject matter of the claims on file as being patentably distinct from the subject matter of the relevant claims of issued patent 2,617,090.

[48] The Applicant's Reply to the Panel Letter did not indicate disagreement with this assessment.

[49] Therefore, we are of the view that the claims on file are unpatentable on the grounds of double-patenting.

ANALYSIS OF THE NEW PROPOSED CLAIMS

[50] Since we consider that the claims on file are unpatentable on the grounds of double-patenting and, as stated in the Panel Letter, consider that the Proposed Claims submitted in response to the FA would introduce a new minor defect, we will consider the New Proposed Claims submitted on November 21, 2016 with the Reply to the Panel Letter.

[51] Aside from the deletion of the subject matter of claim 2 and claims 10-12 of the claims on file, the only significant difference between the New Proposed Claims and corresponding claims of the claims on file is the removal of the reference to salts of the recited compound.

Obviousness

[52] As the New Proposed Claims are narrower in scope than the corresponding claims on file, we consider that the New Proposed Claims comply with section 28.3 of the *Patent Act* for the reasons provided previously with respect to the claims on file.

Double-patenting

[53] As noted in the Panel Letter, the SOR states that "[a]mendment to the claims to remove reference to hydrochloride salts would render the claims patentably distinct from those of granted patent 2,617,090". For that reason, we have reasonable grounds to believe that the New Proposed Claims overcome the double-patenting defect noted in the FA and the SOR with regard to the claims on file.

CONCLUSIONS

[54] We have determined that the claims on file comply with section 28.3 of the *Patent Act*. We have also determined that the claims on file are unpatentable on the grounds of double-patenting.

[55] Finally, we have determined that claims 1-8 as proposed in the letter of November 21, 2016 overcome this defect and do not introduce any new defects. Thus, these proposed claims are considered to be "necessary" under subsection 30(6.3) of the *Patent Rules* for compliance with the *Patent Act* and *Patent Rules*.

RECOMMENDATION OF THE BOARD

[56] We have concluded that the claims on file comply with section 28.3 of the *Patent Act* but are unpatentable on the grounds of double-patenting. We have also concluded that proposed claims 1-8 as proposed in the letter of November 21, 2016 overcome this double-patenting defect 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 1-8 as proposed in the letter of November 21, 2016, are "necessary" for compliance with the *Patent Act* and *Patent Rules*.

Marcel Brisebois Member	Ed MacLaurin Member	Sandra Nevill Member

COMMISSIONER'S DECISION

[57] 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.

[58] 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 1-12 on file; and
ii) insert claims 1-8 proposed in the letter of November 21, 2016.

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Johanne Bélisle
Commissioner of Patents
Dated at Gatineau, Quebec,
this 3rd day of January, 2017