Commissioner’s Decision #1430

Décision de la Commissaire #1430

TOPIC: A20 (Double Patenting)

SUJETS: A20 (Double Brevet)

Application No.: 2,444,597

Demande n°.: 2,444,597

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,444,597, 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.

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INTRODUCTION

[1] This recommendation concerns the review of rejected patent application number 2,444,597, which is entitled "FAB I inhibitors" and is owned by Debiopharm International SA. The outstanding defect to be addressed is whether the claims on file are unpatentable on the grounds of double-patenting in view of the claims in issued patent number 2,387,016 (the "'016" patent), also owned by Debiopharm International SA. William H. Miller, Kenneth A. Newlander, Mark A. Seefeld and Irene N. Uzinskas are named inventors in both the instant application and the '016 patent. 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 application be refused.

BACKGROUND

The application

[2] Patent application 2,444,597 was filed in Canada on April 3, 2002 and published on October 6, 2002.

[3] The application relates to pharmaceutical compounds that inhibit Fab I, an important biosynthetic enzyme involved in the synthesis of bacterial fatty acid. The regulatory role played by Fab I makes this enzyme a good target for an antibacterial treatment. The claims on file are directed to the compound (E)-N-methyl-N-(3-methylbenzofuran-2-ylmethyl)-3-(7-oxo-5,6,7,8-tetrahydro-1,8-naphthyridin-3-yl)acrylamide ("Compound A"), pharmaceutical compositions comprising Compound A, pharmaceutically acceptable salts thereof and uses thereof for the treatment of diseases in which inhibition of Fab I is indicated, including the treatment of a bacterial infection.

Procedural History

[4] On January 27, 2015, a Final Action ("FA") was written pursuant to subsection 30(4) of the *Patent Rules*. The FA explained the potential for obviousness double-patenting in view of the '016 patent should the subject application be allowed.

[5] In a response to the FA ("R-FA") dated July 27, 2015, the Applicant provided arguments as to why the subject-matter of the claims on file is patentably distinct from the claimed invention in the '016 patent.

[6] As the Examiner was not persuaded by the Applicant's arguments and considered that the application still did not comply with the *Patent Act*, the application was forwarded to the Patent Appeal Board ("the Board") for review, along with a Summary of Reasons ("SOR") maintaining the defect identified in the FA for the claims on file.

[7] In a letter dated December 21, 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 March 18, 2016 the Applicant expressed the wish to provide written submissions in response to the SOR and to not participate in an oral hearing.

[8] In a response to the SOR ("R-SOR") dated May 13, 2016, the Applicant presented more focused arguments as to why the person of ordinary skill in the art would understand that Compound A possesses a substantial advantage to support the submission that Compound A is patentably distinct from the compounds claimed in the '016 patent.

[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 April 27, 2017 (the "Panel Letter"), we set out our preliminary analysis and rationale as to why, based on the record before us, the person of ordinary skill in the art would not regard the subject-matter of the claims on file as being patentably distinct from subject-matter claimed in the patent '016 patent. The Panel Letter also invited the Applicant to provide further written submissions in response to the Panel's preliminary review. The Panel Letter indicated that if the Applicant did not inform the Panel by May 15, 2017 of its intention to provide further submissions, the Panel would complete the review and provide its recommendation to the Commissioner without further communication.

[10] Since the Applicant did not reply to the Panel Letter, the Applicant's representative was contacted by phone. On May 30, 2017, the representative confirmed that the Panel Letter had been received and that no reply would be forthcoming.

[11] Because the Applicant expressed the wish to not participate in an oral hearing, an oral hearing was not held.

ISSUE

[12] There is one issue identified in the FA and the SOR provided to the Applicant and to be addressed in this review: whether the claims on file are unpatentable on the grounds of double-patenting in view of the claims in the issued '016 patent.

LEGISLATION AND LEGAL PRINCIPLES

Double-patenting

[13] 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.

[14] 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 Corp v. Camco Inc.*, 2000 SCC 67 ("*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.

[15] 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).

[16] Obviousness double-patenting and obviousness under section 28.3 of the *Patent Act* are both assessed from the perspective of the person of ordinary skill in the art ("POSITA"), taking into account that person's common general knowledge ("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).

Selection patents and double-patenting

[17] It is apparent from the prosecution that considerations relating to selection patents are relevant to the issue before us because the Applicant has submitted that Compound A possesses a substantial advantage over the compounds of the ’016 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] The 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).

[20] In *Sanofi* at paras 113 and 114, the Supreme Court of Canada stated the following with respect to a selection, the special advantage associated with the selection and obviousness double-patenting:

> A selection patent that claims a compound that is patentably distinct from the genus patent will not be invalid for obviousness double patenting. Here, out of the many compounds predicted to be effective as exhibiting platelet aggregation inhibiting activity in the '875 patent, it was found that the dextro-rotatory isomer of the racemate relevant in this case had beneficial properties over both the racemate and the levo-rotatory isomer. As I have explained above, the claims in the '777 patent reflect a patentably distinct compound from the compounds in the '875 patent. As a result, there is no basis for a challenge based on "obviousness" double patenting.
>
> While double patenting requires a comparison of the claims of a genus and selection patent, it is necessary that the specification of the selection patent define 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 *I. G. Farbenindustrie*, at p. 323. Here the '777 specification satisfies this requirement by providing, at p. 1:
>
> In an unexpected manner only the dextro-rotatory enantiomer I_d exhibits a platelet aggregation inhibiting activity, the levo-rotatory enantiomer I_l being inactive. Moreover, the inactive levo-rotatory enantiomer I_l is the less well tolerated of the two enantiomers. [A.R., at p. 156]. [Emphasis added]

[21] In view of the above passage, the advantage of a selection must be properly disclosed in the specification for there to be a patentably distinct compound from the compounds in the genus patent (see also *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 236 at para 45, *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).

ANALYSIS

Double-patenting

[22] In the Panel Letter, we cited a passage from the FA (see FA, page 4) that summarizes why the subject-matter of the claims on file was considered not patentably distinct from the claimed subject-matter of the ’016 patent:

> In sum, based on the claims alone, the person skilled in the art would expect the compounds claimed in '016 to have a particular utility. The applicant is claiming a single compound that falls within that scope and describes it (along with a multitude of other compounds) as having that same utility as the others in the '016 genus. Since it would be obvious that the compound would have this utility, the compound cannot be considered patentably distinct from the genus. Despite the supplemental data submitted, and the argumentation provided, the applicant has not shown that the selection of this compound from the genus is anything but arbitrary. Therefore, on a claim-by-claim comparative basis, the claims on file are obvious and thus not related to subject-matter patentably distinct from claims 1, 2, 10 and 11 in '016. The claims on file therefore cannot be granted in a separate patent.

[23] In the Panel Letter, we summarized the Applicant’s argument as follows:

- Compound A possesses improved antimicrobial activity compared with the claimed compounds of the ’016 patent. This advantage could be readily identified from the instant specification and is confirmed by post-filing data that should be admissible (see R-FA, pages 3, 4, 7 and 8 and R-SOR, pages 3 and 4).

- In an obviousness double-patenting analysis, the question that must be answered is whether the claimed invention in the later filed application is very plain, or self-evident, when compared to the claimed invention in the

earlier filed patent. In that regard, the Applicant submits that Compound A is not self-evident compared with what has been claimed in the ’016 patent (see R-FA, pages 2 and 3).

- A person skilled in the art provided only with generic structures in claims 1 and 2 of the ’016 patent, and even further considering specific chemical structures in other claims of the ’016 patent, would not arrive at Compound A without inventive ingenuity (see R-FA, pages 4-6).

The POSITA and the relevant CGK

[24] In the Panel Letter, we noted that the identity of the POSITA and the relevant CGK were not defined in the FA or the SOR. In the same letter, we identified the POSITA as a team of persons practising in the fields of medicinal chemistry of antibacterial drugs and clinical pharmacology. With respect to the CGK possessed by the POSITA, we stated that the POSITA has CGK in the fields identified above and CGK with respect to organic synthesis and pharmacokinetics. We also specified that the therapeutic uses of Fab I inhibitors as antibacterial agents were also considered CGK.

[25] As there has been no response from the Applicant, the above assessments of the POSITA and the CGK is adopted for the purposes of this review.

Claims comparison

[26] In the Panel Letter, we compared claims 1, 3 and 4 of the instant application and claims 1, 15 and 16 of the ’016 patent claims. Claim 1 on file and claim 1 of the ’016 patent are directed to a compound. Claim 3 on file and claim 16 of the ’016 patent are directed to the use of the same compound for the treatment of diseases in which inhibition of Fab I is indicated. Claim 4 on file and claim 15 of the ’016 patent are directed to the treatment of a bacterial infection. We noted that claim 1 of

the ’016 patent encompasses a genus of compounds defined by a general structural formula and various possible substituents. We further noted that the Applicant does not appear to dispute that Compound A falls within the genus of compounds broadly defined in claim 1 of the ’016 patent. Further, we expressed the preliminary view that claims 1, 3 and 4 on file encompass subject-matter that overlaps with subject-matter of claims 1, 15 and 16 of the ’016 patent, namely Compound A.

[27] As there has been no response from the Applicant, we maintain our view expressed in the Panel Letter and consider that claims 1, 3 and 4 on file and claims 1, 15 and 16 of the ’016 patent encompass Compound A and the same uses thereof.

Substantial advantage

[28] As mentioned above, the Applicant submitted that Compound A possesses improved antimicrobial activity compared to the claimed compounds of the ’016 patent and that such advantage could be readily identified from the instant specification and is confirmed by post-filing data.

[29] After reviewing the claims, the description and the decision in *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60 (“*Sildenafil*”) cited by the Applicant, we expressed the preliminary view in the Panel Letter that the POSITA would not understand from the originally filed specification that Compound A possesses a substantial advantage with regard to its antimicrobial activity or as a FAB I inhibitor and, accordingly, the specification would not serve to render Compound A patentably distinct from the claimed compounds of the ’016 patent.

[30] First, we expressed the view in the Panel Letter that the POSITA would not understand that Compound A “must possess an advantage over the ’016 patent” because the claims are now limited to this compound. We noted that the originally filed application did not contain a claim set that eventually cascaded to Compound A. Hence, we stated that had we accepted the Applicant’s premise that the POSITA

would have inferred the existence of an advantage from the presence of a claim directed to a single compound, the originally filed claims do not support the assertion that a substantial advantage was recognized at the time of filing for Compound A. We stated that it could suggest that the choice of limiting the subject-matter of the claims on file to Compound A during prosecution was based on knowledge which had only been acquired post-filing. In that regard, we pointed out that the potential problem associated with establishing inventiveness retroactively by post-filing amendments was noted in *May and Baker Ltd. et al. v. Boots Pure Drug Company Limited* (1950), 67 R.P.C. 23 at page 57 where it is stated:

> There is a good reason why a patentee should not be allowed to introduce a new selection by amendment: the new selection may be based on knowledge which he has only recently acquired and if it were allowed he would be able to claim something which he had not invented when he got his patent.

[31] We also noted that the Supreme Court indicated in *Sildenafil* that determining whether each claim in a patent concerns a separate invention must be done only after considering the whole specification. We expressed the view that the POSITA would reasonably conclude from the specification as a whole that Compound A is simply another example of a Fab I inhibitor, not necessarily a preferred one, and that nothing distinguishes it from the other Fab I inhibitors disclosed in the instant application or from the compounds claimed in the ’016 patent. We did not find explicit statement in the description or in the claims that may suggest that Compound A is particularly advantageous with regard to its antimicrobial activity or any other functional characteristic. Compound A does not stand out as a compound with special properties or as being a member of a subgroup of compounds having special properties.

[32] We further expressed the view that the passage of the description referred to by the Applicant (see page 34 of the description, lines 17-20) does not support the view that the POSITA would understand from the specification that the Compound A actually possesses an improved antimicrobial activity compared with the claimed compounds

of the ’016 patent (i.e., a minimum inhibitory concentration (MIC) value of less than 64 μg/ml). Although the referenced passage informs the skilled reader about how the results of an antimicrobial activity assay would be considered by the POSITA and about the expectations regarding the compounds disclosed in the instant application, neither the referred passage nor the rest of the specification discloses that a given MIC value has been determined for each of the disclosed compounds or that any result was generated from said antimicrobial activity assays. Hence, we considered that the POSITA would not associate any particular compound disclosed in the description, including Compound A, with a specific MIC value. We also noted that the Applicant’s submissions rest, in part, on the expectation that the POSITA would draw inferences and extrapolations from the specification, which accentuates the shortcomings of the specification with respect to defining in clear terms the nature of the advantage which the Applicant alleges to be possessed by Compound A (see *Sanofi*, para 114, cited by the Applicant on page 2 of the R-SOR).

[33] In any case, we further noted that the ’016 patent also discloses that preferred compounds have a MIC value of less than 64 μg/ml. Accordingly, we expressed the view that even if the instant specification had clearly stated that the antimicrobial activity of Compound A constitutes an advantage, the POSITA would not consider a MIC value of less than 64 μg/mL to be an improved antimicrobial activity because the POSITA would also have believed that the genus of Fab I inhibitors claimed in the ’016 patent encompasses compounds having a MIC value of less than 64 μg/mL.

[34] With regard to the post-filing data submitted by the Applicant that apparently confirm that Compound A possesses antimicrobial activity compared to a compound covered by the claims of the ’016 patent, we stated in the Panel Letter that it was not necessary for the instant review to give further consideration to the post-filing data because the “confirmatory” data did not alter our view with regard to what the POSITA would understand from the information contained in the specification with respect to the disclosure of an advantage for Compound A.

[35] Nevertheless, we offered our observation that the post-filing data does not "confirm" that Compound A possesses an advantage *vis-à-vis* the genus claimed in the '016 patent as the comparison was limited to a single compound (Compound B) and two *Staphylococcus aureus* strains. We stated that the compounds within the genus of '016 patent may have varying levels of antimicrobial activity and the observed antimicrobial activity of a given compound against different bacteria may also differ. In view of that, we considered that the post-filing data is not persuasive evidence to support a finding that the alleged advantageous antimicrobial activity would not be expected to be found in a large number of the other members of the genus or to show that the alleged advantage is substantial and/or peculiar to Compound A. We also pointed out the difficulty associated with such a limited comparison. A fortuitous choice of an unrepresentative compound of the genus could serve to inadvertently exaggerate the advantage of the chosen compound, if any (see *Glaxosmithkline Inc. v. Pharmascience Inc.*, 2008 FC 593, at paras 63 and 70).

[36] For all the reasons above, we maintain our view that the POSITA would not understand from the originally filed specification that Compound A possesses a substantial advantage with regard to its antimicrobial activity or as a FAB I inhibitor and, accordingly, would not serve to render Compound A patentably distinct from the claimed compounds of the '016 patent.

The question that must be answered in an obviousness-type double patenting analysis

[37] As mentioned at para [23], we considered in the Panel Letter certain arguments of the Applicant's submissions found on pages 2 and 3 of the R-FA that suggested that an "obvious to try" analysis is appropriate in the instant case and that in an obviousness type double patenting analysis, the question that must be answered is whether the claimed invention in the later filed application is very plain, or self-evident, when compared to the claimed invention in the earlier patent.

[38] Based on the same legal principles laid out in the "LEGISLATION AND LEGAL PRINCIPLES" section above, we expressed the view in the Panel Letter that the more relevant question is whether Compound A is "patentably distinct" and exhibits "novelty or ingenuity" over those compounds of the '016 patent, referring to *Whirlpool* at paras 66-67. We also stated that the fundamental question in the instant context of an obviousness double-patenting inquiry is not whether the choice of Compound A from the numerous compounds encompassed by the genus of the '016 patent is obvious, but whether Compound A is inventive in view of, or patentably distinct from, the compounds claimed in the '016 patent. That question is reflected in a passage of *Eli Lilly Canada, Inc. v. Apotex Inc.*, 2015 FC 875 that was cited by the Applicant on page 2 of the R-FA. Accordingly, we did not consider relevant for the purpose of this instant review to answer whether the claimed invention in the later filed application is very plain, or self-evident, when compared to the claimed invention in the earlier patent.

[39] However, we made the observation that had we considered the "obvious to try" framework suitable for the instant obviousness double-patenting inquiry, the appropriate question would have been whether it would have been more or less self-evident to the POSITA, based on the claimed Fab I inhibitors of the '016 patent and the CGK, that a compound encompassed by the genus of the '016 patent ought to work as a Fab I inhibitor and be useful for the treatment of bacterial infections. Given that Compound A falls within the claimed genus of '016 patent, we considered that it would have been more or less self-evident to the POSITA that Compound A ought to work as a Fab I inhibitor and be useful for the treatment of bacterial infections. We were of the view that this factor would have been largely determinative of the obvious to try inquiry in this case.

Inventive ingenuity and identification of Compound A among compounds encompassed by the ’016 patent

[40] The Applicant submitted on pages 4 to 6 of the R-FA that inventive ingenuity was required to identify Compound A from the millions of compounds encompassed by the claims of the ’016 patent because there are no specific compounds in the claims of the ’016 patent having a structure similar to Compound A and the teachings of the ’016 patent would not have led the POSITA specifically to Compound A. Therefore, according to the Applicant’s submissions, had the POSITA been presented with the list of possibilities, and asked to decide which to select, the POSITA would have had no reason to choose the exact chemical groups forming Compound A.

[41] In the Panel Letter, we expressed the view that the case law does not indicate that structurally different species of a genus necessarily constitute separate non-obvious inventions. In that respect, we observed that the Federal Court, when presented with similar arguments in *Janssen Inc. v. Teva Canada Ltd*, 2015 FC 247, at paras 39-42, stated that “[a] person of skill is not doing anything inventive when he chooses options provided in a prior patent to build a molecule that he expects will work” and determined that it was flawed thinking to conclude that “a compound that is included within a patented genus of compounds but not exemplified could be reclaimed for the same utility whether or not it was a valid selection with special properties”.

[42] We also expressed the view that the ’016 patent teaches that all the compounds within the genus are Fab I inhibitors, including Compound A that falls into the scope of the genus claimed. Accordingly, we were of the view that the POSITA would not be required to do anything inventive by choosing from obvious options to produce a Fab I inhibitor that is expected and taught to be a Fab I inhibitor.

[43] Further, we observed that the specification as a whole, and Example 99 in particular (the example which describes the preparation of Compound A), does not support the conclusion that the preparation of Compound A would have required inventive ingenuity from the POSITA. Example 99 simply reads:

Example 99

Preparation of (E)-N-methyl-N-(3-methylbenzofuran-2-ylrnethyl)-3-(7-oxo-5,6,7 .8-tetrahydro-1.8-naphthyridin-3-yl)acrylamide

The title compound is prepared following methods analogous to those described in the previous preparations and examples.

CONCLUSION

[44] For the reasons above, it is our view that the POSITA would not regard the subject-matter of the claims on file as being patentably distinct from the subject-matter of claims 1, 2, 10, 13, 15 and 16 of the ’016 patent. Therefore, we are of the view that the claims on file are unpatentable on the grounds of double-patenting.

RECOMMENDATION OF THE BOARD

[45] We recommend that the application be refused because the claims on file are unpatentable on the grounds of double-patenting in view of the claims of issued patent 2,387,016.

Marcel Brisebois Member	Ed MacLaurin Member	Leigh Matheson Member

COMMISSIONER'S DECISION

[46] I concur with the findings of the Patent Appeal Board and its recommendation that the application should be refused because the claims on file are unpatentable on the grounds of double-patenting in view of the claims of issued patent 2,387,016.

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

Johanne Bélisle
Commissioner of Patents
Dated at Gatineau, Quebec,
this 26th day of September, 2017