Citation: Kudos Pharmaceuticals Limited, 2022 CACP 22

Commissioner's Decision #1629
Décision du commissaire nº 1629
Date: 2022-10-20

TOPIC:	A20	Double-patenting
	C00	Ambiguity or indefiniteness
SUJET:	A20	Double-brevet
	C00	Caractère ambigu ou indéfini

Application No. : 2,702,429

Demande nº 2 702 429

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,702,429 having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 (the former *Patent Rules*), has consequently been reviewed in accordance with paragraph 199(3)(c) of the *Patent Rules* (SOR/2019-251). The recommendation of the Patent Appeal Board and the decision of the Commissioner are to refuse the application.

Agent for the Applicant:

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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,702,429, which is entitled “Crystalline Form L 4-[3-cyclopropanecarbonyl-piperazine-1-carbonyl)-4-fluoro-benzyl]-2H-phthalazin-1-one”. Kudos Pharmaceuticals Limited is the sole Applicant. A review of the rejected application has been conducted by a Panel of the Patent Appeal Board pursuant to paragraph 199(3)(c) of the *Patent Rules*.

[2] As explained in more detail below, our recommendation is that the Commissioner of Patents refuse the application.

BACKGROUND

The Application

[3] The application was filed under the *Patent Cooperation Treaty* and has an effective filing date in Canada of October 17, 2008. It was laid open to public inspection on April 23, 2009.

[4] The rejected application claims a crystalline form, Form L, of 4-[3-cyclopropanecarbonyl-piperazine-1-carbonyl)-4-fluoro-benzyl]-2H-phthalazin-1-one (compound A), a known poly(ADP-ribose) polymerase inhibitor (PARP) inhibitor. The claims also cover processes for the preparation of Form L of compound A, pharmaceutical compositions comprising Form L and the use of Form L for the treatment of diseases and disorders that can be ameliorated by PARP inhibition.

[5] The application has 17 claims on file that were received at the Patent Office on March 12, 2019.

Prosecution History

[6] On August 15, 2019, a Final Action was written under subsection 30(4) of the former *Patent Rules*. The Final Action states that the subject-matter of the claims on file at the time of the Final Action is not patentably distinct over the subject-matter of the claims of Canadian Patent 2,664,275 (‘275 Patent) contrary to the doctrine of double-patenting. The Final Action also indicates that claims 1, 2 and 4 are indefinite and therefore non-compliant with subsection 27(4) of the *Patent Act* and claim 3 refers to itself and therefore does not comply with subsection 87(2) of the former *Patent Rules* (now subsection 63(2) of the *Patent Rules*).

[7] In the response to the Final Action dated February 11, 2020, the Applicant argues that the claims of the present application are patentably distinct from those of the ‘275 Patent and that claims 1, 2 and 4 are not indefinite. In addition, the response to the Final Action includes an amended claim set containing proposed claims 1 to 17 [proposed claims] to address the improper claim dependency defect.

[8] On May 29, 2020, the application was forwarded to the Patent Appeal Board for review under paragraph 30(6)(c) of the former *Patent Rules* along with a Summary of Reasons explaining that the rejection is maintained as the Applicant’s arguments presented in the response to the Final Action are not persuasive and that the proposed amendments presented in the response to the Final Action do not overcome all of the defects identified in the Final Action. The Summary of Reasons also identifies a presentation defect with the page numbering of the specification.

[9] In a letter dated June 5, 2020, the Patent Appeal Board forwarded a copy of the Summary of Reasons to the Applicant and requested that they confirm their continued interest in having the application reviewed.

[10] In a letter dated August 10, 2020, the Applicant confirmed their interest in having the review proceed.

[11] The present Panel was formed to review the rejected application under paragraph 199(3)(c) of the *Patent Rules*. On August 30, 2022, the Panel sent a Preliminary Review letter detailing our preliminary analysis and opinion that the claims on file, as well as the proposed claims, are not patentably distinct over the subject-matter

of the claims of Canadian Patent 2,664,275 (‘275 Patent) contrary to the doctrine of double-patenting. In that letter, the Panel further expressed the preliminary opinion that the subject-matter of claims 1, 2 and 4 on file and of proposed claims 1, 2 and 4 complies with subsection 27(4) of the *Patent Act*, that claim 3 on file is improperly dependent, contrary to subsection 63(2) of the *Patent Rules* and that proposed claim 3 overcomes this defect. Finally, the Panel expressed the preliminary opinion and that the pages of the description and claims are not numbered consecutively, contrary to subsection 73(1) of the former *Patent Rules* and this defect is not overcome by the proposed claims. The Preliminary Review letter also provided the Applicant with an opportunity to make oral and/or written submissions.

[12] On September 21, 2022, the Applicant declined the opportunity for an oral hearing and indicated that there would be no written submissions.

Issues

[13] In view of the above, the following issues are considered in this review:

- whether the claims on file are not patentably distinct over the claims of the ‘275 Patent contrary to the doctrine of obviousness double-patenting;
- whether claims 1, 2 and 4 are indefinite contrary to subsection 27(4) of the *Patent Act*;
- whether claim 3 is improperly dependent contrary to subsection 63(2) of the *Patent Rules*; and
- whether there is a defect with the page numbering of the specification contrary to subsection 73(1) of the former *Patent Rules*.

[14] In addition to the claims on file, the proposed claims have also been considered.

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICE

Purposive Construction

[15] According to *Free World Trust v Électro Santé Inc*, 2000 SCC 66 and *Whirlpool*

Corp v Camco Inc, 2000 SCC 67 [Whirlpool], a purposive construction of the claims is performed from the point of view of the person skilled in the art in light of the relevant common general knowledge and considers the specification and drawings. In addition to interpreting the meaning of the terms of a claim, purposive construction distinguishes the essential elements of the claim from the non-essential elements. Whether or not an element is essential depends on the intent expressed in or inferred from the claim, and on whether it would have been obvious to the person skilled in the art that a variant has a material effect upon the way the invention works.

[16] In carrying out the identification of essential and non-essential elements, all elements set out in a claim are presumed essential unless it is established otherwise or where such a presumption is contrary to the claim language.

Obviousness Double-Patenting

[17] There are no express 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": 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, affirming 2009 FC 1249.

[18] 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 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 at paras 66 to 67.

[19] Obviousness double-patenting is assessed from the perspective of the person skilled in the art, taking into account their common general knowledge. The analysis compares the claims in the subject application to the claims of the issued patent: *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc,* 2016 FCA 119 at paras 28 to 29 [Mylan].

Indefiniteness

[20] Subsection 27(4) of the *Patent Act* requires claims to distinctly and explicitly define the subject-matter of the invention:

> The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.

[21] In *Minerals Separation North American Corp v Noranda Mines Ltd*, [1947] Ex CR 306 at 352, 12 CPR 99, the Court emphasized the obligation of an Applicant to make clear in the claims the scope of the monopoly sought, as well as the requirement that the terms used in the claims be clear and precise:

> By his claims the inventor puts fences around the fields of his monopoly and warns the public against trespassing on his property. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own. The terms of a claim must be free from avoidable ambiguity or obscurity and must not be flexible; they must be clear and precise so that the public will be able to know not only where it must not trespass but also where it may safely go.

Reference to Preceding Claim

[22] Under subsection 63(2) of the *Patent Rules*, dependent claims may only reference a preceding claim:

> A dependent claim may only refer to a preceding claim or claims.

Page Numbering

[23] Subsection 73(1) of the former *Patent Rules* requires that:

> The pages of the specification must be numbered consecutively.

ANALYSIS OF THE CLAIMS ON FILE

Following a Purposive Construction, Which Claimed Elements are Essential?

[24] The Preliminary Review letter, on page 5, expresses the preliminary view that all of the elements of the claims on file are essential.

The claims on file

[25] There are 17 claims on file. Claims 1 and 4 to 10 are independent claims. The Preliminary Review letter, on pages 5 to 6, expresses the preliminary view that claims 1 and 4 are representative of the independent claims. Claims 1 and 4 are as follows:

1. Compound A as crystalline Form L comprising the following characteristic peaks in a powder XRD:

Peak	2θ° (±0.1°) (λ=1.5418Å)
1	14.4
2	17.2
3	17.5
4	18.8
5	23.0

4. A method of obtaining compound A as crystalline Form L from compound A as crystalline Form A, comprising slurrying compound A as either Form A or a mixture of Forms A and L in an organic solvent that optionally contains up to 30% water v/v, wherein the organic solvent is selected from the group consisting of methanol, ethanol, acetone, acetonitrile and nitromethane, wherein the crystalline Form L comprising the following characteristic peaks in a powder XRD:

Peak	2θ° (±0.1°) (λ=1.5418Å)
1	14.4
2	17.2
3	17.5
4	18.8
5	23.0

[26] Independent claims 5 to 10 relate to pharmaceutical compositions comprising Form L and the use of Form L in the treatment of various diseases and disorders that can be ameliorated by PARP inhibition.

[27] Dependent claims 2 and 3 define further spectral and thermal characteristics of Form L and claims 11 to 17 define further limitations regarding the use of Form L in the manufacture of a medicament for the treatment of cancer.

[28] In the absence of submissions from the Applicant, we adopt the above identification of claims 1 and 4 as being representative of the independent claims. Likewise, we adopt the above characterization of dependent claims 2, 3 and 11 to 17 as providing further limitations with regard to: additional spectral and thermal characteristics of Form L and limitations regarding the use of Form L in the manufacture of a medicament for the treatment of cancer.

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

[29] The Preliminary Review letter, on pages 3 to 5, states the following with regard to

the identity of the person skilled in the art and their expected common general knowledge:

Neither the Final Action nor the Response to the Final Action identify the person skilled in the art. As indicated above, purposive construction is performed from the perspective of the person skilled in the art. We therefore present our preliminary view regarding the identity of the person skilled in the art and the relevant common general knowledge.

Based on the teachings of the description, the references cited therein and the subject-matter of the claims, our preliminary view is that the person skilled in the art is a drug development team with expertise in organic chemistry, pharmaceutical and formulation sciences having experience with polymorphs and their impact on product performance. In addition, this team would have experience in the use of PARP inhibitors in the treatment of diseases and disorders that can be ameliorated by PARP inhibition.

With regard to the common general knowledge of the person skilled in the art, the Final Action refers to methods of screening for polymorphs as can be found in the following prior art documents D1 to D3:

D1: Bavin, “Polymorphism in Process Development”, Chemistry and Industry, Chapter 11, pages 527 to 529, August 1989.

D2: Caira, “Crystalline Polymorphism of Organic Compounds”, Topics in Curr. Chem., Vol. 198, pages 163 to 208, January 1998.

D3: Byrn *et al.*, “Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations”, Pharma. Res., Vol. 12, No. 7, pages 945 to 954, 1995.

Having reviewed the instant specification, as well as D1 to D3, we are of the preliminary view that the common general knowledge includes knowledge of various methods of screening for polymorphs. D1 to D3 are review articles, all of which discuss methods of preparing and characterizing polymorphs that were generally known and accepted without question by the bulk of those who are engaged in the particular arts of organic chemistry, pharmaceutical and formulation sciences at the claim date.

Further, based on the description, in our preliminary view, the common general knowledge of this team would include the following:

PARP participates in a variety of DNA-related functions including gene amplification, cell division, differentiation, apoptosis, DNA base excision repair and also effects on telomere length and chromosome instability (page 1);

> PARP has also been associated with malignant transformation, certain vascular diseases, septic shock, ischaemic injury, neurotoxicity, retroviral infection and onset of aging characteristics (pages 1 and 2); and
>
> PARP inhibitors are known, including small molecule inhibitors such as phthalazinone derivatives, as is their use in the treatment of diseases and disorders that can be ameliorated by PARP inhibition; (pages 1 and 2).

[30] In the absence of submissions from the Applicant, we adopt the above characterizations of the person skilled in the art and the relevant common general knowledge for our analysis.

Essential elements

[31] The Preliminary Review letter, on page 6, states the following with regard to the elements in the claims that the person skilled in the art would consider to be essential:

> With respect to claim language, our preliminary view is that the person skilled in the art reading claims 1 to 17 in the context of the specification as a whole and in view of their common general knowledge would understand that there is no use of language in the claims indicating that any of the elements are optional, preferred or were otherwise intended to be non-essential, with the exception of the organic solvent of claim 4 which can optionally contain up to 30% water v/v. In addition, claims 4, 8, 9, 12, 13, 16 and 17 define various lists of alternatives. There is no indication on the record before us that any claim elements are non-essential. Therefore, our preliminary view is that the person skilled in the art would consider all of the elements in the claims to be essential.

[32] In the absence of submissions from the Applicant, we adopt the above identification of the claim elements that are essential in this recommendation.

Are the Claims Patentably Distinct From the Claims of the ‘275 Patent?

[33] The Preliminary Review letter, on page 6, expresses the preliminary view that the claims define subject-matter that is not patentably distinct from the claims of the ‘275 Patent.

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

[34] The person skilled in the art and the relevant common general knowledge have

been identified as part of the purposive construction of the claims. Although in this context the information forming the relevant common general knowledge is identified using the publication date, this information is also considered common general knowledge at the claim date and is therefore relevant for assessing obviousness double-patenting.

Claim comparisons

[35] The Preliminary Review letter, on pages 7 to 8, indicates that claim 1 on file of the present application and claim 1 of the '275 Patent are representative claims of the compound, composition and use claims in each document. These claims are as follows:

<table>
<tr><th>Claim 1 on file</th><th>Claim 1 of the '275 Patent</th></tr>
<tr><td>1. Compound A as crystalline Form L comprising the following characteristic peaks in a powder XRD:
<table>
<tr><th>Peak</th><th>2θ° (±0.1°) (λ=1.5418Å)</th></tr>
<tr><td>1</td><td>14.4</td></tr>
<tr><td>2</td><td>17.2</td></tr>
<tr><td>3</td><td>17.5</td></tr>
<tr><td>4</td><td>18.8</td></tr>
<tr><td>5</td><td>23.0</td></tr>
</table>
.</td><td>1. Compound A as crystalline Form A having the following characteristic peaks in a powder XRD:
<table>
<tr><th>Peak</th><th>2θ° (±0.1°) (λ=1.5418Å)</th></tr>
<tr><td>1</td><td>12.0</td></tr>
<tr><td>2</td><td>17.8</td></tr>
<tr><td>3</td><td>21.1</td></tr>
<tr><td>4</td><td>22.3</td></tr>
<tr><td>5</td><td>29.2</td></tr>
</table>
.</td></tr>
</table>

[36] With regard to method claim 4 on file, page 8 of the Preliminary Review letter identifies claim 6 of the '275 Patent as the closest and most relevant claim. These claims are as follows:

<table>
<tr><th>Claim 4 on file</th><th>Claim 6 of the ‘275 Patent</th></tr>
<tr><td>4. A method of obtaining compound A as crystalline Form L from compound A as crystalline Form A, comprising slurrying compound A as either Form A or a mixture of Forms A and L in an organic solvent that optionally contains up to 30% water v/v, wherein the organic solvent is selected from the group consisting of methanol, ethanol, acetone, acetonitrile and nitromethane, wherein the crystalline Form L comprising the following characteristic peaks in a powder XRD:
<table>
<tr><th>Peak</th><th>2θ° (±0.1°) (λ=1.5418Å)</th></tr>
<tr><td>1</td><td>14.4</td></tr>
<tr><td>2</td><td>17.2</td></tr>
<tr><td>3</td><td>17.5</td></tr>
<tr><td>4</td><td>18.8</td></tr>
<tr><td>5</td><td>23.0</td></tr>
</table>
.</td><td>6. A method of obtaining compound A as crystalline Form A having the following characteristic peaks in a powder XRD:
<table>
<tr><th>Peak</th><th>2θ° (±0.1°) (λ=1.5418Å)</th></tr>
<tr><td>1</td><td>12.0</td></tr>
<tr><td>2</td><td>17.8</td></tr>
<tr><td>3</td><td>21.1</td></tr>
<tr><td>4</td><td>22.3</td></tr>
<tr><td>5</td><td>29.2</td></tr>
</table>
comprising the steps of:

(i) suspending compound A in a mixture of water and a C_{1-2} alcohol as the solvent;
(ii) heating the suspension to reflux;
(iii) cooling the solution and seeding with compound A as Form A; and
(iv) drying the resultant product.</td></tr>
</table>

[37] In the absence of submissions from the Applicant, we adopt the above identification of the representative and relevant claims for our analysis.

Claim similarities

[38] The Preliminary Review letter, on pages 9 to 10, identifies the following similarities between the above-mentioned claims:

> Claim 1 on file and claim 1 of the ‘275 Patent both recite a non-solvated crystalline form of compound A, a known PARP inhibitor.

> Claim 4 on file and claim 6 of the ‘275 Patent both recite a method for obtaining a non-solvated crystalline form of compound A, a known PARP inhibitor. The same solvents and solvent pairs that avoid solvent trapping are usedD1 discloses the preparation of crude (*E*) methyl-2-[2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy) phenyl]-3-methoxypropenoate (azoxystrobin) and subsequent purification by crystallization from methanol (see Examples 1 and 2).

[39] In the absence of submissions from the Applicant, we adopt the above identification of the claim similarities.

Claim differences

[40] The Preliminary Review letter, on pages 10 to 15, identifies the following differences between the above-mentioned claims:

> With respect to claim 1 of the instant application and claim 1 of the ‘275 Patent, page 3 of the Final Action submits the only difference is that Form L is simply an alternative non-solvated crystalline form of compound A as compared to Form A (*i.e.*, they have different arrangements of the molecules of compound A in relation to one another in the solid state). The Final Action disagrees that the enhanced thermodynamic stability of Form L as compared to Form A, introduced in the Applicant’s response of January 18, 2019, should be considered as a difference:
>
> > There are no beneficial properties associated with Form L compared to Form A, it is simply an alternative non-solvated crystalline form of Compound A.
> >
> > […]
> >
> > The Applicant attempts to rely on data provided in the enclosed Tables 1 and 2 in support of the thermodynamic stability of Form L compared to Form A. Respectfully, the data present in said Tables <u>have no associated date</u> and <u>are not present in the description as originally filed</u>. As rule in *Novopharm*[1], at paragraph 26, any “subsequently recognized advantages” which are perceived only after the date of the invention cannot assist in the inquiry into inventiveness.
> >
> > Notably, the Supreme Court of Canada in *Whirlpool* indicated that the substance of a double-patenting inquiry – like obviousness – is whether there is “invention” or “ingenuity” in the move from the first patent to the second –see *Whirlpool* at paras. 66-67. Due to these court-noted similarities in reasoning between obviousness and obviousness double patenting, *Novopharm* is relevant jurisprudence for the reliance on

> "subsequently recognized advantages" as they pertain to a patentable distinction. Therefore, subsequently recognized advantages after the date of invention cannot be considered for patentable distinction between two sets of claims.

[footnote: [1]*Novopharm Ltd v Janssen-Ortho Inc*, 2007 FCA 217]

The Response to the Final Action, on pages 1 to 2, disputes this assessment and asserts that the claims of the instant application are patentably distinct from those of the '275 Patent because the advantages of Form L over Form A were recognized prior to the filing date of the instant application and they must be taken under consideration in an inventive ingenuity determination. In this regard, an affidavit confirming that the enhanced thermodynamic stability of Form L had been demonstrated prior to the filing date of the present application was provided.

In addition, the Response to Final Action alleges that the advantages associated with Form L were recognized in the present application as well as the priority application:

> [Emphasis in original] The advantages of Form L were recognized at the priority date
>
> The present application as well as the priority application indicate, at page 3, the advantages of other forms (than form A) of Compound A than those previously disclosed:
>
> "Particular forms of compound A may have advantageous properties, for example with regard to their solubility and/or their stability and/or their bioavailability and/or **their impurity profile** and/or their filtration characteristics and/or their drying characteristics and/or their lack of hygroscopicity, and/or they may be easier to handle and/or micronise and/or form into tablets." (emphasis added)
>
> Thus, Applicant, at the priority date, did recognize the advantages associated with Form L, especially with respect to its impurity profile.

Finally, the Response to the Final Action, on pages 2 to 3, relies on several Canadian Court decisions as standing for the proposition that inherent advantages of the polymorph need not be stated in the description: See *Consolboard v MacMillan Bloedel* (1981), 1 SCR 504 at pages 525 to 526; *Rodi & Wienenberger Aktiengesellschaft v Metalliflex Limited* (1960), 32 CPR 102 (Que QB) at page 184 (aff'd 1961 SCR 117); *R v American Optical* (1950) 11 Fox Patent cases 62 at page 85.

The Summary of Reasons, on page 2, maintains the position that the advantages of Form L are not a patentable distinction as they were not present in the description as originally filed:

> [Emphasis in italics in original] As noted in the Final Action, Tables 1 and 2 were submitted post-filing by the Applicant as part of a response and were therefore not present in the description as originally filed, so there is no support of said advantages via the data of the Tables. The Applicant's argument that the impurity profile advantage was present at page 3 of the instant description does not strengthen the Applicant's argument. The statement at page 3 refers to a list of *nine potentially* advantageous properties, i.e. "*Particular forms* of compound A *may have* advantageous properties, *for example* with regard to their solubility and/or their stability and/or their bioavailability and/or *their impurity profile*… and/or form into tablets." The person of ordinary skill in the art (POSITA), presented with a list of potential advantages, would not be able to realise what the actual inventive property is. Therefore, the data found in Tables 1 and 2 cannot be linked to any statement in the description as originally filed [and therefore none of these potential benefits can form part of the inventive concept of the claims either].

In addition, page 2 of the Summary of Reasons refutes the applicability of the decisions cited in the Response to the Final Action and instead identifies several decisions concerning the obviousness of polymorphic forms as relevant:

> Further, the Applicant argues that the Patentee does not need to present advantages when they filed or made their invention. Consolboard, Metalliflex, and American Optical appear to be cited for the proposition that, since the specification is sufficient if the invention is disclosed, extoling the "advantages" (i.e. benefits) of an invention is not required to overcome a patentable distinction challenge. Respectfully, the Applicant's argument conflates the requirements of sufficiency with those of patentable distinction. These are independent requirements; patentable distinction has its own test and principles to consider. Ingenuity does not have to come from advantages associated with the alleged invention, but it does have to come from somewhere.
>
> Furthermore, it is respectfully pointed out that the beneficial physicochemical properties associated with crystalline forms are often disclosed within the specification. In some cases, such properties may be relevant to patentability and, while the requirements of obviousness are different than obvious double patenting, this is consistent with may previous decisions involving obviousness of polymorphic forms, such as *Pfizer Canada Inc. v. Apotex Inc., 2017 FC 774 [ODV FC 774]; Pfizer Canada Inc v. Teva Canada Ltd 2017 FC 777; Bristol-Myers Squibb*

Canada Co. v. Teva Canada Limited, 2017 FCA 76, 146 C.P.R. (4th) 216 [*Atazanavir*]; *Pfizer Limited v. Ratiopharm Inc.,* 2010 FCA 204, 87 C.P.R. (4th) 185 [*Amlodipine*].

Having considered the referred passage of the description relating to an impurity profile advantage in the context of the entire specification, it is our preliminary view that the person skilled in the art would not understand that Form L of Compound A actually possesses an impurity profile advantage over Form A. In our view, the referred passage does not state that a given impurity profile has been determined for either Form L or Form A. Rather, it generically describes the potential advantageous properties that different polymorphic forms of a compound may have. However, the specification does not disclose the results of any testing of any of the listed properties for any polymorphic form of Compound A. Therefore, it is our preliminary view that the person skilled in the art would not associate Form L with having an impurity profile advantage over Form A.

Further, having reviewed the decisions cited in the Response to the Final Action, we agree with the assessment in the Summary of Reasons that they are not the appropriate authorities to rely on for the legal principles relating to an obviousness double-patenting determination. Indeed, the cited passages from the three decisions all relate to the statutory requirement that the specification sufficiently disclose an invention. Consistent with this view, page 3 of the Response to the Final Action acknowledges that “the properties, including the advantages of Form L were in existence when Form L was first synthesized” and that this “satisfies the statutory requirement for novelty and utility.”

Further, we are not persuaded that inherent advantages can be considered when determining if claims are patentably distinct from those of an earlier patent in cases where the purported advantage is neither mentioned in the claims nor can reasonably be inferred from the specification or drawings contained in the application on its filing date. In our view, the legal principles relating to the inventiveness of a claim laid out in *Apotex Inc v Sanofi–Synthelabo Canada Inc*, 2008 SCC 61 [Sanofi] indicate otherwise.

As indicated in Sanofi at paras 77 and 78, it may be acceptable to read the specification to determine the inventive concept of a claim reciting a bare chemical formula as including an advantage that is apparent from the specification. Further, and to paraphrase Sanofi at paras 113 and 114, it is necessary to consider the specification as a whole to determine if the claims on file reflect a patentably distinct form of compound A (Form L) from Form A of compound A of the ‘275 Patent.

Beyond Sanofi, there are other cases in which the Federal Court of Appeal has upheld the use of the specification to determine the inventive concept where it was not readily discernable from the claims themselves (see *Apotex v Shire*,

2021 FCA 52 at paras 79 to 84 [Apotex]; *Apotex Inc v Allergan,* 2012 FCA 308 at para 72, citing *Apotex Inc v ADIR*, 2009 FCA 222 at para 58).

However, even if recourse to the specification is required to identify the inventive concept of a bare chemical formula claim, it is not all the disclosed or reasonably derivable chemical's properties that will necessary be part of its inventiveness. Properties can be included in the inventiveness inquiry if the patent disclosure is sufficient to construe these properties as forming part of the "solution taught by the patent" with respect to the claimed compound: *Bristol-Myers Squibb Canada Co v Teva Canada Limited*, 2017 FCA 76 at paras 74 to 75; Apotex at para 8.

The views expressed by the Federal Court of Appeal do not support that undisclosed properties can be considered to form part of the inventiveness inquiry as they are not taught by the specification. Therefore, bearing in mind the legal principles relating to the identification of the inventive concept of a claim laid out in Sanofi and applied by the Federal Court of Appeal , we have considered whether the inventive concept of the claims includes inherent properties that were not disclosed in the specification as originally filed. Our preliminary view is that it does not.

First, we note that the claims on file do not define Form L of compound A as being more thermodynamically stable than Form A. However, given that the reference to Form L of compound A in claim 1 is limited to a bare chemical formula and an x-ray diffraction pattern, we consider it appropriate to read the specification as a whole to determine whether additional characteristics, associated with Form L, may be construed as being part of the inventive concept of the claims. This aligns with the process applied by the case law described above.

The description discloses that compound A is a known PARP inhibitor, useful in the treatment or prevention of disorders ameliorated by the inhibition of PARP activity. Likewise, it "provides compound A as Form L as an active compound, specifically, active in inhibiting the activity of PARP" (page 8, lines 1 to 2).

However, we do not find any explicit or implicit statement in the description that may suggest an increased thermodynamic stability associated with Form L as compared to Form A. The description on page 4 discusses a representative DSC trace for compound A as Form L: "Form L of compound A when heated from 25°C to 325°C at 10°C per minute will have an onset of melting at 198.5°C ±1°C. […] A second endotherm corresponds to melting of Form A, to which the melted Form L transforms." Although these data demonstrate that Form L has a different melting point than Form A, we consider that the person skilled in the art would not reasonably infer from these results an increased thermodynamic stability for Form L.

> To the extent that it is submitted by the Applicant that the data provided with the response of January 18, 2019 establish that Form L is more thermodynamically stable than Form A and that this advantage should be considered in determining the inventiveness of the claims, we respectfully disagree.
>
> It is our preliminary view that the case law does not indicate that the inventive concept of a claim may be ascertained by turning to evidence outside of a patent application disclosure in cases where the alleged benefit or advantage is neither mentioned in the claim, indicated in the remainder of the specification nor reasonably derivable by the person skilled in the art from the information contained in the specification. To the contrary, we consider that the basis for understanding the claimed invention for the purpose of determining its compliance with the patentability requirements of the *Patent Act* must be found within the four corners of the patent application: see Whirlpool at para 49(f).
>
> Accordingly, it is our preliminary view that the consideration of an improved thermodynamic stability in the inventive concept of the claims is neither consistent with the language of the claims nor the teachings of the description, as it would be understood from the standpoint of the person skilled in the art. It follows that an improved thermodynamic stability is not a difference between claim 1 of the instant application and claim 1 of the ‘275 Patent.
>
> In our preliminary view, the only difference between claim 1 of the instant application and claim 1 of the ‘275 Patent is with respect to the x-ray powder diffraction pattern of the non-solvated crystalline forms, Form L and Form A, respectively.
>
> With respect to claim 4 on file and claim 6 of the ‘275 Patent, the Final Action expresses the view that “[t]he same solvents and solvent pairs of the ‘275 patent are used to provide Form L, the only differences being the solvent ratio and the temperature.”
>
> The Response to the Final Action did not contest or comment on these differences. However, after reviewing the claims, we would identify the starting material is an additional difference. In claim 4 of the instant application, Form L is prepared by solvent-mediated transformation of Form A or a mixture of Form A and Form L, whereas in claim 6 of the ‘275 Patent, Form A is prepared by solvent-mediated desolvation of compound A at elevated temperatures.
>
> Accordingly, it is our preliminary view that the differences between claim 4 on file and claim 6 of the ‘275 Patent lie in the starting material, solvent ratio and the temperature.

[41] In the absence of submissions from the Applicant, we adopt the above identification of the claim differences.

Are the claims patentably distinct?

[42] The Preliminary Review letter, on pages 16 to 19, explains that in our preliminary view the claims on file are not patentably distinct from the claims of the '275 Patent because there is no invention in providing Form L, an alternative form of compound A:

> The Final Action, on pages 3 to 4, indicates that although the two non-solvated crystalline forms of compound A can be distinguished, they are not patentably distinct, since the claims on file exhibit no inventive ingenuity over the claims of the '275 Patent:
>
> > [Emphasis in original] In the present case, transforming Form A to an alternative form (Form L) would not have required any degree of invention. It is thus concluded that the subject claims do no exhibit any inventive ingenuity over the claims of the '275 Patent.
> >
> > These two non-solvated crystalline forms of compound A can be distinguished, but they are not patentably distinct. A second patent cannot be justified unless the claims exhibit ingenuity over the first patent (*GSK*[1], at para. 88, citing *Consolboard v MacMillan Bloedel*, in reference to *Farb[e]werke Hoechst*).
> >
> > [footnote: [1]*GlaxoSmithKline Inc v Apotex Inc*, 2003 FCT 687]
>
> With regard to the alternative forms, the Final Action, on page 3, indicates that transforming Form A to Form L would not have required any degree of invention in view of the common general knowledge which teaches varying solvent ratios and changing temperatures when screening for polymorphs:
>
> > [Bolding indicates inserted text] However, the CGK **(common general knowledge)** teaches varying solvent ratios and changing temperatures when screening for polymorphs (see CGK documents D1-D3). Using the same solvent pair and systematically varying the ratio of the solvents and the temperatures is considered routine experimentation. There is no indication that the experimentation was prolonged or arduous. It's not surprising that another polymorph was identified, most compounds tend to crystallize in more than one form.
> >
> > In the present case, transforming Form A to an alternative form (Form L) would not have required any degree of invention.
>
> The Response to the Final Action, on page 3, maintains the assertion that obtaining another form of Compound A was not expected:

> As previously asserted, Applicant respectfully submits that no convincing arguments were presented that the skilled person would expect to find a second non-solvated polymorphic form of compound A. While a person of ordinary skills in the art might consider screening for additional polymorphic forms would be common general knowledge, he or she could not predict whether such polymorphs would be identified and whether any polymorph would have superior properties to existing forms. It is perhaps even more surprising that Form L was found using a similar approach to Form A, even though their chemico-physical properties differ.

As explained above, the assessment of obviousness double-patenting is governed by the principles as articulated in Whirlpool and Mylan and most recently applied in Hoffman LaRoche Limited v Sandoz Canada Inc, 2021 FC 384, para 151:

> As it relates to obviousness-type double patenting, the question for this Court is whether there is "invention" or "ingenuity" in the move from the first patent to the second patent (*Whirlpool* at paras 63-67; *Bristol-Myers Squibb Canada Co v Pharmascience Inc*, 2021 FC 1 at para 91, citing *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc*, 2016 FCA 119 at para 28 [*Mylan 2016*]). The policy justification is the "prevention of evergreening an existing patent through what would otherwise be a valid patent but is, in effect, an extension of the patent that has already been granted" (*Mylan 2016*, above at para 28).

Having in mind the principles above, in the context of the present case, it is our preliminary view that the relevant question is whether the claims on file exhibit any inventive ingenuity over the claims of the '275 Patent.

As mentioned above, the '275 Patent discloses the production of the non-solvated Form A of Compound A, a known inhibitor of PARP activity. Further, as indicated above, in light of the common general knowledge, the person skilled in the art would have been aware of various methods of screening for polymorphs. Indeed, it was common practice for those engaged in the particular fields of organic chemistry, pharmaceutical and formulation sciences to conduct routine experimental screening for polymorph formation as part of the drug development process, with the goal of discovering the most optimal form.

In this view, no degree of ingenuity would be required to transform Form A to an alternative form, Form L, by crystallising from the same solvent mixture, wherein the proportions of the solvents and/or conditions are modified. Solvent-mediated transformation of one crystalline form to another is a routine technique that was within the common general knowledge of the person skilled in the art at the relevant date (see for example D1 or D2).

Similarly, the second alternative method disclosed in claim 4 wherein Form L is prepared by a solvent-mediated transformation of a mixture of Form L and Form A, would not have required any inventive ingenuity. As mentioned above, solvent-mediated polymorph transformation was part of the common general knowledge. In addition, the person skilled in the art would have been aware of the well-known technique of using seed crystals to promote nucleation of the desired form. The same technique is used in claim 6 of the ‘275 Patent. In our preliminary view, there is no inventive ingenuity in using a significant amount of the desired final product, Form L, as starting material along with a second form of compound A to drive the nucleation and crystallization of Form L.

Although it is argued at pages 1 to 2 of the Response to the Final Action that Form L exhibits higher thermodynamic stability than the Form A of Compound A and that this advantageous property must be taken into consideration in an inventive ingenuity determination, we reiterate our preliminary view that the person skilled in the art would not consider that the inventive concept of the claims on file includes any benefit or advantage associated with Form L beyond those expected (*i.e.*, as a compound having PARP inhibitory activity). As explained above, there is no teaching or suggestion in the description that Form L exhibits higher thermodynamic stability compared to Form A of Compound A. More specifically, the characterization of Form L of Compound A is limited to spectral characteristics and basic thermal analysis. Beyond that, there is no testing to see whether any properties are affected by these crystal structures, for example, stability and impurity profile. It follows that an unexpected benefit or advantage cannot be considered a relevant factor.

In view of the foregoing, it is our preliminary view that by performing those aspects of a polymorph screen which are routinely used when attempting to find new crystalline forms of a compound, the person skilled in the art would have produced Form L of Compound A. This is consistent with the evidence in the description concerning the course of conduct that led to Form L.

Moreover, in the absence of any further polymorph characterization, there is no inventive ingenuity in simply having an alternative arrangement of the molecules of compound A. The two forms, Form L and Form A, are merely variations of the same compound that, as chemically identical molecules, would be expected to have the same activity as PARP inhibitors.

With respect to the remaining claims, the Response to the Final Action did not identify or associate any specific limitations in these claims with additional ingenuity. Having considered these claims, we note that the only differences are in dependent claims 2 and 3; however, we do not consider that any degree of invention would have been required from the person skilled in the art in respect of the further spectral and thermal characterization of Form L as defined in these claims.

Therefore, in light of the common general knowledge, as of the relevant date, there is no invention in providing Form L, an alternative form of compound A. The claims

> on file are not patentably distinct from the claims of the ‘275 Patent contrary to the doctrine of obviousness double-patenting.

[43] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that the claims on file are not patentably distinct from the claims of the ‘275 Patent contrary to the doctrine of obviousness double-patenting.

Are Claims 1, 2 and 4 Indefinite?

[44] The Preliminary Review letter, on pages 19 to 20, explains our preliminary view that claims 1, 2 and 4 on file are not indefinite:

> The Final Action, on page 4, indicates that claims 1, 2 and 4 are indefinite because of an ambiguity:
>
> > Claims 1, 2 and 4 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. These claims do not end with a period and are, therefore, ambiguous.
>
> Having reviewed claims 1, 2 and 4, as well as the Response to the Final Action, we disagree that the ambiguity identified in the Final Action is present. Each of claims 1, 2 and 4 end with a terminal period. Therefore, it is our preliminary view that claims 1, 2 and 4 comply with subsection 27(4) of the *Patent Act*.

[45] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that claims 1, 2 and 4 comply with subsection 27(4) of the *Patent Act*.

Is Claim 3 Improperly Dependent?

[46] The Preliminary Review letter, on page 20, explains our preliminary view that claim 3 is improperly dependent:

> The Final Action, on page 4, identifies the following claim dependency defect:
>
> > Claim 3 refers to itself and does not comply with subsection 87(2) of the *Patent Rules*. A dependent claim must refer to a preceding claim or claims.
>
> Having reviewed claim 3, we preliminarily agree for the same reasons outlined in the Final Action. Therefore, it is our preliminary view that claim 3 does not comply with subsection 63(2) of the *Patent Rules*.

[47] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that claim 3 does not comply with subsection 63(2) of the *Patent Rules*.

Is There a Defect With the Page Numbering of the Specification?

[48] The Preliminary Review letter, on pages 20 to 21, explains our preliminary view that there is a defect with the page numbering of the specification:

> The Summary of Reasons, on pages 2 to 3, identifies the following presentation defect with the specification:
>
> > The description and claim pages are not numbered consecutively, i.e. the description pages are 1-17 and the claim pages are 21-23. Pursuant to section 193 of the *Patent Rules*, the pages of the description and claims are not numbered consecutively and do not comply with subsection 73(1) of the former *Patent Rules*.
>
> Having reviewed the page numbering of the specification, we preliminarily agree for the same reasons as outlined in the Final Action. Therefore, it is our preliminary view that the specification does not comply with subsection 73(1) of the former *Patent Rules.*

[49] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that the specification does not comply with subsection 73(1) of the former *Patent Rules*.

ANALYSIS OF THE PROPOSED AMENDMENTS

[50] As indicated above, with the response to the Final Action the Applicant submitted proposed claims 1 to 17. According to page 3 of the response to the Final Action, claims 1, 2 and 4 were resubmitted to put the period in bold. In addition, claim 3 has been amended to depend from claim 1 or 2 to address the improper claim dependency defect.

[51] The Preliminary Review letter, on page 21, explains our preliminary view that proposed claim 3 would comply with subsection 63(2) of the *Patent Rules* but that the proposed claims would not overcome the obviousness double-patenting defect or the page numbering defect:

> We agree that the subject-matter of proposed claim 3 would comply with subsection 63(2) of the *Patent Rules*. However, given our opinion expressed above that the subject-matter of the claims on file are not patentably distinct from the claims of the '275 Patent, we are of the preliminary view that the proposed claims would also not comply with the doctrine of obviousness double-patenting.
>
> Further, the pages of the description and the proposed claims are not numbered consecutively. Therefore, our preliminary view is that the specification does not comply with subsection 73(1) of the former *Patent Rules.*
>
> Accordingly, it is our preliminary view that the proposed amendments do not meet the requirements of a necessary amendment under subsection 86(11) of the *Patent Rules*.

[52] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that the proposed amendments do not meet the requirements of a necessary amendment under subsection 86(11) of the *Patent Rules*.

CONCLUSIONS

[53] We have determined that claims 1 to 17 on file are not patentably distinct over the claims of the '275 Patent contrary to the doctrine of obviousness double-patenting.

[54] We have also determined that claim 3 is improperly dependent and does not comply with subsection 63(2) of the *Patent Rules* and that the specification does not comply with subsection 73(1) of the former *Patent Rules* because the description and claim pages are not numbered.

[55] In our view, the proposed claims submitted with the response to the Final Action would not overcome the obviousness double-patenting defect or the page numbering defect and are therefore not considered a "necessary" amendment for compliance with the *Patent Act* and *Patent Rules* as required by subsection 86(11) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[56] In view of the above, the Panel recommends that the application be refused on the grounds that:

- claims 1 to 17 are not patentably distinct over the claims of the ‘275 Patent contrary to the doctrine of obviousness double-patenting;
- claim 3 does not comply with subsection 63(2) of the *Patent Rules*; and
- the specification does not comply with subsection 73(1) of the former *Patent Rules*.

Christine Teixeira	Marcel Brisebois	Philip Brown
Member	Member	Member

DECISION OF THE COMMISSIONER

[57] I concur with the findings of the Board and its recommendation to refuse the application on the grounds that:

- claims 1 to 17 are not patentably distinct over the claims of the ‘275 Patent contrary to the doctrine of obviousness double-patenting;
- claim 3 does not comply with subsection 63(2) of the *Patent Rules*; and
- the specification does not comply with subsection 73(1) of the former *Patent Rules*.

[58] Therefore, in accordance with section 40 of the *Patent Act*, I refuse to grant a patent for this application. Under section 41 of the *Patent Act*, the Applicant has six months to appeal my decision to the Federal Court of Canada.

Konstantinos Georgaras
Commissioner of Patents

Dated at Gatineau, Quebec

this 20th day of October, 2022.