Commissioner’s Decision #1416

Décision du Commissaire #1416

TOPICS: O00 (Obviousness); G00 (Utility)

SUJETS: O00 (Évidence); G00 (Utilité)

Application No.: 2,742,621

Demande n°.: 2,742,621

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,742,621 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 2,742,621, which is entitled "Plant extract compositions for affecting sleep" and owned by Viva Pharmaceutical Inc. The outstanding defects to be addressed are whether the subject matter of the claims on file is obvious, whether the subject matter of the claims on file lacks utility, whether the subject matter of the claims on file lacks support and whether the subject matter of claim 22 is indefinite. 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 2,742,621 was filed in Canada on November 3, 2009 and published on June 3, 2010.

[3] The application relates to compositions containing plant extracts for modulating sleep disorders (e.g., insomnia) and methods for producing said compositions. More specifically, the description discloses the use of compositions containing Baiziren (*Platycladus orientalis*) extracts alone, and compositions containing Baiziren extracts in combination with at least one of Yuanzhi (*Polygala spp.*) extracts and Suanzaoren (*Zizyphus jujube*) extracts for the modulation of sleep disorders.

[4] The description exemplifies the preparation of a *Platycladus orientalis* seed extract, a *Polygala spp.* root extract and a *Zizyphus jujube* seed extract. The different plant extracts were mixed in two different combinations: a composition comprising a *Platycladus orientalis* seed extract and a *Zizyphus jujube* seed extract (combination

BS); and a composition comprising a *Platycladus orientalis* seed extract and a *Polygala spp.* root extract (combination BY).

[5] The description also discloses the results of studies conducted in mice showing that the BS and BY combinations significantly prolonged sleeping time compared to the controls. Moreover, the description discloses that the combinations do not affect the muscle coordination system and the motor functions of mice.

History

[6] On September 11, 2014, 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*, that the claims on file lack support, contrary to section 84 of the *Patent Rules* and that claim 22 is indefinite, contrary to subsection 27(4) of the *Patent Act*.

[7] In a response to the FA ("R-FA") dated March 11, 2015, the Applicant submitted an amended claim set (the "Proposed Claim Set-1") addressing the indefiniteness issue in claim 22 and also provided arguments as to why the subject matter of the claims on file was not obvious and fully supported by the description.

[8] As the Examiner considered that the application still did not to comply with the *Patent Act* and that the Proposed Claim Set-1 submitted by the Applicant in the R-FA would not render the application allowable, the application was forwarded to the Patent Appeal Board ("the Board") for review, along with a Summary of Reasons ("SOR") maintaining the defects identified in the FA for the claims on file. With regard to the proposed amendments made in the R-FA, the SOR explains that indefiniteness defect found with respect to claim 22 would have been withdrawn in light of the proposed amendments had the Proposed Claim Set-1 been found non-obvious in view of the cited prior art and otherwise compliant with the *Patent Act*

and *Patent Rules*. However, the SOR maintains that the subject matter of the claims on file and Proposed Claim Set-1 is obvious in view of the cited prior art and lacks support in the description. The SOR further identifies an alleged new defect on the grounds of lack of utility with respect to the subject matter of the claims on file and Proposed Claim Set-1.

[9] In a letter dated July 27, 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 October 26, 2015 the Applicant expressed the wish to provide written submissions in response to the SOR and to participate in an oral hearing.

[10] In a response to the SOR ("R-SOR") dated February 25, 2016, the Applicant presented arguments as to why the subject matter of the claims on file is not obvious, is useful and is supported by the description. The Applicant also submitted an alternative claim set in response to the SOR ("Proposed Claim Set-2"). The Proposed Claim Set-2 consists of claims 1-21 and 23-26 of the claims on file, claim 22 of the Proposed Claim Set-1 and new claims 27-39.

[11] 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 September 26, 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 does not comply with section 28.3 of the *Patent Act* and does not comply with section 2 of the *Patent Act*. In the same letter, we also expressed the view that addressing the alleged defect that was raised under section 84 of the *Patent Rules* was unnecessary for the purposes of this review as the issue was already presented as a failure to comply with section 2 of the *Patent Act*.

[12] On November 10, 2016 the Applicant replied to the Panel Letter (its "Reply to the Panel Letter") and provided additional submissions to support its position that the subject matter of the claims on file is not obvious, useful and supported by the description. The Applicant also submitted an alternative claim set in response to the Panel Letter ("Proposed Claim Set-3"). The Proposed Claim Set-3 consists of claims 1-21 and 23-26 of the claims on file, claim 22 of the Proposed Claim Set-1, claims 27-39 of the Proposed Claim Set-2 and new claims 40-55.

[13] An oral hearing was held via videoconference on December 12, 2016. During the hearing, the Applicant provided arguments in addition to those presented in its Reply to the Panel Letter. Dr. Xueju Xie, one of the co-inventors, also appeared at the hearing. She argued that the claimed subject matter is inventive and provided contextual information surrounding the content of declarations submitted during the prosecution of the application.

ISSUES

[14] As mentioned in the Panel Letter on page 2 and explained on pages 28 and 29, we consider that addressing the lack of support defect raised under section 84 of the *Patent Rules* in the FA is unnecessary for the purposes of this review as the issue is subsumed within our analysis of the lack of utility issue.

[15] With respect to claim 22 and the defect on the grounds of indefiniteness identified in the FA, we consider that it is only necessary to address this issue if the claims on file are otherwise compliant with the *Patent Act* and the *Patent Rules*. Since that is not the case, there is no need to address the issue.

[16] Therefore, of the four issues identified in the FA and/or SOR, it is necessary to address only the following two issues in order to dispose of the case:

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

2. whether the subject matter defined by the claims on file lacks utility, contrary section 2 of the *Patent Act*.

LEGISLATION AND LEGAL PRINCIPLES

Purposive construction

[17] In accordance with *Free World Trust v Électro Santé Inc.*, 2000 SCC 66 essential elements are identified through a purposive construction of the claims done by considering the whole of the disclosure, including the specification and drawings (see also *Whirlpool Corp v Camco Inc.*, 2000 SCC 67 at paras. 49(f) and (g) and 52 ("*Whirlpool*"). In accordance with the *Manual of Patent Office Practice* §13.05 [revised June 2015; "MOPOP"], the first step of purposive claim construction is to identify the person of ordinary skill in the art ("POSITA") and the 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.

Obviousness

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

> The subject matter defined by a claim in an application for a patent in Canada must be subject matter that would not have been obvious on the

> claim date to a person skilled in the art or science to which it pertains, having regard to
>
> (a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and
>
> (b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

[19] 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?

[20] 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.

> [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.

[21] 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 be understood as including advantageous properties, such as the synergistic effect of two or more active ingredients.

[22] In the context of the fourth step, the Court in *Sanofi* accepted that it may be appropriate in some cases to consider an "obvious to try" analysis.

[23] The Court in *Sanofi* listed the following non-exhaustive factors to be considered in an "obvious to try" analysis:

> (1) Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identifiable predictable solutions known to persons skilled in the art?
>
> (2) What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
>
> (3) Is there a motive provided in the prior art to find the solution the patent addresses?

Utility

[24] Utility is part of the definition of "invention" in section 2 of the *Patent Act* which states that the claimed subject matter must be "useful":

> ***invention*** means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

[25] The utility requirement was described by the Supreme Court of Canada in *Consolboard Inc. v MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] SCR 504, at p. 525:

> There is a helpful discussion in Halsbury's Laws of England, (3rd ed.), vol. 29, at p. 59, on the meaning of 'not useful' in patent law. It means "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do". [Emphasis added]

[26] The asserted utility is fundamental to the utility analysis and must be ascertained at its outset. In *Pfizer Canada Inc. v Canada (Minister of Health),* 2011 FCA 236 at para 17, the Federal Court of Appeal stated that the determination of the asserted utility of a patent is an aspect of patent construction:

> Like claims construction, the promise of the patent is also a question of law (*Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197 [*Eli Lilly*]). In this particular case, the Applications Judge, assisted with expert evidence, needed to purposively ascertain the promise of the patent "within the context of the patent as a whole, through the eyes of the person of skill in the art (POSITA) in relation to the science and information available at the time of filing" (*Eli Lilly*, at paragraph 80).

[27] Utility must be established either by demonstration or sound prediction as of the Canadian filing date. Utility cannot be supported by evidence and knowledge that only became available after the filing date (see *Apotex Inc. v Wellcome Foundation Ltd.*, 2002 SCC 77 at para 56 ("*AZT*").

[28] The doctrine of sound prediction allows establishing asserted utility even where that utility had not been fully verified as of the filing date. However, a patent application must provide a "solid teaching" of the claimed invention as opposed to "mere speculation" (*AZT*, at para 69).

[29] The soundness of a prediction is a question of fact (*AZT*, at para 71). A sound prediction has three elements (*AZT*, at para 70):

> 1) there must be a factual basis for the prediction;
>
> 2) the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and
>
> 3) there must be proper disclosure of the factual basis and line of reasoning.

[30] These elements are assessed from the perspective of the POSITA to whom the patent application is directed taking into account the CGK that the POSITA would have. Further, with the exception of matters of CGK, the factual basis and the line of reasoning must be included in the patent application (see *Bell Helicopter Textron Canada Limitée v. Eurocopter, société par actions simplifiée*, 2013 FCA 219, at paras 152 and 153 ("*Eurocopter*").

[31] Although a prediction does not need to amount to a certainty to be sound, there must be a "*prima facie*" reasonable inference of utility (*Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc.*, 2016 FCA 119, at para 55, *Gilead Sciences, Inc. v. Idenix Pharmaceuticals Inc.*, 2015 FC 1156, at para 251).

ANALYSIS

1. Claim Construction

The POSITA and the relevant CGK

[32] In the Panel Letter, we identified the POSITA as a person having the composite expertise of a sleep medicine specialist, a traditional Chinese medicine (TCM) practitioner and of a person practising in the field of phytochemistry.

[33] In the Reply to the Panel Letter, the Applicant expresses its partial disagreement with our definition of the POSITA and submits that the POSITA is a:

> **TCM practitioner who has significant and extensive knowledge of Chinese herbs and their application to specific disorders including sleeping disorders, who is skilled in treating sleeping disorders in the context of TCM, and who also possesses an understanding of general chemical extraction techniques.** [Emphasis in the original]

[34] We accept the definition of the POSITA proposed by the Applicant and note that it is in general alignment with ours.

[35] With regard to the relevant CGK possessed by the POSITA, we identified the following knowledge in the Panel Letter:

- The symptoms of sleep disorders, the factors influencing the sleep and the common sleep medications, including their advantages, disadvantages and side-effects.

- Chinese herbs and their therapeutic applications, the general traditional methods of producing different forms of plant extracts (e.g., granular, powdered, etc.) from the different plants components (e.g., fruits, seeds, bark, leaves, roots, etc.) and the common extraction, separation and purification techniques used in the fields of traditional Chinese medicine and phytochemistry to produce plant extracts.

- That herbs used in traditional medicine are rarely used alone but rather in combination formulas.

- A given therapeutic effect is not necessarily associated with every part of the plant and a given therapeutic application usually requires the use of a specific part of a plant.

[36] In the Reply to the Panel Letter, the Applicant generally agrees that the POSITA possesses the CGK listed above, except for the reference to the discipline of phytochemistry. As stated above, we accept the definition of the POSITA proposed by the Applicant, as well as the Applicant's submission that although the POSITA does not necessarily practise in the field of phytochemistry, the POSITA possesses an understanding of general chemical extraction techniques. In the same letter on pages 6-8, the Applicant submits that additional relevant CGK should be considered:

- when any herbal ingredient is changed, altered or removed, the function of the composition may be totally different;

- formulating a TCM composition does not simply involve the piling up or combining of different herbs with similar functions; and

- herbs selected for use in the composition would play different roles based on the diagnosis.

[37] We generally agree that the additional knowledge listed above is relevant CGK possessed by the POSITA but we will add that formulating a TCM composition does not exclude combining different herbs with similar functions.

[38] In the same passage of the Reply to the Panel Letter, the Applicant also submits that a specific passage of one of the cited prior art document informs the CGK of the POSITA:

> The following passage from page 400 of D1 also informs the common general knowledge of the POSITA:

> The importance of herbal/TCM treatment in the management of illness is increasingly being recognised. There has been a long tradition in TCM of using specific herbs, fungal, animal, and mineral ingredients, mostly in composite formulas, for treating insomnia. While both western and oriental herbal treatment equally have not been subjected to rigorous study, it is apparent that TCM has a greater variety of herbs and formulations available for the treatment of insomnia. More basic and clinical studies are required, however, to demonstrate their safety and efficacy. [emphasis added]

[39] We take the Applicant's point that D1 mentions the requirement that clinical studies be done to demonstrate the safety and efficacy of herbal remedies. Although the POSITA is arguably aware of such considerations as part of their CGK, they are not, in our view, necessarily relevant to questions of patentability. In the present case, we are assessing an application to determine whether an invention is non-obvious and useful for compliance with the *Patent Act*. We are not assessing a new drug submission for compliance with the *Food and Drug Act*. In *AZT* at para 77, the Supreme Court has acknowledged a distinction between the two regulatory contexts:

> The appellants . . . argue that utility must be demonstrated by prior human clinical trials establishing toxicity, metabolic features, bioavailability and other factors. These factors track the requirements of the Minister of Health when dealing with a new drug submission to assess its "safety" and "effectiveness".
>
> …
>
> The prerequisites of proof for a manufacturer who wishes to market a new drug are directed to a different purpose than patent law. The former deals with safety and effectiveness. The latter looks at utility, but in the context of inventiveness.

The problem to be solved and the proposed solution

[40] In the Panel Letter, we expressed the view that the problem to be solved is a need for a new treatment for physiological sleep disorders and that the solution proposed by the application is the production of a composition comprising a *Platycladus orientalis* extract and a *Polygala ssp.* extract or a composition comprising a

Platycladus orientalis extract, *Polygala ssp.* extract and a *Zizyphus jujube* extract and their uses for modulating physiological sleep disorders

[41] Neither the Applicant's Reply to the Panel Letter nor the Applicant's submissions at the hearing indicates disagreement with this assessment.

The essential elements of the claims that solve the identified problem

[42] In the Panel Letter, we expressed the view that the POSITA would consider that each plant extract recited in the independent claims and the modulation of physiological sleep disorders are essential elements.

[43] The Reply to the Panel Letter does not indicate disagreement with this assessment.

Meaning of certain phrases

[44] In the Panel Letter on pages 9 and 10, with respect to the phrase "modulating physiological sleep disorders" and the term "extract", we expressed the view that: i) the expression "for modulating" at least includes the alleviation of a physiological sleep disorder; ii) the expression "physiological sleep disorders" at least include dysomnias, insomnia, circadian rhythm sleep disorders, hypersomnia and parasommas; and iii) the term "extract" is not limited to a particular plant component in independent claims 1, 2 and 16 or to a particular extraction method or extraction solvent in independent claims 1 and 2.

[45] The Applicant's Reply to the Panel Letter and the Applicant's submissions at the hearing do not indicate disagreement with our interpretation of the meaning of the expression "for modulating" and the term "extract".

[46] In the Reply to the Panel Letter on page 14, the Applicant disagrees with our interpretation of the meaning of "sleep disorders" and submits that "the POSITA

would interpret the meaning of 'sleep disorder' as it is provided in the present application: that is, sleep disorders may include (and not at least include) dysomnia, insomnia, circadian rhythm sleep disorders, hypersomnia and parasomnia" because the relevant portion of the description uses the permissive language "may include" and not "at least include". The Applicant further submits with respect to making a promise of utility that "the present application, at best, may only be construed as making a promise for the treatment of insomnia".

[47] Although we agree that language such as "may include" is permissive, we maintain our view that the plural expression "sleep disorders" in the context of the claims on file encompasses more disorders than just insomnia. Our view is aligned with the limitation found in dependent claims 6 and 15. According to the principle of claim differentiation[1], the independent claims 1 and 2 cannot be read as having the limitation found in these dependent claims. Further, the Markush language of claims 6 and 15 explicitly defines "sleep disorders" as insomnia or parasomnia.

[48] In any case, the exact meaning of "sleep disorders" is not central to any of the identified issues as our preliminary views presented in the Panel Letter with respect to the obviousness and the lack of utility of the claims on file were applicable to the specific treatment of insomnia.

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

Identify the POSITA and the relevant CGK

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

[1] In its simplest form, the claim differentiation principle presumes that the limitation of a dependent claim not be read into an independent claim (see *Halford v. Seek Hawk Inc.*, 2004 FC 88 at para 93 (aff'd 2006 FCA 275).

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

[50] In the Panel Letter, we expressed the view that the inventive concept of the independent claims is a composition consisting of two plant extracts (*Platycladus orientalis* and *Polygala ssp.*) and one or more pharmaceutically acceptable carriers or excipients (claims 1 and 16), or three plant extracts (*Platycladus orientalis*, *Polygala ssp.* and *Zizyphus jujube*) and one or more pharmaceutically acceptable carriers or excipients (claim 2), for modulating physiological sleep disorders.

[51] We also noted the Applicant's suggestion in the R-FA that the inventive concept of the claimed invention should also take into account the synergistic effect of the extracts when combined, rather than simply the summation of their individual effects when assessed in isolation of one another.

[52] After reviewing the claims, the description, three declarations from Dr. Xueju Xie and the jurisprudence on claim construction and the identification of the inventive concept, we expressed the view in the Panel Letter on page 17 that the inventive concept of the claims on file does not include a synergistic effect for the following reasons.

[53] First, we expressed the view that there is no need to refer to the remainder of the specification because an inventive concept is readily discernable from the claims themselves. We noted that the claims on file do not define the recited composition as synergistic. Neither the Applicant's Reply to the Panel Letter nor the Applicant's submissions at the hearing indicates disagreement with this assessment.

[54] Second, we stated that a purposive reading of the specification as a whole, including the examples portion of the description, did not suggest that a synergistic effect is associated with the claimed compositions. The Applicant's Reply to the Panel Letter and Applicant's submissions at the hearing do not express disagreement with the

Panel's view. The Applicant maintains, however, that disclosure of a synergistic effect in the specification is not a requirement in Canadian patent law or practice.

[55] Third, we expressed the view that the case law does not indicate that information absent from the specification can be included in the inventive concept.

[56] In its Reply to the Panel Letter and at the hearing, the Applicant disagreed on this third point and submitted that although the basis for understanding the specification is found within the four corners of the patent application, there are decisions in the case law that suggest the inventive concept may be ascertained by turning to evidence outside of a patent disclosure. In support of this argument, the Applicant cited the decisions in *Re Application for Patent of Lilly Industries Ltd.* 1982, 69 CPR (2d) 183 ("*Lilly Industries*") and *Bristol-Myers Squibb Canada Co v. Teva Canada Limited*, 2016 FC 580 ("*BMS*").

[57] Having reviewed the two cases cited by the Applicant and additional decisions from the Federal Courts (introduced and discussed below), we are not persuaded that the inventive concept of a claim may be taken as including an advantageous property, such as a synergistic effect, in cases where the property or effect is neither mentioned in the claim nor indicated in the remainder of the specification. In our view, the case law indicates otherwise.

[58] *Lilly Industries* is a Commissioner's decision that predates the seminal *Whirpool* and *Sanofi* decisions of the Supreme Court. The case is distinguishable from the present application because the Board in *Lilly Industries* was of the view that the invention claimed included a synergistic effect that was indicated in the description. The Board was also of the view that information demonstrating a synergistic effect submitted post-filing by way of affidavit was a "bona fide attempt to prosecute the application rather than a belated attempt by applicant to provide additional disclosure" (see paras 8-10 of *Lilly Industries*).

[59] By contrast, as explained on page 14 of the Panel Letter, the specification of the instant application does not indicate a synergistic effect. Although there is a statement on page 3 lines 1-3 regarding a "surprising" effect of the invention, it is apparent that the effect equally applies to compositions comprising *Platycladus orientalis* seed extract alone or to combinations comprising that extract.

[60] Again unlike the situation in *Lilly Industries*, we are also of the view that the declaration submitted post-filing in this case provides, for the first time, an indication that a synergistic effect should be part of the Applicant's inventive concept. We reiterate that the Applicant in its Reply to the Panel Letter or at the hearing did not indicate disagreement with the Panel's view on our conclusions.

[61] *BMS* was cited in the Panel Letter as a case suggesting that properties not mentioned in either the claims or description cannot form part of the inventive concept. In *BMS*, the inventive concepts of the patents at issue were not readily discernable from the claims themselves and a reading of the patent lead to the conclusion that alleged advantageous properties do or do not form part of the claimed invention (see paras 104-146 and 413-446 of *BMS*).

[62] In its Reply to the Panel Letter on page 24, the Applicant submitted that *BMS* cannot stand for the proposition that "it is unacceptable to turn to affidavit evidence evincing 'synergistic effects' of claimed compositions, as determined prior to the filing date of a patent application, to support evidence of an invention" because *BMS* is silent on the specific issue. Further, the Applicant submitted in the same letter on pages 24 and 25 and at the hearing that *BMS* suggests that the inventive concept may be ascertained by turning to evidence outside of a patent disclosure because expert evidence, that does not form a part of the patent specification as originally filed, was introduced and considered in *BMS* and in a case cited therein (*Alcon Canada Inc. v. Apotex Inc.*, 2014 FC 699 at para 167 ("*Alcon*")).

[63] In our view, *BMS* is a recent example of a case where the inventive concept was identified in light of the description (see also *Sanofi*, *Eurocopter*, and *Apotex Inc. v. Allergan Inc. and Minister of Health*, 2015 FCA 137). Although *BMS* mentions several cases where judges have declined to consider the descriptive portion of a patent in identifying the inventive concept, including *Alcon* mentioned above, *BMS* advises at para 114 that "these decisions are of limited assistance, as each has to be considered in light of the specific wording of the patents at issue states" [Emphasis added]. None of these cases stand for the proposition that the inventive concept can be identified as including an unexpected advantage on the basis of disclosure of the advantage only in declaratory evidence submitted post-filing.

[64] The Applicant submits that *BMS* "provides an example of going beyond the patent specification to determine the 'inventive concept'", that expert evidence is regularly admitted to determine the inventive concept, and that expert evidence should be considered analogous to extrinsic evidence of the existence of a property. We respectfully disagree.

[65] In our view, the case law indicates that expert evidence can inform the background in the relevant art and what the POSITA would understand from the information contained in the specification. Taken as such, there would be a basis for the expert evidence in the specification that may be regarded as information provided to attempt to advance prosecution, rather than an attempt to provide additional disclosure. The three declarations of Dr. Xueju Xie are considered in this light accordingly.

[66] Having reviewed the three declarations of Dr. Xueju Xie, and as explained in the Panel Letter, we consider that:

- The content of the Declaration-1 essentially provides the description of the preparation of additional herbal extract combinations and the results of studies in mice showing that the combinations BS (*Platycladus*

orientalis and *Zizyphus jujube* extracts), BY (*Platycladus orientalis* and *Polygala ssp*. extracts), SY (*Zizyphus jujube* and *Polygala ssp*. extracts) and BSY (*Platycladus orientalis*, *Zizyphus jujube* and *Polygala ssp*. extracts) significantly prolonged the sodium barbital-induced sleeping time compared to the controls.

- The conclusion found in Declaration-2 with regard to the existence of synergistic effect associated with combining two or more of a *Platycladus orientalis* extract, a *Polygala* spp. extract, and a *Zizyphus jujube* in a composition for the treatment of insomnia is essentially based on inferences drawn from the information received from Professor Zhang with respect to the lack of efficacy of the single extract compositions and the results presented in Declaration-1.

- Declaration-3 discloses the results of studies that appear to show that individual extracts are less efficacious *vis-à-vis* insomnia in comparison to any of the three combinations tested. We noted the size of the population tested for each extract and combinations thereof (8-10 volunteers), the length (7 days) and the degree of subjectivity in testing ("did not feel any improvement", "felt a slight improvement" and "had significantly improved sleep quality, such as failing asleep quickly and not waking").

[67] We consider that the evidence found in the declarations, taken as a whole, is not the sort that provides relevant observations as to what the POSITA would understand the inventive concept to be based on information contained in the specification. It is therefore not persuasive in establishing that the inventive concept includes an unexpected synergistic effect for the claimed compositions.

[68] In support of our view that the inventive concept of the claims on file does not include an unexpected synergistic effect for the claimed compositions, one relevant

case is *Lundbeck Canada Inc. v. Ratiopharm Inc.*, 2009 FC 1102, that states the following at paragraph 229:

> A claim to a synergistic effect requires some unexpected advantage: in particular, an advantage caused by an unpredictable cooperation between the elements of the combination. If the synergistic effect is to be relied upon, it must be possessed by everything covered by the claim and it must be described in the specification: see *Cipla Ltd. et al. v. Glaxo Group Ltd.*, [2004] EWHC 477 (Ch), at paras. 16-17, 103, and 113-114. [Emphasis added]

[69] In the present case, the synergistic effect the Applicant wishes to include in the inventive concept, is not considered described in the specification (see para [54] above) and may not be possessed by everything covered by the claims. The compositions covered by the claims are not limited to the specific plant extract compositions that showed a synergistic effect according to the studies described in Declaration-3. The claims on file cover compositions containing extracts of plant parts other than those of *Platycladus orientalis* seeds, *Polygala spp.* roots and *Zizyphus jujube* seeds (claims 1-26) and for which synergistic effects are not described in Declaration-3.

[70] In view of the above, we maintain our view expressed in the Panel Letter that the inventive concept of the independent claims on file is a composition consisting of two plant extracts (*Platycladus orientalis* and *Polygala ssp.*) and one or more pharmaceutically acceptable carriers or excipients (claims 1 and 16), or three plant extracts (*Platycladus orientalis*, *Polygala ssp.* and *Zizyphus jujube*) and one or more pharmaceutically acceptable carriers or excipients (claim 2), for modulating physiological sleep disorders.

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

[71] Three references are cited in the FA for obviousness:

- Wing, *Hong Kong Medical Journal*, 7(4), pages 392-402, December 2001 (D1)

- Chen and Chen, *Chinese Medical Herbology and Pharmacology*, L. Crampton ed., pages 11-14 and 754-776, 2004 (D2)

- Kimura et al. *International Collation of Traditional and Folk Medicine: Northeast Asia I*, World Scientific Publishing Company, 1998 (D3)

[72] In the Panel Letter at pages 19-20, we summarized what we consider the matter forming the "state of the art" and the differences between the "state of the art" and the inventive concept of the claims on file:

> In view of the above, our preliminary view is that the difference between the "state of the art" and the inventive concept of the claims is that, although the traditional individual use of each of *Platycladus orientalis* seeds, *Zizyphus jujube* seeds and *Polygala ssp.* roots for treating insomnia were known and that a formula for the treatment of insomnia comprising the three extracts among other ingredients was also known, the "state of the art" does not specifically disclose a composition consisting of *Platycladus orientalis*, *Polygala ssp.* extracts and one or more pharmaceutically acceptable carriers or excipients or a composition consisting of *Platycladus orientalis*, *Polygala ssp*, *Zizyphus jujube* plant extracts and one or more pharmaceutically acceptable carriers or excipients for modulating physiological sleep disorders.

[73] In the Reply to the Panel Letter on pages 25-26, the Applicant states that:

> Applicant generally agrees with the Correspondence's conclusions provided at pages 19-20 of the Correspondence. Namely, the state of the art does not disclose compositions consisting of the herbal extracts recited in the claims of the present application.
>
> …
>
> There is no disclosure or discussion in the cited prior art references regarding the combination of *polygala spp.* (yuanzhi) with *platycladus orientalis* (baiziren) and *zizyphus jujube,* or the combination of *polygala spp.* (yuanzhi) with *platycladus orientalis* (baiziren).

> There is no disclosure or discussion in the cited prior art references regarding the synergistic effect obtained when *polygala spp.* (yuanzhi) is combined with *platycladus orientalis* (baiziren) and *zizyphus jujube*, or when *polygala spp.* (yuanzhi) is combined with *platycladus orientalis* (baiziren), in treating sleeping disorders (e.g. insomnia) over the *platycladus orientalis* (baiziren), *zizyphus jujube*, and *polygala spp.* (yuanzhi) individually.

[74] We agree with the Applicant that none of the cited prior art references discloses or teaches a synergistic effect associated with the combination of *Platycladus orientalis* and *Polygala ssp.* extracts the combination of *Platycladus orientalis*, *Polygala ssp* and *Zizyphus jujube* plant extracts. However, as we have discussed above, we are of the view that the inventive concept of the claims on file does not include a synergistic effect, and therefore the lack of disclosure with regard to a synergistic effect is immaterial to the instant analysis of the differences between the "state of the art" and the inventive concept of the claims on file.

[75] With regard to prior art disclosure relating to the specific combinations of the plant extracts recited in the claims on file, we stated in the Panel Letter that the "state of the art" does not provide an explicit motive to produce the specific combinations of ingredients recited in the claims. However, we noted on page 21 of the same letter that D2 identifies *Platycladus orientalis* seeds and *Zizyphus jujube* seeds as the two most frequently used herbs among the nine "nourishing herbs that calm the shen (spirit)" (see page 776 of D2) and teaches that *Polygala ssp.* roots potentiates the effect of other herbs by prolonging sleeping time (see page 754 of D2).

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?

[76] In the Panel Letter on pages 20-22, we expressed our view that:

- it was self-evident that any composition consisting of two or more extracts of plants traditionally used for treating insomnia ought to work for treating insomnia, including a composition recited in the claims;

- the POSITA could produce a composition consisting of *Platycladus orientalis* seed extract, *Polygala ssp.* root extract and one or more pharmaceutically acceptable carriers or excipients or a composition consisting of *Platycladus orientalis* seed extract, *Polygala ssp.* root extract, *Zizyphus jujube* seed extract and one or more pharmaceutically acceptable carriers or excipients and use it for treating insomnia without prolonged and arduous experimentation; and

- the POSITA would not be required to do anything inventive in order to combine different known herb extracts having well-known therapeutic effects against insomnia into a composition for the same therapeutic use.

[77] Accordingly, we expressed the view that independent claims 1, 2 and 16 of the claims on file would have been obvious to the POSITA at the claim date in view of the state of the art.

[78] Based on submissions provided in the Reply to the Panel Letter and at the hearing, the Applicant's arguments supporting the non-obviousness of the claims on file can be summarized as follows:

- In absence of disclosure or discussion regarding the combination of the specific herbs recited in the claims on file in any of the cited documents, combining the specific herbs recited in the claims on file constitutes a step that require a degree of invention.

- Individual herbal extracts are co-acting in a composition to achieve a combined result, the combined result being an improvement over the result of the herbal extracts individually and while the individual herbal extracts "are old and were already known in the art as separate entities", the recited combinations and the benefits derived therefrom are now and therefore satisfy the requirements of an invention under Canadian patent law (citing the Supreme Court of Canada in *Canada v. Uhlemann Optical* Co., [1952] 1 SCR 143 ("*Uhlemann*").

- It would not be possible for a POSITA to find the claimed compositions "more or less self-evident" to work because D1 teaches a formula consisting of 12 essential ingredients for treating insomnia, there are 300 000 plus combinations of ingredients that can be made with the 19 discrete ingredients disclosed in D1 and there is no teaching or suggestion that a composition consisting of the 2 or 3 specific ingredients claims in the instant application would work in modulating sleeping disorders (e.g., insomnia).

- The cited documents D1, D2 and D3 do not teach or suggest the absence of potential herb-herb interactions between the herbs recited in the claims on file, do not disclose clinical studies to confirm the effectiveness of the individual herb extracts in treating insomnia and do not disclose potential adverse effects.

- The trials carried out in the present application would not be considered routine by the POSITA as the number of possible combination from the traditional *Tian Wang Bu Xin Dan* formula disclosed in D1 suggests that it was not a trivial experimental task to arrive at the specifically claimed compositions in the present application, in view of the disclosure of D1.

- The cited prior art references need to provide the motivation to arrive at the presently claimed compositions and the cited prior art references does not provide a reason or motivation for the POSITA to arrive at the presently claimed compositions.

[79] We have considered the Applicant's arguments but are not persuaded that the claimed subject matter of independent claims 1, 12 and 16 would not have been obvious to the POSITA.

[80] First and foremost, we maintain our preliminary view expressed in the Panel Letter on page 21 that combining different known herb extracts having well-known therapeutic anti-insomnia effects (independently disclosed in D2 and D3) into a composition for the same therapeutic use does not constitute a step that requires any degree of invention from the POSITA.

[81] Given the nature of the claimed invention and the emphasis of Applicant's submissions with regard to the *Sanofi* factors to be considered in an "obvious to try" analysis, we have taken these factors into consideration in this fourth step of the obviousness inquiry.

[82] We maintain our preliminary view expressed in the Panel Letter on page 21 that it was self-evident that any composition consisting of two or more extracts of plants traditionally used for treating insomnia ought to work for treating insomnia, including a composition consisting of *Platycladus orientalis* seed extract, *Polygala ssp.* root extract and one or more pharmaceutically acceptable carriers or excipients or a composition consisting of *Platycladus orientalis* seed extract, *Polygala ssp.* root extract, *Zizyphus jujube* seed extract and one or more pharmaceutically acceptable carriers or excipients. We consider that this factor is largely determinative as to the obviousness to try of the subject matter of the claims on file.

[83] We note that the Applicant's submissions on this point and more generally regarding the non-obviousness of the claimed compositions put emphasis on the *Tian Wang Bu Xin Dan* formula disclosed in D1 that is traditionally used to treat insomnia and how the POSITA would not possibly extrapolate the specifically claimed compositions from it. In our view, the *Sanofi* factor "Is it more or less self-evident that what is being tried ought to work?", and the inventiveness of the claimed invention in general, should be assessed in the context of the "state of the art" as a whole rather than focussing on a specific piece of knowledge.

[84] The Applicant specifically acknowledges on page 6 of the Reply to the Panel Letter that the CGK includes the "Chinese herbs and their therapeutic applications". We are of the view that the documents D2 and D3 are TCM reference textbooks that are illustrative of the CGK relating to *Platycladus orientalis* seed extract, *Polygala ssp.* root extract and *Zizyphus jujube* seed extract and their therapeutic application, including the treatment of insomnia. The documents D2 and D3 identify each of *Platycladus orientalis* seeds, *Zizyphus jujube* seeds and *Polygala ssp.* roots as being useful for the treatment of insomnia. Further, the document D2 identifies *Platycladus orientalis* seeds and *Zizyphus jujube* seeds as the two most frequently used herbs among the nine "nourishing herbs that calm the shen (spirit)" and teaches that *Polygala ssp.* roots potentiates the effect of other herbs by prolonging sleeping time. The use of *Platycladus orientalis* seed extract, *Polygala ssp.* root extract and *Zizyphus jujube* seed extract in the *Tian Wang Bu Xin Dan* formula disclosed in D1 is aligned with the disclosures of D2 and D3 (i.e., herb extracts individually known to be useful for the treatment of insomnia are found in a traditional formula used for the same therapeutic application).

[85] With regard to the absence in D1, D2 and D3 of teachings that relate to the potential herb-herb interactions between the herbs recited in the claims on file, we consider that the POSITA would have been mindful of any reported herb-herb interactions and significant adverse effects before combining ingredients into a composition and, given the "state of the art", the POSITA would not expect any negative herb-herb

interaction between *Platycladus orientalis* seeds, *Zizyphus jujube* seeds and *Polygala ssp.* roots or associated adverse effects.

[86] We acknowledge that D1, D2, and D3 do not disclose clinical studies to confirm the effectiveness of the individual herb extracts in treating insomnia and potential adverse effects. As indicated at para [39] au-dessus, we are of the view that clinical studies demonstrating safety and efficacy of a herbal remedy may be relevant for the purpose of drug regulatory approval but are not necessarily relevant in the context of an obviousness analysis. Further, we consider that the absence of clinical studies would not generally be a concern for a TCM practitioner, TCM being an art that has been practised since antiquity according to page 5 of the Reply to the Panel Letter.

[87] With regard to the extent, nature and amount of effort required to achieve the invention, the Applicant submits on pages 29 and 30 of the Reply to the Panel Letter that "the trials carried out in the present application would not be considered routine by the POSITA" and that "it was not a trivial experimental task to arrive at the specifically claimed compositions in the present application, in view of the disclosure of D1".

[88] Having considered page 6 the description that describes the preparation and combination of the *Platycladus orientalis* seed extract, *Polygala ssp.* root extract and *Zizyphus jujube* seed extract and the method for producing a composition for modulating physiological sleep disorders defined in independent claim 16, we are of the view that general traditional methods of producing different forms of plant extracts from the different plant components and common extraction, separation and purification techniques of the sort identified above as part of the CGK were carried out in the present application to arrive at compositions encompassed by the claims on file. We consider that the POSITA would have carried out essentially the same CGK methods and techniques as the ones found in the instant description to produce a composition consisting of *Platycladus orientalis* seed extract, *Polygala ssp.* root extract and one or more pharmaceutically acceptable carriers or excipients or a

composition consisting of *Platycladus orientalis* seed extract, *Polygala ssp.* root extract, *Zizyphus jujube* seed extract and one or more pharmaceutically acceptable carriers or excipients and use it for treating insomnia.

[89] In the Reply to the Panel Letter, the Applicant submits that "there is no motivation in the cited prior art references, in combination with the CGK, to arrive at the solution that this present application addresses". We maintain our preliminary view expressed in the Panel Letter that although the "state of the art" does not provide an explicit motive to produce the specific combinations of ingredients recited in the claims, the motivation of combining ingredients in TCM is generally high. We would add that D2 provides a motive to combine a *Polygala ssp.* root extract that prolongs the sleeping time (see page 754) with one or two of the most frequently used "nourishing herbs that calm the shen (spirit)" (see page 776). Further, we do not consider that the expression "prior art" used to describe the third "obvious to try" factor in *Sanofi* refers exclusively to the cited prior art references as suggested by Applicant on pages 30 and 31 of the Reply to the Panel Letter. In our view, *Sanofi* does not support the assertion that the motive has to be exclusively grounded in the cited prior art references. The Supreme Court explicitly included CGK as part of the "prior art" considered under the third "obvious to try" factor in *Sanofi* at para 90:

> It is well known that the pharmaceutical industry is intensely competitive. Market participants are continuously in search of new and improved medications and want to reach the market with them as soon as possible. So demand for an effective and non-toxic product to inhibit platelet aggregation might be assumed to exist. However, nothing in the '875 patent or common general knowledge provided a specific motivation for the skilled person to pursue the '777 invention. The prior patent was a genus patent, and selection might be expected. However, the prior patent did not differentiate between the efficacy and the toxicity of any of the compounds it covered. This suggests that what to select or omit was not then self-evident to the person skilled in the art. [Emphasis added]

[90] The Applicant provided another argument in relation to the inventiveness of the claimed subject matter on pages 26 and 27 of the Reply to the Panel Letter. It appears that the Applicant suggests that *Uhlemann* establishes that subject matter

satisfying the definition of a combination also necessarily satisfies all the requirements of an invention under Canadian patent law. We respectfully disagree. Whether the compositions recited in the claims on file satisfy the definition of a "combination" does not, in our view, meaningfully support the non-obviousness of the claimed subject matter as the more pertinent question is whether the "combination" is obvious or not. With regard to the "benefits" derived from combining the recited plant extracts, we already expressed our view that the inventive concept of the claims on file does not include a synergistic effect. We further note that each individual "old" mounting element in *Uhlemann* serves a different purpose in achieving the combined result of a configuration which avoids lens breakage. In the present case, the *Platycladus orientalis* seeds, *Polygala ssp.* roots, and *Zizyphus jujube* seed extracts all share a common known therapeutic purpose with respect to treating insomnia.

[91] We have also considered the submissions made by Dr. Xueju Xie at the hearing. Dr. Xueju Xie provided contextual information and comments surrounding the content of the declarations submitted during the prosecution of the application that she considered relevant to the inventiveness of the claimed invention. Discussing the content of Declaration-1, Dr. Xueju Xie commented on the results recited in a table summarizing the observed sleeping time of different groups of mice that received distilled water, a tranquilizing muscle-relaxant drug or different combinations of *Platycladus orientalis* seeds, *Polygala ssp.* roots, and *Zizyphus jujube* seed extracts. Dr. Xueju Xie put emphasis on the smaller *P*-value that is reported in the table for a particular dose of the combination *Platycladus orientalis* seeds and *Polygala ssp.* root extracts and suggested that it was surprising that only this particular dose of this particular herbal combination showed such a small *P*-value ($P<0.001$ v. $P<0.05$ for certain doses of other herbal combinations). It is our understanding that the *P*-value indicates the probability of finding a sleeping time difference between the control group and each of the groups that received the herbal combinations as greater than the difference one would expect to observe a matter of pure chance. However, in our view, the *P*-value does not indicate the magnitude of the difference in sleeping time.

For example, depending on the sample size and the sleeping time variations among a given group, a difference in sleeping time between the control and the tested group can be statistically highly significant (e.g., $P<0.001$) but nonetheless unimportant in practical effect (e.g., 40 minutes of sleeping time instead of 39 minutes).

[92] The data presented in the table of Declaration-1 and the comparable data presented in Table 1 of the present application show that certain doses of the tested herbal combinations had similar effects with respect to increasing the sleeping time and that some of the observed effects for each of the tested herbal combinations are likely not due to chance at different levels of statistical significance. In our view, the POSITA would not perceive anything particularly surprising with respect to the reported effect of the combination *Platycladus orientalis* seeds and *Polygala ssp.* root extracts on the sleeping time as compared to the other herbal combinations presented in the table of Declaration-1 and in Table 1 of the present application. With respect to particular doses, we note that the claims on file do not include any fixed dose limitation as the broadest claims simply recite "therapeutically effective amounts for modulating physiological sleep disorders". Given that the specification does not teach what "therapeutically effective amounts" of the recited extracts could conceivably mean for a human subject suffering from insomnia, we consider that the specification relies on the POSITA and the relevant CGK to determine the appropriate dose.

[93] Finally, at the hearing Dr. Xueju Xie also submitted that the Declaration-3 provides evidence that a synergistic effect is associated with the combination *Platycladus orientalis* seeds and *Polygala ssp.* root extracts, the combination *Platycladus orientalis* seeds and *Zizyphus jujube* seed extracts and the combination *Platycladus orientalis* seed, *Polygala ssp.* root, and *Zizyphus jujube* seed extracts. For the same reasons presented above, the submissions of Dr. Xueju Xie do not alter our view with regard to what the POSITA would understand to be, based on the information contained in the instant specification, the inventive concept of the claims at issue and

we already expressed our view that the inventive concept of the claims on file does not include a synergistic effect.

Dependent claims

[94] In the Panel Letter on page 21, we expressed the preliminary view that dependent claims 3-15 and 17-26 of the claims on file are also obvious in view of the state of the art. Dependent claims 3-6, 9-12, 21, 22 and 24-26 would have been obvious to the POSITA at the claim date for the reasons provided previously with respect to the independent claims 1, 2 and 16. With respect to dependent claims 7, 8, 13-15, 17-20, and 23, we state on page 22 of the same letter that the specification does not mention any unexpected or surprising effect associated with any particular dosage form, particular ratio of the amount of *Polygala ssp.* extract and *Platycladus orientalis* extract, the use of a particular solvent other than water or the addition of a de-watering step and that claims 14 and 15 simply reiterate or further define the use of the composition that is already recited in independent claims 1 and 2.

[95] In the Reply to the Panel Letter and at the hearing, the Applicant provided no submissions or arguments specifically addressing the inventiveness of these dependent claims beyond the arguments provided with respect to the independent claims.

Conclusion on obviousness

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

3. Lack of utility of the claims on file (section 2 of the *Patent Act*)

[97] In the Panel Letter on pages 26-28, we assessed the relevant elements of the sound prediction test from the perspective of the POSITA and expressed our views as to why the POSITA would not have soundly predicted that compositions containing extracts of plant parts other than those of *Platycladus orientalis* seeds, *Polygala spp.* roots and *Zizyphus jujube* seeds or obtained by using a solvent other than one containing water will alleviate sleep disorders, including insomnia. To summarize, we expressed the view that:

- the relevant factual basis, in the description or forming part of the CGK, does not factually establishes or even suggests that the active compounds of the tested compositions that are effective in prolonging sleeping time are also present in extracts of plant parts other than those of *Platycladus orientalis* seeds, *Polygala spp.* roots and *Zizyphus jujube* seeds or also present in extracts obtained by using a solvent other than one containing water; and

- that a sound line of reasoning would not be apparent to the POSITA because having considered the factual basis, the POSITA would not know if the necessary active compound(s) and associated properties are found or expected to be found in extracts produced from other plant components or obtained by using a solvent other than one containing water.

[98] The Applicant did not indicate disagreement with these specific assessments of the factual basis and line of reasoning but submitted on page 32 and 33 of the Reply to the Panel Letter that, in any event, the limitations introduced into Proposed Claim Set-3 addressed the above issues.

[99] We will address the proposed claims in detail below but we note the absence of a limitation with regard to the solvent in claims 40-55 of the Proposed Claim Set-3.

When we specifically shared this observation with the Applicant at the hearing, the Applicant essentially submitted that such a limitation with regard to the solvent can be easily avoided by the potential infringers but did not submit specific arguments as to why the observed sleep-prolonging properties of the tested compositions comprising extracts obtained with an aqueous solvent could be extrapolated to compositions comprising extracts obtained with a solvent other than one containing water.

[100] As mentioned above, the Applicant in the Reply to the Panel Letter and at the hearing did not provide specific arguments addressing the soundness of the prediction that compositions containing extracts of plant parts other than those of *Platycladus orientalis* seeds, *Polygala spp.* roots and *Zizyphus jujube* seeds or obtained by using a solvent other than one containing water would be effective in alleviating insomnia. However, the Reply to the Panel Letter on page 13 states:

> Applicant respectfully submits that the "utility" requirement of the present application under Canadian practice and law is satisfied for at least the following reasons: (i) there is no promise of a specific result, and therefore no particular level of utility is required; and (ii) pre-filing data related to the administration of the claimed compositions to humans suffering from sleeping problems is available and was provided as evidence during prosecution. Applicant further submits that: (iii) the invention is not related to a "new use", and the "sound prediction" test should not be applied herein; and (iv) Applicant has no obligation to disclose the synergistic effects of the claimed compositions in the disclosure.

[101] We will address the Applicant's arguments in order.

(i) there is no promise of a specific result, and therefore no particular level of utility is required

[102] In the Panel Letter, having considered independent claims 1, 2 and 16 on file, we expressed the view that these claims are certain and unambiguous in stating the asserted utility and we construed the asserted utility of the recited compositions to be that the compositions are effective in modulating physiological sleep disorders. We

also expressed the view that the expression "for modulating" at least includes the alleviation of a physiological sleep disorder.

[103] In the Reply to the Panel Letter, the Applicant appears to disagree on this point and essentially submits on pages 13-15 that there was no promise in the present application of a specific result, and therefore no particular level of utility is required. The Applicant does not address the language of the claims but instead relies on different passages of the description (page 1, lines 8-10, when read together with page 3, lines 1-3) to support its view that the modulation of physiological sleep disorders is not a promise but a goal or hoped-for result.

[104] We respectfully disagree. When a result is asserted in the claims, it will generally be seen as a promise of utility (see *Apotex Inc. v. Pfizer Canada Inc.*, 2014 FCA 250, at para 71). We reiterate that we consider that independent claims 1, 2 and 16 on file are explicit in stating the asserted utility of the recited composition. Claims 1, 2 and 16 all recite "a composition for modulating physiological sleep disorders".

[105] Further, the passages of the description cited by the Applicant do not support its view that the modulation of physiological sleep disorders is not an asserted utility but a goal or hoped-for result.

[106] The first cited passage is found at page 1, lines 8-10 of the description and reads as follows:

> Sleep disorders may include dysomnias, insomnia, circadian rhythm sleep disorders, hypersomnia and parasommas.

[107] On page 15 of the Reply to the Panel Letter, the Applicant states with respect to the passage above that the use of the word "may" illustrates that this not a promise but a goal or hoped-for result. We consider that the word "may" solely relates to what the expression "sleep disorders" means in the context of the present application and does

not inform the POSITA as regards to whether modulating physiological sleep disorders with the recited compositions is a promise of a specific result or a goal or hoped-for result.

[108] The second passage cited by the Applicant is found at page 3, lines 1-3 of the description and reads as follows:

> Surprisingly, it has been found that compositions comprising Baiziren extract alone, and in combination with at least one of Yuanzhi extract and Suanzaoren extract are useful for modulation of sleep disorders, e.g., insomnia. [Emphasis added]

[109] We consider that the above passage contains clear and unambiguous language relating to the asserted utility of the recited compositions that is aligned with the language of the claims and of the sort identified in *Eli Lilly Canada Inc. v. Hospira Healthcare Corporation*, 2016 FC 47, at para 31 ("*Lilly*"):

> Lilly's argument that the promise of the Patent is limited to the bare requirement of measurable *in vitro* cytotoxic activity is untenable because it ignores clear and unambiguous language in the specification bearing on utility and, in particular, the opening sentence:
>
> > This invention relates to the novel pyrrolopyrimidine derivatives which are useful as anti-tumor agents, the production and utilization thereof. [Emphasis added in the original]

[110] As mentioned at para [46] au-dessus, the Applicant alternatively submits on pages 14 and 15 of the Reply to the Panel Letter that "the present application, at best, may only be construed as making a promise for the treatment of insomnia".

[111] Although our view differs from Applicant's submissions with respect to the exact meaning of "sleep disorders" and as to whether this expression is limited to insomnia in the context of the claims on file (see para [47] au-dessus), we agree nonetheless

with the Applicant that the asserted utility of the recited compositions includes that the compositions encompassed by the claims are effective in the alleviation of insomnia. We already considered this limited interpretation in our preliminary analysis of dependent claims 6 and 15 that specifically define insomnia as one of the contemplated sleep disorders and expressed the view that these dependent claims lack utility for reasons common to all claims on file, independently of the exact nature of the sleep disorder to be alleviated.

(ii) pre-filing data related to the administration of the claimed compositions to humans suffering from sleeping problems is available and was provided as evidence during prosecution

[112] On pages 15 and 16 of the Reply to the Panel Letter, the Applicant submits that the results provided in Declaration-3 and the results provided in Example 3 of the present application demonstrate that the claimed compositions are useful for alleviating insomnia.

[113] Our preliminary views on the lack of utility of claims 1-26 were based on the finding that the claims on file encompass compositions containing extracts of plant parts other than those of *Platycladus orientalis* seeds, *Polygala spp.* roots and *Zizyphus jujube* seeds (claims 1-26) or obtained by using a solvent other than one containing water (claims 1-15).

[114] The results disclosed in the present application and the results disclosed in the Declaration-3 were obtained by using compositions comprising extracts from *Platycladus orientalis* seeds, *Polygala spp.* roots and/or *Zizyphus jujube* seeds. Further, the compositions exemplified in the application were obtained from heated aqueous extracts and the Declaration-3 does not disclose the method used to produce the different herbal extracts. Therefore, we respectfully disagree that the results provided in Declaration-3 and the results provided in Example 3 of the present

application demonstrate that all the compositions encompassed by the claims on file are useful.

(iii) the invention is not related to a "new use", and the "sound prediction" test should not be applied herein

[115] On pages 16 and 17 of the Reply to the Panel Letter, the Applicant submits that the doctrine of "sound prediction" only comes into consideration in the analysis of utility "where the new use is the *gravamen* of the invention", citing *AZT* at para 2, 23, 48, 56 and 82 and *Astrazeneca Canada Inc. et al. v. Apotex Inc.*, 2014 FC 638 at para 140-142 ("*Astrazeneca*") in support for its submission. The Applicant further submits that since the claimed compositions in the present application are not a "new use for an old product" the sound prediction doctrine is not applicable in determining the utility of the claimed compositions in the present application and that our analysis provided in the Panel Letter on pages 25-28 is not applicable in determining whether or not the claimed compositions have utility.

[116] We respectfully disagree with both submissions. First, although the principles of the sound prediction doctrine were applied in *AZT* in the context of a new use for an old chemical compound, we do not understand *AZT* to limit the application of the sound prediction doctrine to the narrow context of a "new use for an old product" as submitted by the Applicant. The utility statutory requirement found in section 2 of the *Patent Act* is the same for all types of inventions. At its most basic, the overarching concept is that, as of the filing date, there must have been a demonstration of the utility of the claimed invention, or, failing that, a sound prediction of utility based on the specification and the CGK available at the time of the prediction.

[117] The sound prediction principles laid out in *AZT* have since been applied numerous times by the Federal Courts in contexts other than a "new use for an old product" type of invention, including a new landing gear (see *Eurocopter*), a novel compound

(see for example *Lilly*), a new formulation of an old compound (see for example *Allergan Inc. v. Apotex Inc.*, 2016 FC 344 ("*Allergan*")) and a new composition comprising two old compounds (see for example *Leo Pharma Inc. v. Teva Canada Limited*, 2015 FC 1237).

[118] With respect to the *Astrazeneca* decision cited by the Applicant to support its interpretation of *AZT*, we understand that in this decision Justice Rennie expressed his views in paras 140-142 with regard to the meaning of the proper disclosure element of the requirement of the sound prediction test laid out in *AZT* but, nevertheless, acknowledged and applied the sound prediction test in the context of new compound claims. Simply put, he expressed the view that the factual basis for a sound prediction of utility does not need to be disclosed in the patent itself except in new use patents. Therefore, we do not accept that *Astrazeneca* supports the view that the doctrine of sound prediction as a whole only comes into consideration in the analysis of utility for a "new use of an old compound" type of invention.

[119] In any event, the Applicant did not indicate, and we are not aware of, any factual basis that existed outside the patent application as of the filing date that supports the prediction that compositions containing extracts of plant parts other than those of *Platycladus orientalis* seeds, *Polygala spp.* roots and *Zizyphus jujube* seeds or obtained by using a solvent other than one containing water would be effective in alleviating insomnia. Therefore, adopting Justice Rennie's interpretation of the proper disclosure element of the sound prediction test would not have altered our views expressed with regard to the factual basis and the line of reasoning, the two requirements of a sound prediction that were determinative to our expressed conclusions.

(iv) Applicant has no obligation to disclose the synergistic effects of the claimed compositions in the disclosure

[120] On page 19 of its Reply to the Panel Letter, the Applicant essentially submits "that "synergistic effects" of the combination of herbal extracts were demonstrated prior to the filing of the present application (see for example Declaration-3)" and that "there is still no requirement under Canadian patent practice or law to disclose evidence of such synergism in the patent application itself".

[121] As explained at paras [50]-[70] au-dessus and expressed in the Panel Letter on page 26, we do not consider that the asserted utility comprise a synergistic effect.

[122] We further note the absence of any evidence on the record, in a declaration or in the application itself, that demonstrates or evinces a synergistic effect for compositions containing extracts of plant parts other than those of *Platycladus orientalis* seeds, *Polygala spp.* roots and *Zizyphus jujube* seeds or obtained by using a solvent other than one containing water, the claimed subject matter at issue with regard to the lack of utility defect. The results disclosed in the Declaration-3 were obtained by using compositions comprising extracts from *Platycladus orientalis* seeds, *Polygala spp.* roots and/or *Zizyphus jujube* seeds and the Declaration-3 does not disclose the solvent used to produce the different herbal extracts. Therefore, we respectfully disagree that the results provided in Declaration-3 of the present application demonstrate that the claimed subject matter at issue with regard to the lack of utility defect is useful. Accordingly, we consider unnecessary to address this specific argument.

Conclusion on lack of utility

[123] We maintain our view expressed in the Panel Letter on page 28 that the POSITA would not have soundly predicted that compositions containing extracts of plant parts other than those of *Platycladus orientalis* seeds, *Polygala spp.* roots and *Zizyphus jujube* seeds (claims 1-26) or obtained by using a solvent other than one containing water (claims 1-15) will alleviate insomnia for the reasons expressed in the Panel Letter and the reasons expressed above.

[124] Accordingly, we are of the view that claims 1-26 on file lack utility and do not comply with section 2 of the *Patent Act*.

ANALYSIS OF THE PROPOSED CLAIMS

[125] Since we consider that the claims on file are unpatentable on the grounds of obviousness and lack of utility, we will consider the Proposed Claim Set-3 submitted on November 21, 2016 with the Reply to the Panel Letter that comprises all the post-FA proposed amendments as it consists of claims 1-21 and 23-26 of the claims on file, claim 22 of the Proposed Claim Set-1, claims 27-39 of the Proposed Claim Set-2 and new claims 40-55.

[126] The only significant difference between the Proposed claim Set-3 and corresponding claims of the claims on file is that the scope of some of the proposed independent claims (claims 27-55) is limited by features already found in dependent claims on file. The independent claims that have the narrowest scopes in Proposed claim Set-3 are claims 40, 41, 45, 52 and 55 that recite a specific sleep disorder (i.e., insomnia), extracts of specific plant parts (i.e., *Platycladus orientalis* seed extract, *Polygala spp.* root extract and *Zizyphus jujube* seed extract) and a particular ratio of the amount of *Polygala ssp.* extract and *Platycladus orientalis* extract (i.e., a ratio between 1:1 to 2.48:1).

Obviousness

[127] We have presented our view that, taking into account the treatment of insomnia and the aqueous extracts of *Platycladus orientalis* seeds, *Polygala spp.* roots and *Zizyphus jujube* seeds, the claims on file are obvious in view of the state of the art for the reasons given above. Moreover, we expressed our view that the POSITA would not consider that an inventive step would be required to use a ratio between 1:1 to

2.48:1 of the amount of *Polygala ssp.* extract and *Platycladus orientalis* extract in compositions for alleviating insomnia and that there is no evidence of an unexpected or surprising effect associated with any of the encompassed ratio range. As mentioned above, the Applicant provided no submissions or arguments in the Reply to the Panel Letter or at the hearing specifically addressing the inventiveness of the recited ratio range.

[128] As the Proposed Claim Set-3 only encompasses subject matter already considered obvious with respect to the claims on file, we are of the view that the subject matter of claims 1-55 of the Proposed Claim Set-3 would have been obvious to the POSITA at the claim date for the reasons provided previously.

Lack of utility

[129] We have presented our view that the POSITA would not have soundly predicted that compositions containing extracts of plant parts other than those of *Platycladus orientalis* seeds, *Polygala spp.* roots and *Zizyphus jujube* seeds or obtained by using a solvent other than one containing water will alleviate insomnia.

[130] Claims 1-27, 29, 31-36, 38 of the Proposed Claim Set-3 all encompass compositions containing extracts of plant parts other than those of *Platycladus orientalis* seeds, *Polygala spp.* roots and *Zizyphus jujube* seeds for the treatment of insomnia.

[131] Claims 1-12, 14, 15, 27-43 and 52-55 of the Proposed Claim Set-3 all encompass compositions containing extracts obtained by using a solvent other than one containing water for the treatment of insomnia.

[132] Accordingly, we are of the view that claims 1-43 and 52-55 of the Proposed Claim Set-3 lack utility and do not comply with section 2 of the *Patent Act*.

CONCLUSIONS

[133] In our view, the claims on file do not comply with section 28.3 of the *Patent Act* and do not comply with section 2 of the *Patent Act*.

[134] We consider that claims 1-55 as proposed in the letter of November 21, 2016 do not overcome our view regarding the obviousness of the claims on file and that claims 1-43 and 52-55 do not overcome our view regarding the lack of utility of the claims on file.

RECOMMENDATION OF THE BOARD

[135] The panel recommends that the application be refused because the claims on file do not comply with section 28.3 of the *Patent Act* and do not comply with section 2 of the *Patent Act*.

[136] Further, the proposed claims do not overcome these defects and therefore do not constitute specific amendments that are "necessary" under subsection 30(6.3) of the *Patent Rules*.

Marcel Brisebois Member	Ed MacLaurin Member	Andrew Strong Member

COMMISSIONER'S DECISION

[137] I concur with the findings and the recommendation of the Board and its recommendation that the application should be refused because the claims on file do not comply with section 28.3 of the *Patent Act* and do not comply with section 2 of the *Patent Act*.

[138] 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 23rd day of February, 2017