Citation: Currax Pharmaceuticals LLC, 2022 CACP 25

Commissioner's Decision #1632
Décision du commissaire nº 1632
Date: 2022-12-30

TOPIC:	F00	Novelty
	O00	Obviousness
	C00	Ambiguity or indefiniteness
SUJET:	F00	Nouveauté
	O00	Évidence
	C00	Caractère ambigu ou indéfini

Application No. 2,687,118

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,687,118 having been rejected under subsection 199(1) of the *Patent Rules*, has consequently been reviewed in accordance with paragraph 86(7)(c) of the *Patent Rules*. 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 2,687,118, which is entitled "Methods of using low-dose doxepin for the improvement of sleep". Currax Pharmaceuticals LLC is the sole Applicant. A review of the rejected application has been conducted by a Panel of the Patent Appeal Board pursuant to paragraph 86(7)(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 May 18, 2007. It was laid open to public inspection on December 13, 2007.

[4] The rejected application relates to methods of improving sleep in patients with primary insomnia by administration of low doses of doxepin. More particularly, the administration of 3 mg and 6 mg of doxepin demonstrated significant improvement in sleep onset, sleep maintenance and delay of early morning awakenings.

[5] The application has 29 claims on file that were received at the Patent Office on April 27, 2018.

Prosecution History

[6] On November 26, 2019, a Final Action was written under subsection 86(5) of the *Patent Rules*. The Final Action states that the subject-matter of claims 1 to 29 on file at the time of the Final Action is anticipated contrary to paragraphs 28.2(1)(a) and 28.2(1)(b) of the *Patent Act* and is further obvious contrary to section 28.3 of the *Patent Act*. The Final Action also indicates that claims 1, 5, 9, 11, 18 and 22 are

indefinite and therefore non-compliant with subsection 27(4) of the *Patent Act*.

[7] In the Response to the Final Action dated March 25, 2020, the Applicant argues that the claims of the present application are novel and inventive over the cited prior art. In addition, the Response to the Final Action includes an amended claim set containing proposed claims 1 to 29 to address the indefiniteness defect in claims 1, 5, 9, 11, 18 and 22.

[8] On July 21, 2020, the application was forwarded to the Patent Appeal Board for review under subsection 86(7) of the *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.

[9] In a letter dated July 24, 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 October 22, 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 November 3, 2022, the Panel sent a Preliminary Review letter detailing our preliminary analysis and opinion that claims 1 to 7, 9, 11, 13, 14, 16 to 24, 26, 28 and 29 on file, as well as proposed claims 1 to 7, 9, 11, 13, 14, 16 to 24, 26, 28 and 29, are anticipated contrary to paragraph 28.2(1)(a) of the *Patent Act* and that all of the claims on file, as well as all of the proposed claims, are obvious contrary to section 28.3 of the *Patent Act*. In that letter, the Panel further expressed the preliminary opinion that the subject-matter of claims 1, 5, 9, 11, 18 and 22 on file is indefinite contrary to subsection 27(4) of the *Patent Act* and that proposed claims 1, 5, 9, 11, 18 and 22 overcome this defect. The Preliminary Review letter also provided the Applicant with an opportunity to make oral and/or written submissions.

[12] On November 14, 2022, the Applicant declined the opportunity for an oral hearing and on November 29, 2022 the Applicant 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 anticipated contrary to subsection 28.2(1) of the *Patent Act*;
- whether the claims on file are obvious contrary to section 28.3 of the *Patent Act*; and
- whether claims 1, 5, 9, 11, 18 and 22 are indefinite contrary to subsection 27(4) of the *Patent Act*.

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

FOLLOWING A PURPOSIVE CONSTRUCTION, WHICH CLAIMED ELEMENTS ARE ESSENTIAL?

[15] In our view, all of the elements of the claims on file are essential.

Legal Background

[16] According to *Free World Trust v Électro Santé* Inc, 2000 SCC 66 and *Whirlpool Corp v Camco Inc*, 2000 SCC 67, 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.

[17] 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.

Analysis of the claims on file

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

[18] 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:

> On page 4, the Final Action identifies the person skilled in the art and the relevant common general knowledge:
>
> > The person skilled in the art is presumed to be a medicinal chemist and/or physician familiar with the treatment of insomnia. They would be aware of the diagnostic criteria for insomnias of various types, common clinical measures of the severity of insomnia, and the use of pharmacological approaches to treat insomnia. In particular, they would recognize that symptoms including early awakenings from a period of sleep were common to a variety of forms of insomnia (see D4, D5, and para. 2-3 of the instant application).
>
> The Response to the Final Action did not contest or comment on these characterizations. After reviewing the specification and the references cited therein, we consider that the characterization of the person skilled in the art presented in the Final Action is reasonable, and therefore we adopt it in this review.
>
> With regard to the common general knowledge of the person skilled in the art, the Final Action refers to diagnostic criteria for various forms of insomnia referred to in paras 2 to 3 of the description, as well as taught in prior art documents D4 and D5:
>
> D4: Edinger *et al.*, “Derivation of Research Diagnostic Criteria for Insomnia: Report of an American Academy of Sleep Medicine Work Group”, Sleep, Vol. 27, No. 8, pages 1567 to 1596, 2004.
>
> D5: International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Version for 2007, World Health Organization, Chapters V and VI, Retrieved from: https://web.archive.org/web/20070607010958/http://www.who.int/classifications/apps/icd/icd10online/

Having reviewed the instant specification, as well as D4 and D5, we are of the preliminary view that the above characterization of the common general knowledge is reasonable. Consistent with the teachings of the description at paras 2 to 3, both D4 and D5 describe insomnia as a condition of unsatisfactory quantity or quality of sleep with patients reporting difficulty initiating sleep, difficulty maintaining sleep and waking up too early. These symptoms were generally known and accepted without question by the bulk of those who are engaged in the particular arts of medicinal chemistry, medicine and the treatment of insomnia at the claim date: *Eli Lilly & Co v Apotex Inc*, 2009 FC 991 at para 97, aff'd in 2010 FCA 240.

Although the identification of the common general knowledge was provided in the context of the obviousness analysis, it is our preliminary view that the above identified elements were also relevant common general knowledge as of the publication date of the instant application.

Further, based on certain points in description, in our preliminary view, the common general knowledge of the person skilled in the art would also include the following:

- Polysomnography is a diagnostic test during which a number of physiologic variables are measured and recorded during sleep (para 0028);
- Common sleep measures, including wake time during sleep, wake time after sleep, wake after sleep onset, latency to persistent sleep, total sleep time and sleep efficiency are based on polysomnographic findings (paras 0028 to 0034);
- Diagnostic and Statistical Manual of Mental Disorders, fourth Edition (DSM-IV) is an international classification system with defined diagnostic criteria for insomnia (para 0122); and
- pharmaceutical formulations and pharmacological treatment of insomnia (paras 0005 and 0077 to 0093).

[19] 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 final analysis.

The claims on file

[20] There are 29 claims on file. Claims 1, 5, 9, 11, 14, 16, 18, 22, 26 and 28 are independent claims. The Preliminary Review letter, on pages 5 to 6, expresses the preliminary view that claims 1 and 18 are representative of the independent claims. Independent claims 1 and 18 are as follows:

> 1. Use of doxepin or a pharmaceutically acceptable salt thereof in a dosage of 6 mg for treating sleep maintenance insomnia characterized by early awakenings during the 8th hour of sleep in a patient who is identified to have a sleep disorder in which, for a given 8 hour period of desired sleep, the patient experiences a sleep period that terminates during the final 60 minutes of said period**.**
>
> 18. Use of doxepin, or a pharmaceutically acceptable salt thereof, in a dosage of 6 mg in the preparation of a medicament for use in treating sleep maintenance insomnia characterized by early awakenings during the 8th hour of sleep in a patient having a sleep disorder in which, for a given 8 hour period of desired sleep, the patient experiences a sleep period that terminates during the final 60 minutes of said period.

[21] Independent claims 5 and 22 are directed to the same use as claims 1 and 18, respectively but with a dosage of 3 mg and the patient is further defined as elderly. Similarly, independent claims 9, 11, 14, 16, 26 and 28 are directed to the use of doxepin at a dosage of 6 mg or 3 mg for an elderly patient to treat insomnia characterized by a different symptom.

[22] The dependent claims 2 to 4, 6 to 8, 10, 12, 13, 15, 17, 19 to 21, 23 to 25, 27 and 29 define further limitations to the time of termination of a sleep period (claims 2, 3, 6, 7, 19, 20, 23 and 24), the form of doxepin (claims 4, 8, 10, 13, 15, 17, 21, 25, 27 and 29) and the duration of insomnia (claim 12).

[23] In the absence of submissions from the Applicant, we adopt the above identification of claims 1 and 18 as being representative of the independent claims. Likewise, we adopt the above characterization of dependent claims 2 to 4, 6 to 8, 10, 12, 13, 15, 17, 19 to 21, 23 to 25, 27 and 29 as providing further limitations with regard to: the time of termination of a sleep period, the form of doxepin and the duration of insomnia.

Essential elements

[24] 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 29 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. In addition, 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.

[25] 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 ANTICIPATED?

[26] In our view, claims 1 to 7, 9, 11, 13, 14, 16 to 24, 26, 28 and 29 on file define subject-matter that was publicly available before the claim date.

Legal Background

[27] Subsection 28.2(1) of the *Patent Act* requires claimed subject-matter to be new:

> The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
>
> (a) before the one-year period immediately preceding the filing date or, if the claim date is before that period, before the claim date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;
>
> (b) before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in Canada or elsewhere;
>
> (…).

[28] In *Apotex Inc v Sanofi–Synthelabo Canada Inc*, 2008 SCC 61 at paras 24 to 29 [Sanofi], the Supreme Court of Canada clarifies that there are two separate requirements that must be satisfied in order to show that a prior art document anticipates a claimed invention: prior disclosure and enablement.

[29] The prior disclosure requirement means that the prior art must disclose subject-matter which, if performed, would necessarily result in infringement of the invention as claimed. It is not necessary for the person performing the subject-matter to

know they are infringing: Sanofi at para 25, citing a reference from *Synthon B.V. v SmithKline Beecham plc*, [2006] 1 All ER 685, [2005] UKHL 59 [Synthon] at para 22:

> [W]hether or not it would be apparent to anyone at the time, whenever subject matter described in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied.

[30] Further, at this stage, there is no room for trial and error or experimentation by the person skilled in the art. The prior art is simply read "for the purposes of understanding it": see Sanofi at para 25, citing Synthon.

[31] The enablement requirement means that the person skilled in the art would have been able to perform the invention as claimed without undue burden. Unlike the prior disclosure stage, at this stage the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work: see Sanofi at paras 26 to 27.

Analysis of the claims

[32] The Preliminary Review letter, on pages 7 to 8, identifies the prior art documents that were cited in the Final Action, as well as three additional prior art documents considered to be relevant to the assessment of anticipation:

> On page 3, the Final Action cites the following documents as relevant art:
>
> | | | | |
> |---|---|---|---|
> | D1: | Hsu, T. et al., Sleep , 28, Abstract Supplement A50, 2005 | | |
> | D2: | Kavey, N.B. | US 6, 211, 229 | 3 April 2001 (03-04-2001) |
> | D3: | Kavey, N.B. | US 5,643, 897 | 1 July 1997 (01-07-1997) |
>
> While we agree that D1 to D3 are applicable art, we have retrieved three additional prior art documents that we consider to be pertinent to the assessment of anticipation of the claims on file and, in accordance with subsection 86(9) of the *Patent Rules*, now give the Applicant notice of these documents:
>
> D6: Somaxon Pharmaceuticals Press Release, "Somaxon Pharmaceuticals Announces Positive Results in a Phase II Dose-Finding Study of Low-Dose Doxepin in Elderly Patients with Primary Sleep Maintenance Insomnia", April 21, 2005,

Retrieved from:
https://web.archive.org/web/20061117003844/http://www.somaxon.com/media/pdf/press2005/DoxelderlyP2_PR_4-21-05.pdf.

D7: Somaxon Pharmaceuticals Press Release, "Somaxon Pharmaceuticals, Inc. Initiates Phase III Clinical Trials of SILENOR™ in Patients with Insomnia", June 9, 2005, Retrieved from:
https://web.archive.org/web/20061117003848/http://www.somaxon.com/media/pdf/press2005/PhaseIII_Adult_Study_PR.pdf.

D8: Somaxon Pharmaceuticals Press Release, "Somaxon Pharmaceuticals Announces Positive Phase 3 Results with SILENOR™ for the Treatment of Adults with Chronic Insomnia", April 10, 2006, Retrieved from:
https://web.archive.org/web/20060624181504/http://somaxon.com/media/pdf/press2006/SOMX_Silenor_Adult_P3_News_Release_4-10-06.pdf

D6, Disclosure and Enablement

[33] The Preliminary Review letter, on pages 8 to 10, explains that in our preliminary view claims 1 to 3, 5 to 7, 9, 11, 14, 16, 18 to 20, 22 to 24, 26 and 28 are disclosed and enabled by D6:

> D6, Disclosure requirement
>
> D6 discloses the results of a Phase II dose-finding study of low dose doxepin in elderly patients with primary sleep maintenance insomnia. Relative to placebo, doxepin at 1 mg, 3 mg and 6 mg demonstrated statistically significant improvements in various parameters including polysomnography wake time during sleep, wake after sleep onset, sleep efficiency and total sleep time.
>
> As indicated above, insomnia is a condition characterized by unsatisfactory quantity or quality of sleep with patients reporting difficulty initiating sleep, difficulty maintaining sleep and waking up too early. In this view, the Final Action argues on pages 3 to 4 that treatment of sleep maintenance insomnia would inherently involve treating symptoms of insomnia, including those encompassed by the claims:
>
> > Likewise, treatment of sleep maintenance insomnia would be understood to inherently involve treating early awakenings and/or fragmented sleep during the 8th hour of sleep given that such symptoms were commonly associated with sleep maintenance insomnia.

The Response to the Final Action, on pages 2 to 3, disagrees with this assessment and argues that the claims are directed to treating sleep maintenance insomnia associated with specific sleep disorders that are distinct from patients suffering from sleep maintenance in general:

> The sleep maintenance insomnia to be treated is associated with the following specific sleep disorders in patients:
>
> sleep disorder in a patient who experiences a sleep period that terminates during the final 60 minutes of a given 8 hour period of desired sleep (claims 1, 5, 18 and 22);
>
> sleep disorder in a patient who is identified to suffer from fragmented sleep during the 8th hour of a sleep period (claims 9, 11, 26 and 28);
>
> sleep disorder in a patient who is identified to suffer from a sleep deficiency associated with one or more of the following: LPS, WASO, TST, TWT, SE, latency to State 2 sleep, WTDS, or WTAS during the final 60 minutes of a desired 8 hour sleep period (claims 14 and 16).
>
> (…)
>
> In his report, the Examiner asserts that the drop in average sleep efficiency in the 8th hour for patients given placebo actually indicates that early awakenings and fragmented sleep is an inherent symptom of sleep maintenance insomnia. However, the Applicant respectfully disagrees. Table 8 of the present application indicates that the patients receiving placebo had a range of sleep efficiencies during the 8th hour, from as low as 0% efficiency to has high as 100% efficiency. Moreover, the median sleep efficiency for patients on placebo in this trial was 94.2% during the 8th hour. Thus, these data clearly show that it is not inherent characteristic that all patients with insomnia have low sleep efficiency during the 8th hour of sleep. Rather, half of the placebo-treated patients in the trial had a sleep efficiency of at least 94.2% during the 8th hour.

> Accordingly, the group of patients suffering from the specific claimed sleep disorders i), ii) and iii) mentioned above is distinct from patients suffering from sleep maintenance in general. [Emphasis in original]

The Summary of Reasons, on page 2, disputes the interpretation that the group of patients suffering from the sleep disorders claimed is distinct from those suffering from sleep maintenance insomnia arguing that the definition of symptoms that are inherent to a given disorder does not result in a distinct patient population being treated.

We agree with the assessment in the Final Action and the Summary of Reasons that the symptoms of early awakening and fragmented sleep during the eighth hour of sleep are associated with sleep maintenance insomnia. These symptoms are encompassed by the diagnostic criteria of DSM IV primary insomnia which include, difficulty initiating/maintaining sleep, waking too early, and/or non-restorative sleep. It follows that treatment of sleep maintenance insomnia as disclosed in D6 encompasses treating patients with these symptoms.

Further, it does not matter whether or not these symptoms are specifically disclosed as being treated in D6. To meet the disclosure requirement, D6 does not have to be an “exact description” of the claimed invention but needs to disclose subject-matter which, if performed, would necessarily result in an infringement of the claims if the instant application subsequently issued to patent.

In following the disclosure of D6, the person skilled in the art would be led to use 3 mg of doxepin to treat elderly patients with primary sleep maintenance insomnia, a population that necessarily includes, but is not limited to, patients with sleep maintenance insomnia characterized by early awakenings and fragmented sleep in the eighth hour of sleep. Therefore, even though it was not recognized in D6, the treatment of elderly patients with primary sleep maintenance insomnia would necessarily result in the treatment of early awakenings and fragmented sleep in the eighth hour of sleep in those patients who experience these symptoms. This is consistent with the teachings of D7 which confirm that additional data from the Phase II trial of D6 demonstrate that low dose doxepin produced statistically significant improvements in sleep efficiency at hours seven and eight.

Therefore, it is our preliminary view that D6 discloses subject-matter which, if performed by the person skilled in the art, would necessarily result in the infringement of claims 1 to 3, 5 to 7, 9, 11, 14, 16, 18 to 20, 22 to 24, 26 and 28 if a patent were to issue for the claimed subject-matter.

However, D6 fails to disclose the use of doxepin to treat transient insomnia in any patients or that the dosage form of doxepin is an oral tablet formulation. Therefore, it is our preliminary view that D6 fails to disclose the subject-matter of claims 4, 8, 10, 12, 13, 15, 17, 21, 25, 27 and 29.

D6, Enablement requirement

D6 discloses the use of doxepin in a dosage of 3 mg for treating elderly patients with primary sleep maintenance insomnia which includes patients having symptoms of early awakenings and fragmented sleep in the eighth hour of sleep. In our preliminary view, these teachings would enable the person skilled in the art to put into practice the subject-matter of claims 1 to 3, 5 to 7, 9, 11, 14, 16, 18 to 20, 22 to 24, 26 and 28 without difficulty or the need for undue experimentation.

In light of the above, it is our preliminary view that claims 1 to 3, 5 to 7, 9, 11, 14, 16, 18 to 20, 22 to 24, 26 and 28 are anticipated by D6 contrary to paragraph 28.2(1)(a) of the *Patent Act*.

Since the disclosure requirement is not met in respect of the subject-matter of claims 4, 8, 10, 12, 13, 15, 17, 21, 25, 27 and 29, there is no need to consider enablement for these claims.

D8, Disclosure and Enablement

[34] The Preliminary Review letter, on pages 11 to 12, explains that in our preliminary view claims 1 to 4, 11, 13, 16 to 21, 28 and 29 are disclosed and enabled by D8:

D8, Disclosure requirement

D8 discloses the results of a Phase 3 study of the safety and efficacy of 3 mg and 6 mg oral tablet formulation doxepin in adults with chronic primary insomnia as defined by DSM IV. Statistically significant results in the primary endpoint, polysomnography defined wake after sleep onset, were observed at both doses for all time points. Statistically significant improvements in total sleep time and sleep efficiency were also observed. In addition, in a third-of-the-night analysis, doxepin at these dosages generally demonstrated statistically significant improvement in sleep efficiency in the final third of the night.

As indicated above, insomnia is a condition characterized by unsatisfactory quantity or quality of sleep with patients reporting difficulty initiating sleep, difficulty maintaining sleep and waking up too early. The common general knowledge of the person skilled in the art would include symptoms of early awakening and fragmented sleep during the eighth hour of sleep as being associated with sleep maintenance insomnia. It follows that treatment of sleep maintenance insomnia as disclosed in D8 encompasses treating patients with these symptoms.

Further, it does not matter whether or not these symptoms are specifically disclosed as being treated in D8. To meet the disclosure requirement, D8 does not have to be an “exact description” of the claimed invention but needs to disclose subject-matter

which, if performed, would necessarily result in an infringement of the claims if the instant application subsequently issued to patent.

In following the disclosure of D8, the person skilled in the art would be led to use a 6 mg oral tablet formulation of doxepin to treat adult patients with chronic primary insomnia, a population that necessarily includes, but is not limited to, patients with sleep maintenance insomnia characterized by early awakenings and fragmented sleep in the eighth hour of sleep. Therefore, even though it was not recognized in D8, the treatment of adult patients with chronic primary insomnia would necessarily result in the treatment of early awakenings and fragmented sleep in the eighth hour of sleep in those patients who experience these symptoms. This is consistent with the observation that low dose doxepin produced statistically significant improvements in wake after sleep onset at all time points.

Therefore, it is our preliminary view that D8 discloses subject-matter which, if performed by the person skilled in the art, would necessarily result in the infringement of claims 1 to 4, 11, 13, 16 to 21, 28 and 29 if a patent were to issue for the claimed subject-matter.

However, D8 fails to disclose the use of doxepin to treat chronic insomnia in elderly patients or its use to treat transient insomnia in any patients. Therefore, it is our preliminary view that D8 fails to disclose the subject-matter of claims 5 to 10, 12, 14, 15 and 22 to 27.

D8, Enablement requirement

D8 discloses the use of an oral tablet formulation of doxepin at a dosage of 6 mg for treating adult patients with DSM IV primary insomnia. As indicated above, this population necessarily includes patients having symptoms of early awakenings and fragmented sleep in the eighth hour of sleep. In our preliminary view, these teachings would enable the person skilled in the art to put into practice the subject-matter of claims 1 to 4, 11, 13, 16 to 21, 28 and 29 without difficulty or the need for undue experimentation.

In light of the above, it is our preliminary view that claims 1 to 4, 11, 13, 16 to 21, 28 and 29 are anticipated by D8 contrary to paragraph 28.2(1)(a) of the *Patent Act*.

Since the disclosure requirement is not met in respect of the subject-matter of claims 5 to 10, 12, 14, 15 and 22 to 27, there is no need to consider enablement for these claims.

[35] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that claims 1 to 3, 5 to 7, 9, 11, 14, 16, 18 to 20, 22 to 24, 26 and 28 are anticipated by D6 and claims 1 to 4, 11, 13, 16 to 21, 28 and 29 are anticipated by D8 contrary to paragraph 28.2(1)(a) of *the Patent Act*.

ARE THE CLAIMS OBVIOUS?

[36] In our view, the claims on file define subject-matter that would have been obvious to the person skilled in the art in view of information that was publicly available before the claim date.

Legal Background

[37] Section 28.3 of the *Patent Act* requires that the subject-matter of a claim not be obvious to the person skilled in the art:

> 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 before the one-year period immediately preceding the filing date or, if the claim date is before that period, before the claim 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.

[38] In Sanofi, the Supreme Court of Canada states 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?

Analysis of the Claims

[39] The Preliminary Review letter, on pages 13 to 16, explains that in our preliminary view the claims on file define subject-matter that would have been obvious to the person skilled in the art in view of the cited prior art and the relevant common general knowledge:

> The person skilled in the art and the relevant common general knowledge
>
> 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.
>
> Identify the inventive concept of the claim in question or, if that cannot readily be done, construe it
>
> On page 5, the Final Action identifies a common inventive concept that links the claims: "the inventive concept of the claims is the use of 3 or 6 mg of doxepin to treat sleep maintenance insomnia causing disruptions to sleep efficiency in the 8th hour of a sleep period."
>
> The Response to the Final Action does not contest or comment on this characterization. However, in disputing the obviousness of the claims, the Response to the Final Action on pages 2 to 3 submits that none of the cited prior art disclose the use of doxepin in a dosage of 3 mg or 6 mg for treating sleep maintenance insomnia which is associated with the specific sleep disorders as claimed.
>
> As mentioned above, our preliminary view is that the person skilled in the art would consider all of the elements in the claims to be essential, and so they should be reflected in the inventive concepts of the claims. Therefore, for the purpose of this assessment we take into account all of the essential elements of the claims. In our

preliminary view, the combination of essential elements of the claims represents their inventive concepts as well.

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

For the purpose of anticipation we have already determined what has been disclosed and taught by D6 and D8.

With respect to D7, we have already identified that D7 discloses that low dose doxepin produced statistically significant improvements in sleep efficiency at hours seven and eight in elderly patients. We further note that D7 discloses that this improvement, which occurred without demonstrating impairment in measures of next day residual sedation relative to placebo, was observed in adult patients as well.

In our preliminary view the main difference between the inventive concept of the claims and any of D6 to D8 lies in the specific sleep disorders as claimed. Although D7 discloses that low dose doxepin produced an increase in sleep efficiency during the final hour of an eight hour sleep period, it is not known whether this improvement was due to prevention of early awakening, prevention of fragmented sleep or both.

Additional differences over the cited prior art include the use of low dose doxepin to treat transient insomnia in adults and the use an oral tablet formulation of doxepin to treat insomnia in elderly patients.

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?

Although, the Court in Sanofi provides a four-step approach for addressing the issue of obviousness, it is important to remember that the obviousness analysis is concerned with whether bridging the difference between the prior art and a second point constitutes steps that require any degree of invention: *Bristol-Myers Squibb Canada Co v Teva Canada Limited*, 2017 FCA 76 at para 65

> It may be helpful to keep in mind that the obviousness analysis asks whether the distance between two points in the development of the art can be bridged by the Skilled Person using only the common general knowledge available to such a person. If so, it is obvious. The first of those points is the state of the prior art at the relevant date. References in the jurisprudence to "the inventive concept", "the

solution taught by the patent", "what is claimed" or simply "the invention" are attempts to define the second point.

In view of the foregoing and in the context of the present case, what must be considered at this step is whether it would have been obvious to the person skilled in the art, based on the disclosures of D6 to D8 and their common general knowledge, that the successful use of low dose doxepin to treat sleep maintenance insomnia in the eighth hour of sleep disclosed therein suggests that doxepin would improve symptoms of early awakenings and fragmented sleep during the eighth hour of sleep. In our preliminary view, this difference would have been obvious having regard to either D6 or D8, in view of D7 and the relevant common general knowledge.

As explained above, insomnia is a condition characterized by unsatisfactory quantity or quality of sleep with patients reporting difficulty initiating sleep, difficulty maintaining sleep and waking up too early. The common general knowledge of the person skilled in the art would include symptoms of early awakening and fragmented sleep during the eighth hour of sleep as being associated with sleep maintenance insomnia. In this regard, it has already been noted that D7 discloses that low dose doxepin produced statistically significant improvements in sleep efficiency at hours seven and eight in adult and elderly patients. This means that an improvement in the total sleep time was observed in the eighth hour of sleep. In our preliminary view, the person skilled in the art would consider that an improvement in the total sleep time during the final hour of sleep could only be achieved by preventing early awakenings and/or fragmented sleep. Therefore, it is our preliminary opinion that it would have been obvious to the person skilled in the art to treat patients with sleep maintenance insomnia characterized by either of these symptoms in view of D7 and the relevant common general knowledge.

Further, it is our preliminary view that it would have been obvious to the person skilled in the art to use a 3 mg oral tablet formulation of doxepin to treat insomnia in elderly patients given that D8 discloses this specific formulation of doxepin was used to successfully treat sleep maintenance insomnia in adult patients.

Finally, it is our preliminary view that it would have been obvious to the person skilled in the art to use doxepin in a dosage of 6 mg for treating patients with transient sleep maintenance insomnia characterized by fragmented sleep in the eighth hour of sleep in view of the teachings of D8. In particular, D8 discloses that this dosage of doxepin demonstrated significant improvements in the primary endpoint, wake after sleep onset, for all time points, as well as statistically significant improvements in sleep efficiency in the final third of the night in patients with chronic primary insomnia. In addition, D8 discloses that this dose of doxepin was well tolerated, side effects were comparable to placebo, there were no statistically significant differences versus placebo in next day residual measures and memory impairment and anticholinergic effects were not observed. Therefore, we are of the preliminary opinion that in view of the positive results and in the absence of

> amnesia, anticholinergic and next day residual effects, no degree of invention would have been required on the part of the person skilled in the art to use doxepin as disclosed in D8 to treat patients experiencing transient insomnia.
>
> Accordingly, our preliminary view is that the differences between the inventive concepts of the claims on file and either D6 or D8, in view of D7, are not steps which would require any degree of invention from the person skilled in the art in view of their common general knowledge.
>
> Therefore, it is our preliminary view that the claims on file define subject-matter that would have been obvious to the person skilled in the art, as of the relevant date, having regard to either D6 or D8, in view of D7 and their common general knowledge, contrary to section 28.3 of the *Patent Act*.

[40] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that the claims on file define subject-matter that would have been obvious to the person skilled in the art, as of the relevant date, having regard to either D6 or D8, in view of D7 and their common general knowledge, contrary to section 28.3 of the *Patent Act*.

ARE CLAIMS 1, 5, 9, 11, 18 AND 22 INDEFINITE?

[41] In our view, claims 1, 5, 9, 11, 18 and 22 on file are indefinite.

Legal Background

[42] 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.

[43] 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.

Analysis of claims 1, 5, 9, 11, 18 and 22

[44] The Preliminary Review letter, on pages 17 to 18, explains that in our preliminary view claims 1, 5, 9, 11, 18 and 22 on file are indefinite:

> The Final Action, on page 6, indicates that claims 1, 5, 9, 11, 18 and 22 are indefinite because of a clarity defect:
>
> > Claims 1, 5, 9, 11, 18 and 22 are indefinite, such that they do not comply with subsection 27(4) of the *Patent Act*. In each of the above claims, the disorder to be treated is identified both in terms of a pathology that is "characterized" by certain symptoms and in terms of patients who have been "identified" to have disorders with certain symptoms. This results in a complex web of provisos that obscure what disorder is actually to be treated and what elements of said disorder are of significance.
>
> The Response to the Final Action does not contest or comment on these defects. Instead, the Response to the Final Action proposes amendments to the claims to remove the expressions that were identified as characterizing the disorder to be treated in terms of a pathology. The Summary of Reasons agrees that these proposed amendments would address the concerns raised in the Final Action and render the claim clear.
>
> Having reviewed claims 1, 5, 9, 11, 18 and 22, we agree that the clarity defects identified in the Final Action are present. Therefore, it is our preliminary view that claims 1, 5, 9, 11, 18 and 22 do not 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, 5, 9, 11, 18 and 22 do not comply with subsection 27(4) of the *Patent Act*.

THE PROPOSED CLAIMS DO NOT REMEDY THE DEFECTS

[46] As indicated above, with the Response to the Final Action the Applicant submitted proposed claims 1 to 29. According to page 2 of the Response to the Final Action,

claims 1, 5, 9, 11, 18 and 22 were amended to address the clarity defect.

[47] The Preliminary Review letter, on page 18, explains our preliminary view that proposed claims 1, 5, 9, 11, 18 and 22 would comply with subsection 27(4) of the *Patent Act* but that the proposed claims would not overcome the anticipation or obviousness defects:

> We agree that the subject-matter of proposed claims 1, 5, 9, 11, 18 and 22 would comply with subsection 27(4) of the *Patent Act*.
>
> However, given that proposed claims 1 to 29 are identical to claims 1 to 29 on file with the exception of the amendments to address the clarity issues in claims 1, 5, 9, 11, 18 and 22, it is our preliminary view that they share the same essential elements and inventive concepts that have already been identified in respect of claims 1 to 29 on file.
>
> Therefore, with regard to the anticipation defect identified above for claims 1 to 7, 9, 11, 13, 14, 16 to 24, 26, 28 and 29 on file, as there is no meaningful difference between the claims, our preliminary view is that proposed claims 1 to 7, 9, 11, 13, 14, 16 to 24, 26, 28 and 29 would not comply with paragraph 28.2(1)(a) of the *Patent Act* for the same reasons provided for claims 1 to 7, 9, 11, 13, 14, 16 to 24, 26, 28 and 29 on file.
>
> Likewise, with regard to the obviousness defect identified above for the claims 1 to 29 on file, as there is no meaningful difference between the claims, our preliminary view is that proposed claims 1 to 29 would not comply with section 28.3 of the *Patent Act* for the same reasons provided above for claims 1 to 29 on file.
>
> 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*.

[48] 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

[49] We have determined that claims 1 to 7, 9, 11, 13, 14, 16 to 24, 26, 28 and 29 are anticipated contrary to paragraph 28.2(1)(a) of the *Patent Act* and that claims 1 to 29 are obvious contrary to section 28.3 of the *Patent Act*.

[50] We have also determined that claims 1, 5, 9, 11, 18 and 22 are indefinite contrary to subsection 27(4) of the *Patent Act*.

[51] In our view, the proposed claims submitted with the Response to the Final Action would not overcome the anticipation or obviousness defects 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

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

- claims 1 to 7, 9, 11, 13, 14, 16 to 24, 26, 28 and 29 are anticipated contrary to paragraph 28.2(1)(a) of the *Patent Act*;
- claims 1 to 29 are obvious contrary to section 28.3 of the *Patent Act*; and
- claims 1, 5, 9, 11, 18 and 22 are indefinite contrary to subsection 27(4) of the *Patent Act*.

Christine Teixeira	Marcel Brisebois	Owen Terreau
Member	Member	Member

DECISION OF THE COMMISSIONER

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

- claims 1 to 7, 9, 11, 13, 14, 16 to 24, 26, 28 and 29 are anticipated contrary to paragraph 28.2(1)(a) of the *Patent Act*;
- claims 1 to 29 are obvious contrary to section 28.3 of the *Patent Act*; and
- claims 1, 5, 9, 11, 18 and 22 are indefinite contrary to subsection 27(4) of the *Patent Act*.

[54] 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.

Virginie Ethier
Assistant Commissioner of Patents

Dated at Gatineau, Quebec

this 30th day of December, 2022.