Citation: Currax Pharmaceuticals LLC, 2022 CACP 26

Commissioner's Decision #1633
Décision du commissaire nº 1633
Date: 2022-12-30

TOPIC: O00 Obviousness

SUJET: O00 Évidence

Application No. : 2,687,124

Demande nº 2 687 124

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,687,124 having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019, has consequently been reviewed in accordance with paragraph 199(3)(c) of the *Patent Rules* (SOR/2019-251). The recommendation of the Patent Appeal Board and the decision of the Commissioner are to refuse the application.

Agent for the Applicant:

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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,687,124, which is entitled “Low dose doxepin formulations, including buccal, sublingual and fastmelt formulations, and uses of the same to treat insomnia”. 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 199(3)(c) of the *Patent Rules*.

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

BACKGROUND

The Application

[3] The application was filed under the *Patent Cooperation Treaty* and has an effective filing date in Canada of May 18, 2007. It was laid open to public inspection on December 13, 2007.

[4] The rejected application relates to low dose oral doxepin formulations and their use to promote sleep. More particularly, the application discloses an orally disintegratable pharmaceutical composition comprising low dose doxepin to promote sleep onset by avoiding first-pass metabolism of the drug in the liver.

[5] The application has 58 claims on file that were received at the Patent Office on May 4, 2018.

Prosecution History

[6] On October 21, 2019, a Final Action was written under subsection 30(4) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 (the former *Patent Rules*). The Final Action states that the subject-matter of claims 1 to 58 on file at the time of the Final Action is obvious contrary to section 28.3 of the *Patent Act*. The Final Action also indicates that claim 56 is improperly dependent and therefore non-compliant with subsection 87(2) of the former *Patent Rules*.

[7] In the Response to the Final Action dated April 20, 2020, the Applicant argues that the claims of the present application are inventive over the cited prior art. In addition, the Response to the Final Action includes an amended claim set containing proposed claims 1 to 58 to address the improper claim dependency defect in claim 56.

[8] On December 8, 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 December 21, 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 March 19, 2021, 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 10, 2022, the Panel sent a Preliminary Review letter detailing our preliminary analysis and opinion 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 claim 56 on file is improperly dependent contrary to subsection 63(2) of the *Patent* Rules and that proposed claim 56 overcomes this defect. The Preliminary Review letter also provided the Applicant with an opportunity to make oral and/or written submissions.

[12] On November 18, 2022, the Applicant declined the opportunity for an oral hearing and on December 8, 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 obvious contrary to section 28.3 of the *Patent Act*; and
- whether claim 56 is improperly dependent contrary to subsection 63(2) of the *Patent Rules*.

[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 3, the Final Action identifies the person skilled in the art and the relevant common general knowledge:
>
> The skilled artisan in this case is assumed to be a medicinal chemist or pharmacologist familiar with the etiology and treatment of insomnia and the preparation of oral dosage forms. With respect to his understanding of insomnia, he would be aware that the term “insomnia” encompassed a variety of symptoms. In particular, he would be cognisant that one of the foremost symptoms of insomnia was difficulty falling asleep (see para. 2 of the instant application).
>
> Turning to aspects of oral formulations, the skilled artisan would be aware that ingestion of drugs can lead to high degrees of metabolism by the liver (*i.e.*, the effects of first-pass metabolism as mentioned in **D12** and **D14**). More particularly, he would be aware that doxepin was one particular drug that was particularly subject to first-pass metabolism upon ingestion (see **D10**). Finally, as indicated in **D12**, he would be aware that first-pass metabolic effects can be avoided by judicious selection of dosage route (such as the oral mucosa).
>
> 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 preliminary review.
>
> With regard to the common general knowledge of the person skilled in the art, the Final Action discusses the symptoms of insomnia referred to in para 2 of the description, as well as the influence of first-pass metabolism on the bioavailability of a drug as taught in prior art documents D10, D12 and D14:
>
> D10: Ziegler et al., “Doxepin Kinetics” (1978) 23(5) Clin. Pharmacol. Ther. 573 to 579.
>
> D12: Hardman and Limbird, eds. Goodman & Gilman’s The Pharmacological Basis of Therapeutics, Ninth Edition (New York: McGraw-Hill, 1996), pages 3 to 27.

D14: Gennaro, ed. Remington: The Science and Practice of Pharmacy, 20th Edition (Baltimore: Lippincott Williams & Wilkins, 2000), pages 1098 to 1155.

Having reviewed the instant specification, as well as D10, D12 and D14, we are of the preliminary view that the above characterization of the common general knowledge is reasonable. D10 is a journal article demonstrating the kinetics of doxepin following oral administration. In our preliminary view, this information would have formed part of the common general knowledge of the person skilled in the art defined above who is familiar with the drug doxepin and its use for treating sleep disorders, such as insomnia (see Background of the Invention at para 0002 of the description).

This view is also consistent with the teachings of D12, a textbook which specifically discusses the hepatic metabolism of tricyclic antidepressants (page 434) and discloses the kinetics of doxepin following oral administration (Table 17-4). Likewise, D14 is a textbook which also discloses that the class of drugs known as tricyclic antidepressants have rapid clearances as a result of hepatic metabolism (page 1150) and that doxepin hydrochloride is a member of this class (page 1438).

In addition, both D12 and D14 discuss how the route of administration can affect the bioavailability of a particular drug. For example, oral ingestion can result in low bioavailability if the drug is subject to first-pass metabolism through the liver, however sublingual administration results in rapid absorption through the oral mucosa and avoids this effect (see for example D12 at page 7). We consider that these basic principles of pharmacokinetics were generally known and accepted without question by the bulk of those who are engaged in the particular arts of medicinal chemistry and/or pharmacology 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.

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

- Low doses of doxepin can be used to treat sleep disorders, such as insomnia (para 0002);

- Doxepin is marketed under the commercial name SINEQUAN™ and in generic form, and can be obtained in the United States generally from pharmacies in capsule form in amounts of 10, 25, 50, 75, 100 and 150 mg dosage. The capsule formulations contain Doxepin HCl with cornstarch and magnesium stearate/sodium lauryl sulfate (para 0082);

- Acceptable excipients for therapeutic use are well known in the pharmaceutical art, and are described, for example in Handbook of Pharmaceutical Excipients, 5th edition (Raymond C Rowe, Paul J Sheskey

and Siân C Owen, eds. 2005) and Remington: The Science and Practice of Pharmacy, 21st edition (Lippincott Williams & Wilkins, 2005) (para 0149);

- Additional information related to formulations, excipients and carriers well known to pharmaceutical chemists such as found in Baldrick P. "Pharmaceutical excipient development: the need for preclinical guidance." Regul. Toxicol. Pharmacol. 32(2):210- to 2188 (2000), Charman WN "Lipids, lipophilic drugs, and oral drug delivery-some emerging concepts." J Pharm Sci. 89(8): 967 to 978 (2000) and the citations therein (para 0153); and

- The amounts of excipients will be determined by drug dosage and dosage form size and favorable quick dissolve delivery systems are known (paras 0156 to 0160).

[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 58 claims on file. Claims 1, 20, 51 and 55 are independent claims. The Preliminary Review letter, on pages 5 to 6, expresses the preliminary view that claim 1 is representative of the independent claims. Independent claim 1 reads as follows:

> 1. An orally disintegratable pharmaceutical composition for use in reducing the time to sleep onset, the composition comprising from about 0.1 to about 9 mg of doxepin, or a pharmaceutically acceptable salt thereof, or a doxepin-related compound which is N-desmethyldoxepin, hydroxydoxepin, hydroxyl-N-doxepin, doxepin N-oxide, N-acetyl-N-doxepin, N-desmethyl-N-formyldoxepin, quaternary ammonium-linked glucuronide of doxepin, 2-O-glucuronyldoxepin, didoxepin, 3-O-glucuronyldoxepin, or N-acetyldidoxepin, or a pharmaceutically acceptable salt of the doxepin-related compound, and from about 15% to about 99.9% w/w of an orally disintegrating excipient**.**

[21] Independent claim 20 is directed to the same use as claim 1 but the pharmaceutical composition comprises doxepin and at least one excipient for oral disintegration. Similarly, independent claim 51 is also directed to the same use but claims an orally disintegratable pharmaceutical unit dosage form comprising 1 mg, 3 mg, or 6 mg of doxepin and at least one excipient. Independent claim 55 defines a specific pharmaceutical composition comprising doxepin, an orally disintegrating

excipient, mannitol and a disintegrant for use in reducing the time to sleep onset.

[22] The dependent claims 2 to 19, 21 to 50, 52 to 54 and 56 to 58 define further limitations to the composition (claims 2 to 19, 21 to 50 and 56 to 58) and the unit dosage form (claims 52 to 54).

[23] In the absence of submissions from the Applicant, we adopt the above identification of claim 1 as being representative of the independent claims. Likewise, we adopt the above characterization of dependent claims 2 to 19, 21 to 50, 52 to 54 and 56 to 58 as providing further limitations with regard to the composition and the unit dosage form.

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 58 in the context of the specification as a whole and in view of their common general knowledge would understand that there is no use of language in the claims indicating that any of the elements are optional, preferred or were otherwise intended to be non-essential with the exception of claim 51 which defines an optional coating. There is no indication on the record before us that any other claim elements are non-essential. Therefore, our preliminary view is that the person skilled in the art would consider the optional coating in claim 51 to be non-essential and all other 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 OBVIOUS?

[26] 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

[27] 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.

[28] 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?

[29] 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. For a finding that an alleged invention is "obvious to try", it must be more or less self-evident to try to obtain the alleged invention in advance of routine testing. The mere possibility that something might work is not sufficient.

[30] The Court in Sanofi listed the following non-exhaustive factors to be considered in an “obvious to try” analysis [defined terms added]:

> 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? [Self-Evident Factor]
>
> 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? [Extent and Effort Factor]
>
> Is there a motive provided in the prior art to find the solution the patent addresses? [Motive Factor]

Analysis of the Claims

[31] The Preliminary Review letter, on pages 8 to 13, 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 pages 3 to 4, the Final Action identifies a common inventive concept that links the claims: “the inventive concept underlying the claims is the provision of orally disintegrable low dose formulations of doxepin for use as improved treatments of sleep onset insomnia. Such improvements include avoiding undesired first-pass metabolism of doxepin.”
>
> 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 page 2 submits that in addition to being directed to an orally disintegratable pharmaceutical composition comprising doxepin, for use in reducing the time to sleep onset, each of the independent claims further defines specific

features including at least the content of the active ingredient and/or the nature of the excipient(s).

As mentioned above, our preliminary view is that, with the exception of an optional coating in claim 51, 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 consider 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

On pages 5 to 6, 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)
D13:	Kavey, N.B.	US 5,643, 897	1 July 1997 (01-07-1997)

While we agree that D1, D2 and D13 are applicable art, we have retrieved an additional prior art document that we consider to be pertinent to the assessment of obviousness of the claims on file and, in accordance with subsection 86(9) of the *Patent Rules*, now give the Applicant notice of this document:

D15: 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

D15 discloses the results of a Phase 3 study of the safety and efficacy of 3 mg and 6 mg oral tablet formulations of doxepin in adults with chronic primary insomnia as defined by DSM IV. A statistically significant reduction in latency to persistent sleep was observed for both doses. Compared to latency of persistent sleep of 45 minutes for placebo, both 3 mg and 6 mg of doxepin shorten the time to sleep onset to 27 minutes.

In our preliminary view the main difference between the inventive concept of the claims and D15 lies in specifying that the oral tablet formulation is disintegratable.

Additional differences over the cited prior art include the specific nature of the excipient(s).

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?

First, we note that the subject-matter of the present claims relates to the medical and pharmaceutical fields which are "areas of endeavor where advances are often won by experimentation" (Sanofi at para 68) and we therefore are of the preliminary view that an "obvious to try" analysis is appropriate in the instant case.

Self-Evident Factor

This factor considers whether it would have been more or less self-evident that what is being tried ought to work in advance of routine testing. The mere possibility that something might work is not sufficient but an amount of uncertainty is allowed in the "obvious to try" analysis. In *Les Laboratoires Servier v Apotex Inc*, 2019 FC 616 at para 269, Justice Roy stated the following in that regard:

> There is no need to have certainty that the "try" in the obvious to try will be successful. It is rather that is more or less self-evident that the "try" ought to work in view of the common general knowledge and the prior art; a mere possibility will not suffice but an amount of uncertainty is allowed in the obvious-to-try analysis. It would not be obvious to try if certainty was required.

In view of the foregoing and within the context of the claimed subject-matter, we consider that the relevant question is whether it would have been more or less self-evident to the person skilled in the art, based on the disclosure of D15 and the relevant common general knowledge, that an oral disintegrating formulation of doxepin ought to be effective in reducing the time to sleep onset.

In this regard, it has already been noted that D15 discloses that both 3 mg and 6 mg oral tablet formulations of doxepin produced statistically significant reductions in latency to persistent sleep at the initial treatment period in patients with primary insomnia. This means that patients who were treated with an oral formulation of doxepin were able to fall asleep faster than patients who were given placebo. Given the observed reduction in time to sleep onset at the initial treatment period in D15, it is our preliminary view that the person skilled in the art, aware of the influence of first-pass metabolism on the bioavailability of doxepin associated with standard capsules, would consider that an oral tablet formulation of doxepin capable of avoiding at least in part the effects of first-pass metabolism through the liver was used in order to significantly shorten the time to sleep onset from 45 minutes with the placebo to 27 minutes with doxepin.

Further, based on the disclosure in D15 of an oral formulation of doxepin, in dosages encompassed by the claims, that successfully reduces the time to sleep onset at the initial treatment period, it is our preliminary view that a skilled medicinal

chemist or pharmacologist would only have a finite number of identified predictable solutions for the formulation.

Moreover, the person skilled in the art would know that oral transmucosal absorption of the formulation would be required to ensure that first-pass metabolism of doxepin is avoided and usefulness to treat insomnia patients having difficulty falling asleep. In our preliminary view, oral transmucosal absorption is readily determined through routine tests for a person skilled in the art of medicinal chemistry and pharmacology with their knowledge of formulations, excipients and carriers.

In light of the above assessment, it is our preliminary view that it would have been more or less self-evident to the person skilled in the art, based on the disclosure of D15 and the relevant common general knowledge, that an oral disintegrating formulation of doxepin ought to be effective in reducing the time to sleep onset.

Although we consider that the above assessment is largely determinative of the "obvious to try" inquiry in this case, we make the following observations with regard to the other non-exhaustive factors to be considered in an "obvious to try" analysis.

Extent and Effort Factor

In regard to the Extent and Effort Factor, the Federal Court of Appeal has referred to the actual course of conduct factor as "an elaboration of the second factor": *Bristol-Myers Squibb Canada Co v Teva Canada Ltd*, 2017 FCA 76 at para 44. We will thus consider the Applicant's course of conduct as part of the "extent, nature and amount of effort required to achieve the invention". In that regard, Example 3, found on pages 49 to 50 of the description, discloses several formulations comprising doxepin with various commercially available quick dissolving excipients.

There is no evidence that these formulations are not routine or that an arduous investigation of excipients used was required. Moreover, the person skilled in the art is knowledgeable in excipients for therapeutic use and would have been directed to the preparation of useful formulations for a given mode of administration as defined in, for example, Handbook of Pharmaceutical Excipients, 5th edition (Raymond C Rowe, Paul J Sheskey and Siân C Owen, eds. 2005) and Remington: The Science and Practice of Pharmacy, 21st edition (Lippincott Williams & Wilkins, 2005), two references described at para 0149 of the description, as well as, Baldrick P. "Pharmaceutical excipient development: the need for preclinical guidance." Regul. Toxicol. Pharmacol. 32(2):210- to 2188 (2000) and Charman WN "Lipids, lipophilic drugs, and oral drug delivery-some emerging concepts." J Pharm Sci. 89(8): 967 to 978 (2000) and the citations therein, two references found at para 0153 of the description.

We further note that there is no evidence that any of these formulations were tested for their ability to reduce time to sleep onset, but instead are proposed for that purpose on the expectation that they would be effective. This is consistent with the

> Applicant's assertions, as indicated at page 4 of the response dated May 4, 2018, "Applicant asserts that the transmucosal absorption of doxepin had been identified as possible by the art at the time of invention."
>
> Therefore, in view of the foregoing, it is our preliminary view that the determination of the specific formulations as recited in the claims required nothing more than routine experimentation to achieve.
>
> *Motive Factor*
>
> Regarding the Motive Factor, which includes considerations provided in the prior art to find the solution the patent addresses, we offer the following views.
>
> As indicated above, D15 discloses an oral formulation of doxepin, in dosages encompassed by the claims, that successfully reduces the time to sleep onset at the initial treatment period. Although the specific formulation is not disclosed, in our preliminary view the person skilled in the art would know that these results could be achieved using an oral transmucosal absorbing formulation. Therefore, the next logical step would have been the development of a dosage formulated using orally disintegrating excipients to ensure that first-pass metabolism of doxepin is avoided and usefulness to treat insomnia patients having difficulty falling asleep.
>
> Regarding the specific nature of the excipient(s) defined in some of the claims, we do not consider that any degree of invention would have been required from the person skilled in the art in respect of specifying the amounts or type of excipients, weight of the composition or particle size of doxepin or filler, in view of their common general knowledge. In our preliminary opinion, determining specific therapeutic formulations would be based on their common general knowledge of sleep onset insomnia, efficacy of doxepin in treating sleep onset insomnia, absorption, distribution and elimination of doxepin and excipients for therapeutic use.
>
> In light of the above considerations, it is our preliminary view is that the differences between the inventive concepts of the claims on file and D15 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 D15 in view of their common general knowledge, contrary to section 28.3 of the *Patent Act*.

[32] 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 D15 in view of their common general knowledge, contrary to section 28.3

of the *Patent Act*.

IS CLAIM 56 IMPROPERLY DEPENDENT?

[33] In our view, claim 56 is improperly dependent.

Legal Background

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

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

Analysis of claim 56

[35] The Preliminary Review letter, on page 13, explains that in our preliminary view claim 56 is improperly dependent:

> The Final Action, on page 7, identifies the following claim dependency defect:
>
> > Claim 56 does not comply with subsection 87(2) of the *Patent Rules*, as it does not depend on a preceding claim or claims. Said claim refers to non-existent claim 59.
>
> Having reviewed claim 56, we preliminarily agree that it is defective for the same reasons outlined in the Final Action. Therefore, it is our preliminary view that claim 56 does not comply with subsection 63(2) of the *Patent Rules*.

[36] In the absence of submissions from the Applicant, we adopt the foregoing reasoning and conclude that claim 56 is improperly dependent and does not comply with subsection 63(2) of the *Patent Rules*.

THE PROPOSED CLAIMS DO NOT REMEDY THE DEFECTS

[37] As indicated above, with the Response to the Final Action the Applicant submitted proposed claims 1 to 58. According to page 1 of the Response to the Final Action, claim 56 was amended to address the improper dependency defect.

[38] The Preliminary Review letter, on page 14, explains our preliminary view that

proposed claim 56 would comply with subsection 63(2) of the *Patent* Rules but that the proposed claims would not overcome the obviousness defect:

> We agree that the subject-matter of proposed claim 56 would comply with subsection 63(2) of the *Patent Rules*.
>
> However, given that proposed claims 1 to 58 are identical to claims 1 to 58 on file with the exception of the amendment to address the improper dependency in claim 56, 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 58 on file.
>
> Therefore, with regard to the obviousness defect identified above for the claims 1 to 58 on file, as there is no meaningful difference between the claims, our preliminary view is that proposed claims 1 to 58 would not comply with section 28.3 of the *Patent Act* for the same reasons provided above for claims 1 to 58 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*.

[39] 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

[40] We have determined that claims 1 to 58 are obvious contrary to section 28.3 of the *Patent Act*.

[41] We have also determined that claim 56 is improperly dependent contrary to subsection 63(2) of the *Patent Rules*.

[42] In our view, the proposed claims submitted with the Response to the Final Action would not overcome the obviousness defect and are therefore not considered a necessary amendment for compliance with the *Patent Act* and *Patent Rules* as required by subsection 86(11) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

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

- claims 1 to 58 are obvious contrary to section 28.3 of the *Patent Act*; and
- claim 56 is improperly dependent contrary to subsection 63(2) of the *Patent Rules*.

Christine Teixeira	Marcel Brisebois	Owen Terreau
Member	Member	Member

DECISION OF THE COMMISSIONER

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

- claims 1 to 58 are obvious contrary to section 28.3 of the *Patent Act*; and
- claim 56 is improperly dependent contrary to subsection 63(2) of the *Patent Rules*.

[45] 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.