Citation: Janssen Biotech, Inc. (Re), 2025 CACP 13
Commissioner's Decision #1694
Décision du commissaire nº 1694
Date: 2025-10-14

TOPIC:	F01	Novelty—Anticipation
	O00	Obviousness

SUJET :	F01	Nouveauté—Antériorité
	O00	Évidence

Application No. 3127807
Demande n^{o} 3127807

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

The Commissioner refuses patent application number 3127807 based on the Patent Appeal Board's recommendation. The Board reviewed the application under paragraph 86(7)(c) of the *Patent Rules*, SOR/2019-251 ("*Patent Rules*"), following the application's rejection under subsection 199(1) of the *Patent Rules*.

Agent for the Applicant:

Norton Rose Fulbright Canada LLP
2500 —1 Place Ville Marie
Montréal, Quebec
Canada, H3B 1R1

INTRODUCTION

[1] This recommendation concerns the review of rejected patent application number 3127807, which is entitled “Materials and methods for treating juvenile idiopathic arthritis” and is owned by Janssen Biotech, Inc. The Patent Appeal Board (“the Board”) reviewed the rejected application pursuant to paragraph 86(7)(c) of the *Patent Rules*, SOR/2019-251 (“*Patent Rules*”). As explained below, we recommend that the Commissioner of Patents refuse the application.

BACKGROUND

The application

[2] Canadian patent application 3127807 was filed under the provisions of the *Patent Cooperation Treaty* and has an effective filing date in Canada of April 26, 2021. It was laid open to public inspection on October 27, 2021.

[3] The claimed invention relates to golimumab and its use in the treatment of juvenile idiopathic arthritis (JIA). Golimumab is a fully human monoclonal antibody, comprising a heavy chain having an amino acid sequence of SEQ ID NO: 36 and a light chain having an amino acid sequence of SEQ ID NO: 37, that inhibits tumor necrosis factor alpha (TNFα) activity. TNFα is a key inflammatory mediator, with elevated levels implicated in the pathophysiology of the disease. Clinical studies of anti-TNFα agents have shown that blocking TNFα activity can prevent the harmful effects associated with excessive TNFα.

Prosecution history

[4] On January 31, 2024, a Final Action was issued pursuant to subsection 86(5) of the *Patent Rules*. The Final Action indicated that claims 1 to 32, dated July 13, 2023 (“claims on file”), are anticipated and that the pages of the specification are not numbered consecutively. The Response to the

Final Action disagreed with the assessment in the Final Action and submitted further arguments in favour of the patentability of the claims on file. The Applicant also submitted proposed claims 1 to 32 (“proposed claims”) with the Response to the Final Action. The Summary of Reasons maintained that the claims on file are anticipated. The Summary of Reasons also indicated that the proposed claims would not overcome the anticipation or page numbering defects. The rejected application was forwarded to the Patent Appeal Board for review on behalf of the Commissioner.

[5] A Panel of the Patent Appeal Board, comprised of the undersigned, was formed to review the application and make a recommendation to the Commissioner as to its disposition. We sent a Preliminary Review letter that detailed our preliminary analysis and opinion that the subject-matter of claims 1 to 32 on file was not anticipated and that the pages of the specification were not numbered consecutively. We further noted that, in our preliminary view, the claims on file, as well as the proposed claims were obvious and notified the Applicant of this defect under subsection 86(9) of the *Patent Rules*. Finally, the Preliminary Review letter provided the Applicant with an opportunity to make oral and/or written submissions.

[6] On June 18, 2025, the Applicant confirmed that a hearing was not required and indicated that written submissions would be provided.

[7] The Response to the Preliminary Review letter disagreed with our preliminary assessment of obviousness, without specifying whether it related to the claims on file or the proposed claims. In addition, the Response to the Preliminary Review letter submitted further arguments in support of the patentability of the claims, which we understood to apply to both sets of claims.

THE ISSUES

[8] In view of the above, we have considered the following issues in this review:

- whether claims 1 to 32 on file are anticipated contrary to paragraph 28.2(1)(a) of the *Patent Act*, RSC 1985, c P-4 ("*Patent Act*");
- whether claims 1 to 32 on file are obvious contrary to section 28.3 of the *Patent Act*; and
- whether the pages of the specification are not numbered consecutively contrary to subsection 50(1) of the *Patent Rules*.

[9] In addition, we have considered whether the proposed claims submitted with the Response to the Final Action would make the application allowable and be a necessary amendment under subsection 86(11) of the *Patent Rules*.

PURPOSIVE CONSTRUCTION

Legal principles

[10] Purposive construction is antecedent to any consideration of validity (*Free World Trust v Électro Santé Inc*, 2000 SCC 66 at para 19 [*Free World Trust*]; and *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 43 [*Whirlpool*]). Purposive construction is performed from the point of view of the person skilled in the art in light of the relevant common general knowledge, considering the whole of the disclosure including the specification and drawings (*Free World Trust* at paras 31, 44, 51 to 52 and 55 to 60; *Whirlpool* at paras 45 to 49 and 52 to 53; and Patent Notice: Patentable Subject-Matter under the *Patent Act* (CIPO, November 2020) [*PN2020–04*] at Purposive Construction).

[11] Regarding the person skilled in the art, several court decisions have provided additional context for their identification. In Whirlpool at para 53, the Supreme Court of Canada explained that, a patent specification is addressed to “skilled individuals sufficiently versed in the art to which the patent relates to enable them on a technical level to appreciate the nature and description of the invention”. Moreover, “in the case of patents of a highly technical and scientific nature, that person may be someone possessing a high degree of expert scientific knowledge and skill in the particular branch of science to which the patent relates” (Consolboard Inc v MacMillan Bloedel (Sask) Ltd, [1981] 1 SCR 504 at page 525).

[12] In addition, the person skilled in the art can represent a composite of scientists—highly skilled and trained persons who conduct scientific research to advance knowledge in an area of interest—and researchers (*Bayer Aktiengesellschaft v Apotex Inc* [1995] 60 CPR (3d) 58 at page 79):

> The notional skilled technician can be a composite of scientists, researchers and technicians bringing their combined expertise to bear on the problem at hand: “This is particularly true where the invention relates to a science or art that transcends several scientific disciplines.” (*Per* Wetston J. in *Mobil Oil Corp. v. Hercules Canada Inc.* (unreported, September 21, 1994, F.C.T.D., at p. 5 [now reported 57 C.P.R. (3d) 488 at p. 494, 82 F.T.R. 211].)

[13] Regarding the identification of the common general knowledge, it is well established that the common general knowledge is limited to knowledge which is generally known at the relevant time by persons skilled in the field of art or science to which a patent relates (*Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at para 37 [*Sanofi*]; and *Free World Trust* at para 31). Accordingly, the common general knowledge is with respect to the subset of patents, journal articles and technical information which is generally acknowledged by persons skilled in the art as forming part of the common general knowledge in the field to which a patent relates.

[14] Established reference works (such as textbooks, review articles, handbooks, etc.) or demonstrated commonality of certain knowledge in a number of disclosures in the field are relevant to the identification of the common general knowledge (*Manual of Patent Office Practice* (CIPO) [*MOPOP*] at §12.02.02c, revised October 2019).

[15] Furthermore, information in a specification may also be evidence of the common general knowledge as it could be reasonable to consider general or broadly worded assertions of conventional practice or knowledge as common general knowledge (*Corning Cable Systems LLC v Canada (Attorney General)*, 2019 FC 1065 at para 56; and *Newco Tank Corp v Canada (Attorney General)*, 2015 FCA 47 at para 10).

[16] 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] As indicated under Purposive Construction in *PN2020–04*, “all elements set out in a claim are presumed essential, unless it is established otherwise or is contrary to the language used in the claim” (see also *Free World Trust* at para 57, *Distrimedic Inc v Dispill Inc*, 2013 FC 1043 at para 201).

[18] Since both interpretation of term meaning and identification of the essential elements are done in light of the relevant common general knowledge, the person skilled in the art must first be identified to determine their common general knowledge (*MOPOP* at §12.02.01, revised June 2015).

Analysis

[19] The Preliminary Review letter, on pages 6 to 7, stated the following with regard to the identity of the person skilled in the art and their expected common general knowledge:

> The person skilled in the art and the relevant common general knowledge
>
> Neither the Final Action nor the Response to the Final Action identifies the person skilled in the art and the relevant common general knowledge.
>
> Having reviewed the specification as a whole, we consider that the person skilled in the art to whom the application is directed is a clinician specializing in pediatric rheumatology with a strong foundation in inflammatory diseases such as JIA. This is consistent with page 1 of the present description which identifies the invention as relating to “compositions and methods utilizing anti-TNF antibodies . . . for use in the treatment of juvenile idiopathic arthritis (JIA), and in particular for polyarticular juvenile idiopathic arthritis (pJIA).”
>
> Regarding the relevant common general knowledge, based on certain points in the description, it is our preliminary view that the common general knowledge of the person skilled in the art at the publication date includes the following:
>
> - Golimumab is a fully human monoclonal antibody which binds to TNFα with high affinity and specificity and neutralizes TNFα bioactivity. TNFα is a key inflammatory mediator implicated in the pathophysiology of diseases such as rheumatoid arthritis and JIA (pages 117, 133 and 134 of the description);

- Simponi™ is the commercial name for golimumab and is available for subcutaneous or intravenous administration (pages 3 and 117 of the description);

- JIA is a diagnosis of exclusion that encompasses all forms of arthritis that begin before the age of 16 years, persist for more than six weeks and are of unknown cause (page 134 of the description); and

- Approved biologic therapies for the treatment of polyarticular JIA include the TNFα inhibitors etanercept, adalimumab, abatacept, and tocilizumab (page 135 of the description).

In view of the above, it is our preliminary view that the common general knowledge also includes:

- Familiarity with interpreting clinical trial data, including efficacy endpoints such as the JIA American College of Rheumatology (ACR) 30, 50, 70 response criteria—which measure percentage improvement in six core response variables—and the Juvenile Arthritis Disease Activity Scores (JADAS), a separate composite measure used to assess disease activity in 71, 27 or 10 joints; and

- Knowledge of the pharmacokinetics and pharmacodynamics of monoclonal antibodies, as well as the safety and efficacy considerations for treating pediatric populations with biologics.

[20] The Response to the Preliminary Review letter did not contest or comment on these characterizations of the person skilled in the art and the relevant common general knowledge. Accordingly, we adopt the above characterizations for our final review.

The claims on file

[21] There are 32 claims on file. Independent claims 1, 5, 9 and 13 are directed to golimumab for use in the treatment of JIA and independent claims 17, 21, 25 and 29 are directed to the use of golimumab in the preparation of a medicament for the treatment of JIA. Claims 1 and 17 are illustrative and read as follows:

1. An anti-TNF antibody comprising a heavy chain (HC) comprising an amino acid sequence of SEQ ID NO: 36 and a light chain (LC) comprising an amino acid sequence of SEQ ID NO: 37, for use in the treatment of juvenile idiopathic arthritis (JIA) to achieve a sustained response of JIA American College of Rheumatology (JIA ACR) 30, JIA ACR 50, or JIA ACR 70 after 52 weeks of treatment, and wherein the anti-TNF antibody is for intravenous (IV) administration at a dose of 80 mg/m^2 at weeks 0, 4, and then 8 weeks thereafter for at least 52 weeks.

17. Use of an anti-TNF antibody comprising a heavy chain (HC) comprising an amino acid sequence of SEQ ID NO: 36 and a light chain (LC) comprising an amino acid sequence of SEQ ID NO: 37, in the preparation of a medicament for the treatment of juvenile idiopathic arthritis (JIA) to achieve a sustained response of JIA American College of Rheumatology (JIA ACR) 30, JIA ACR 50, or JIA ACR 70 after 52 weeks of treatment, and wherein the anti-TNF antibody is for intravenous (IV) administration at a dose of 80 mg/m^2 at weeks 0, 4, and then 8 weeks thereafter for at least 52 weeks.

[22] Independent claims 5 and 21 describe the treatment of JIA to achieve a sustained response to the JADAS counting 71 joints.

[23] Independent claims 9 and 25 describe the treatment of JIA to achieve a sustained response of JIA ACR inactive disease.

[24] Independent claims 13 and 29 describe the treatment of JIA to achieve a sustained response of JIA ACR clinical remission.

[25] The dependent claims 2 to 4, 6 to 8, 10 to 12, 14 to 16, 18 to 20, 22 to 24, 26 to 28 and 30 to 32 introduce features such as specifying: the age of the patient (claims 2, 6, 10, 14, 18, 22, 26 and 30), that the JIA is polyarticular (claims 3, 7, 11, 15, 19, 23, 27 and 31) and the co-administration of methotrexate (claims 4, 8, 12, 16, 20, 24, 28 and 32).

Terms requiring clarification

[26] As indicated above, purposive construction is performed from the point of view of the person skilled in the art in light of their relevant common general knowledge and includes interpreting the meaning of the terms of a claim.

[27] In our view, as was presented in the Preliminary Review letter, there is no indication in the prosecution record of any issues with respect to the claim language, for example, the meaning of terms or claim ambiguity. The claims on file do not appear to include any terms that would be unfamiliar to the person skilled in the art in light of their relevant common general knowledge. In our preliminary view the person skilled in the art would readily understand the meaning and scope of all terms defined in the claims on file.

[28] The Response to the Preliminary Review letter did not address these characterizations of the claims on file. Accordingly, we adopt the above views for our review.

Essential elements

[29] As stated above, 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.

[30] The Preliminary Review letter, on pages 8 to 9, stated the following with regard to the elements in the claims that the person skilled in the art would consider to be essential:

> With the above considerations in mind, our preliminary view is that the person skilled in the art reading claims 1 to 32 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 any of the claims indicating that any of the elements are optional, preferred or were otherwise intended as being non-essential. Although claims 1 and 17 include alternative embodiments, it is our preliminary view that the person skilled in the art would understand that each alternative or combination of the alternatives, when chosen, is an essential feature of the claims. Therefore, our preliminary view is that the person skilled in the art would consider all of the elements in the claims to be essential.

[31] The Response to the Preliminary Review letter made no submissions on the identification of the essential elements of the claims on file. Accordingly, we adopt the above identification of all the claim elements as essential in this review.

CLAIMS 1 TO 32 ARE NOT ANTICIPATED

[32] In our view, claims 1 to 32 on file define subject-matter that was not disclosed before the claim date.

Legal principles

[33] 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;
>
> ….

[34] In *Sanofi*, the Supreme Court of Canada clarified 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.

[35] 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.

[36] 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” (Sanofi at para 25, citing Synthon).

[37] 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 but inventive steps are not permitted (*Sanofi* at paras 26 to 27, 33 and 37).

[38] With regard to implicit or inherent features, in the context of anticipation by reverse infringement, *MOPOP* at §18.01.04, revised October 2019, states:

> Where features implicit or inherent in a previously disclosed invention are being considered when assessing anticipation, it is important to recognise that such features do not create a new invention if a person using the previously disclosed invention would already have achieved the benefits arising from the presence of the implicit or inherent features. . . . Performing the earlier invention would provide the benefits arising from the implicit or inherent features; under the principle of anticipation by reverse infringement . . . the earlier disclosure would be anticipatory.

Analysis

[39] The Preliminary Review letter, on page 11, identified the prior art document that was cited in the Final Action:

D2: Janssen Research & Development, “A study to evaluate the pharmacokinetics, efficacy and safety of intravenous golimumab in pediatric patients with active polyarticular course juvenile idiopathic arthritis despite methotrexate therapy (GO-VIVA)”, ClinicalTrials.gov, NIH Clinical Trials NCT02277444, October 27, 2014.

[40] As we noted in the Preliminary Review letter, the Final Action referred to a study record version of the clinical trial dated October 29, 2014, however there is no version with this date. Instead, we find that the version dated October 27, 2014, as indicated above, is relevant.

[41] The Preliminary Review letter, on pages 11 to 14, expressed our preliminary view that claims 1 to 32 are not anticipated by D2:

> The Final Action, on pages 2 to 3, asserts that D2 discloses a clinical trial which inherently anticipates the subject-matter of claims 1 to 32. Specifically, D2 describes the same method of treatment of JIA in the same pediatric patient population, using the same anti-TNFα antibody (golimumab) and the same dosage regimes as the claimed invention. While the claims specify particular desired outcomes that are not explicitly disclosed in D2, the Final Action takes the position that these outcomes are inherent to the practice of the invention and cannot confer novelty.
>
> The Response to the Final Action, on pages 2 to 3, disputes that the claims are anticipated. The Applicant contends that the novelty of the invention lies in the surprising, long-lasting clinical effectiveness of intravenous administration of golimumab in pediatric patients with JIA, which is not disclosed in D2. In this regard, the Applicant cites *Abbott Laboratories v Canada (Minister of Health)*], 2006 FCA 187 [*Abbott FCA*], to support the view that, “for a feature to be ‘inherently’ disclosed, this feature must necessarily be present in the disclosure.” The applicant also argues that *Abbott FCA* equates inherency with anticipation and contends that practising D2 would not infringe the present claims under the disclosure requirement of *Sanofi*. Furthermore, the applicant argues that D2 does not “plant a flag” at the precise point later claimed by the applicant, as required for anticipation.
>
> Prior disclosure
>
> Having reviewed the study details disclosed in D2, and applying the framework of anticipation by reverse infringement, we agree with the assessment in the Final Action that D2 teaches the same treatment as the claimed invention. D2 describes administering intravenous

golimumab, at a dose of 80 mg/m^2 at weeks 0, 4 and every 8 weeks through week 244, along with methotrexate at a weekly dose of 10 to 30 mg/m^2 through week 28, to pediatric patients, aged 2 years to 18 years and with active pJIA in order to determine the pharmacokinetics, efficacy and safety of the treatment protocol.

We also agree that D2 does not explicitly disclose the claimed clinical outcomes. However, we do not agree that these outcomes are necessarily or inevitably the result of performing the protocol described in D2. On this point, we agree with the Response to the Final Action that "a person practicing D2 would not infringe the present claims under the first arm of *Sanofi*"—D2 does not satisfy the prior disclosure requirement.

Although *Abbott FCA*, at para 24, confirms that disclosure may be made without any recognition of what is present or what is happening, as noted in *Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research*, 2020 FCA 30, paras 71 to 72, the relevant inquiry is whether the essential elements of each claim are disclosed, and each claim should be considered separately (see also *Biogen Canada Inc v Taro Pharmaceuticals Inc*, 2020 FC 621, paras 131 to 135; and *Takeda Canada Inc v Apotex Inc*, 2024 FC 106, paras 155 and 172 to 177). As indicated in *Sanofi* at para 25, to meet this requirement "there is no room for trial and error or experimentation by the skilled person. He is simply reading the prior patent for the purposes of understanding it".

In the present case, the relevant question is whether the claimed clinical outcomes would inevitably result from carrying out the treatment described in D2. In our preliminary view, a person skilled in the art following the teachings of D2 would not inevitably achieve the claimed outcomes. Although the title of D2 suggests that efficacy and safety of golimumab in pediatric patients with active pJIA are to be evaluated, the study description identifies its primary outcome

measures as serum trough concentration and Bayesian area under the curve at steady state—i.e., pharmacokinetic parameters. Further, D2 does not set out a study protocol or describe any testing that was in progress or expected results regarding the efficacy of the proposed treatment regimen. For example, there is no indication that efficacy should be assessed using JIA ACR30/50/70 response criteria or JADAS scores across 71 joints, as required by the claims.

In the absence of any express or implied reference to those specific efficacy endpoints, we do not consider the claimed clinical outcomes to be a necessary result of following D2. Measuring pharmacokinetics alone does not inherently disclose those outcomes. Accordingly, it is our preliminary view that D2 does not disclose all the essential elements of the claims, either explicitly, implicitly or inherently.

Enablement

Although enablement is not sufficient on its own for anticipation, we have also considered whether the person skilled in the art, in light of the common general knowledge, would be able to perform the claimed invention based on the teachings of D2. As described above, D2 provides a detailed phase III clinical trial protocol involving intravenous administration of golimumab in combination with methotrexate to pediatric patients with pJIA. In our preliminary view, the person skilled in the art—a clinician specializing in pediatric rheumatology with a strong foundation in inflammatory diseases such as JIA—would be able to perform the treatment protocol described in D2. Further, using their common general knowledge, they would be able to assess treatment efficacy using measures such as the JIA ACR30/50/70 response criteria, as well as the JADAS for disease activity across 71 joints. In view of this, we are of the preliminary view that person skilled in the art would be able to perform the claimed

> invention, without the need for inventive ingenuity or undue experimentation.
>
> **Conclusion on anticipation**
>
> In light of the above analysis, it is our preliminary view that the subject-matter of claims 1 to 32 on file is not anticipated by D2 and complies with paragraph 28.2(1)(a) of the *Patent Act*.

[42] The Response to the Preliminary Review letter did not address our preliminary assessment of anticipation. Accordingly, we adopt the above reasons here. The subject-matter of claims 1 to 32 on file is not anticipated by D2 and complies with paragraph 28.2(1)(a) of the *Patent Act*.

CLAIMS 1 TO 32 ARE OBVIOUS

[43] In our view claims 1 to 32 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 principles

[44] 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.

[45] In *Sanofi* at para 67, 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?

[46] In the context of the fourth step, the Court in *Sanofi* stated that it may be appropriate in some cases to consider an "obvious to try" analysis and it identified 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 identified 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]

[47] For a finding that an invention was “obvious to try”, it must have been “more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough” (*Sanofi* at para 66).

Analysis

[48] As noted on page 15 of the Preliminary Review letter, no defect was raised in the Final Action or Summary of Reasons based on obviousness. However, as noted above, the Final Action identified prior art document D2 for anticipation. In the Preliminary Review letter, we considered that D2 and the following prior art document, cited for obviousness in the Office Action dated March 16, 2023, were relevant to the assessment of the obviousness of the claims on file:

D1: Brunner et al., “Subcutaneous golimumab for children with active polyarticular-course juvenile idiopathic arthritis: results of a multicentre, double-blind, randomised-withdrawal trial”, *Annals of the Rheumatic Diseases*, 2018, volume 77, pages 21 to 29.

[49] The Response to the Preliminary Review letter noted, on page 1, that an obviousness rejection based on D1 alone was previously addressed during examination. However, overcoming arguments that relied on D1 alone does not preclude considering D1 in combination with other references, because obviousness is assessed based on the state of the art as a whole at the claim date.

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

[50] The person skilled in the art and the relevant common general knowledge were identified above in the context of the purposive construction of the claims as of the publication date. On page 16 of the Preliminary Review letter, we expressed our preliminary view that this common general knowledge also applied as of the claim date and was therefore relevant for assessing obviousness. The Response to the Preliminary Review letter did not contest or comment on the common general knowledge in this context. Accordingly, it is our view that the above identified information was relevant common general knowledge at the claim date of the present application.

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

[51] The Preliminary Review letter, on page 16, stated the following with regard to the inventive concepts of the claims on file:

> 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 purposes 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.

[52] The Response to the Preliminary Review letter did not contest or comment on the inventive concepts of the claims on file. Accordingly, we adopt the above identification of the combination of essential elements of the claims as representative of their inventive concepts in this review.

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

[53] The Preliminary Review letter, on pages 16 to 17, stated the following with regard to the differences that exist between the matter cited as forming part of the "state of the art" and the inventive concepts of the claims on file:

> As indicated above, we consider that D1 and D2 are relevant to the obviousness assessment. D1 discloses the results of the GO-KIDS clinical trial which investigated the safety, pharmacokinetics and efficacy of subcutaneous golimumab in children with active pJIA despite background methotrexate therapy (see Introduction, page 21). Although the primary endpoint of JIA flares, in patients who met JIA ACR30 at week 16 (see Methods, page 22), was not met, "treatment with golimumab in children with active [p]JIA resulted in rapid, clinically meaningful improvement that was maintained over time even in patients who received placebo after week 16" (see Discussion, page 28). In addition to measuring JIA flares, secondary endpoints included JIA ACR30/50/70/90 responses, changes in JIA core response variables compared with baseline and the presence of inactive disease and clinical remission. Patients improved on golimumab as early as week 4, and JIA ACR30/50/70/90 response rates increased over time. At week 16, 89% of patients had a JIA ACR30 response and 79.2%/65.9%/36.4% demonstrated JIA ACR50/70/90 responses with 34.1% achieving clinically inactive disease (see Results, page 24 and Figure 2). For post-hoc exploratory analysis, the JADAS71 was also calculated (see Assessments and outcome measures, page 22). Exposure to "[g]olimumab was well tolerated, and no unexpected safety events occurred" (see Abstract, page 21).
>
> As indicated above, D2 discloses the study description of a Phase III clinical trial specifically investigating the treatment of pediatric

> patients, aged 2 years to 18 years old and with active pJIA, by administering intravenous golimumab, at a dose of 80 mg/m^2 at weeks 0, 4 and every 8 weeks through week 244, along with methotrexate at a weekly dose of 10 to 30 mg/m^2 through week 28.
>
> In our preliminary view the main differences between the inventive concepts of the claims on file and the disclosures of D1 and D2 are:
>
> - Neither D1 nor D2 disclose that after 52 weeks of treatment, a sustained response of JIA ACR30/50/70, JADAS71 for low disease activity, JIA ACR inactive disease or JIA ACR clinical remission was achieved; and
>
> - D1 also does not disclose the intravenous administration of golimumab at a dose of 80mg/m2 at weeks 0, 4, and then 8 weeks thereafter for at least 52 weeks.

[54] The Response to the Preliminary Review letter did not contest or comment on the differences between the cited prior art documents and inventive concepts of claims on file. Accordingly, we adopt the above identification of the relevant differences that exist between the matter cited as forming part of the "state of the art" and the inventive concepts of the claims on file.

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?

[55] The Preliminary Review letter, on pages 17 to 18, explained why, in our preliminary view, we considered that it was appropriate to apply an "obvious to try" analysis in the present case:

> Given that the subject-matter of the present claims relates to the field of therapeutic treatments of pJIA, a field which we consider an area

> of endeavor “where advances are often won by experimentation” (*Sanofi* at para 68), we are of the preliminary view that an “obvious to try” analysis is appropriate here. Accordingly, we will consider the three factors identified above in the “Legal principles” section.

[56] The Response to the Preliminary Review letter did not contest or comment on the relevance of an “obvious to try” analysis and presented arguments that were aligned with the “obvious to try” approach applied in the Preliminary Review letter. Accordingly, we adopt the “obvious to try” analytical framework for our final analysis.

[57] The Preliminary Review letter, on pages 18 to 21, expressed our preliminary view that it was obvious to try to obtain the subject-matter of the claims on file, as the combination of D1 and D2 provides a strong rationale, a reasonable expectation of success, and a clear path for testing the claimed subject-matter, all without requiring inventive effort:

> SELF-EVIDENT FACTOR
>
> In our preliminary view, and consistent with the first factor, it would have been more or less self-evident to the person skilled in the art that the intravenous dosing regimen of golimumab proposed in D2 ought to work. In the context of this factor, a finding that it would have been more or less self-evident that what is being tried “ought to work” does not require certainty of success. Indeed, the obvious to try analysis is used precisely in areas where progress is achieved through experimentation and success cannot be guaranteed in advance (*Les Laboratoires Servier v Apotex Inc*, 2019 FC 616 at para 269). As explained in *Janssen Inc v Apotex Inc*, 2021 FC 7 at para 135, the relevant question is whether success would have been expected, not assured:
>
> > As to “ought to work”, it is clear that certainty of success is not required otherwise there would be no point in describing it as something “to try”. “Trying” implies the possibility of failure

> but with the expectation of success. While never easy to define on a spectrum of likely success, it is neither a Boston College Doug Flutie “Hail Mary” pass nor a Wayne Gretsky “open net shot”. Some limited experimentation is permitted in the context of the second factor. It is not to be arduous, inventive or unusual.

In this case, the relevant question is whether it would have been more or less self-evident to the person skilled in the art, in light of the disclosures in D1 and D2 and the common general knowledge, that the intravenous use of golimumab to treat pJIA ought to achieve JIA ACR30/50/70 responses, the presence of inactive disease and clinical remission, as well as JADAS71 responses for low disease activity, in a proportion of the patients receiving treatment.

D2 discloses a Phase III clinical trial protocol for treating pediatric patients with active pJIA using intravenous golimumab in combination with methotrexate. Although D2 does not report trial results, it provides a clear plan for treatment, including dosing and patient population. D1, on the other hand, presents detailed results from the GO-KIDS clinical trial, in which subcutaneous golimumab was administered to the same patient population as D2. Despite not meeting its primary endpoint, D1 reports that golimumab was well tolerated and resulted in rapid and clinically meaningful improvements, including high JIA ACR30/50/70/90 response rates and the achievement of inactive disease by a substantial proportion of patients. Improvements were observed as early as week 4 and were sustained in some patients who switched to placebo at week 16.

While it is true that D1 and D2 propose different dosing routes and regimens, these differences would not have undermined the expectation of success. D1 itself refers to prior clinical trials in adults with rheumatoid arthritis to support the use of subcutaneous

golimumab in pediatric patients with pJIA. According to the Product Monograph for Simponi™, the subcutaneous dosing regimen used in adults with rheumatoid arthritis —50 mg once monthly—corresponds to that used in D1, adjusted for pediatric patients by body surface area. Similarly, Simponi™ IV (intravenous) was already approved for use in adults with rheumatoid arthritis at a dose and schedule consistent with that proposed in D2 for pediatric patients.

Thus, both the subcutaneous and intravenous formulations of golimumab had been validated in adult populations, and both were being considered for pediatric use based on known pharmacological profiles, clinical practices, and expectations of parallel efficacy. The person skilled in the art would have understood that the mechanism of action and pharmacokinetics of golimumab were well characterized, and that switching routes of administration—particularly with body surface area-adjusted dosing—was a conventional and predictable step, not one that introduced significant uncertainty.

Therefore, it is our preliminary view that it would have been more or less self-evident to the person skilled in the art that intravenous administration of golimumab, as proposed in D2, would likely produce clinical benefits based on the positive safety and efficacy profile of subcutaneous golimumab in D1. The observed durability of response in D1 would also support the expectation that a proportion of patients could achieve sustained improvements at 52 weeks using the intravenous route. The endpoints in the claims (e.g., JIA ACR30/50/70, JADAS71, inactive disease, and remission) were well-established measures of efficacy and were already employed in D1. Accordingly, while the specific outcomes at 52 weeks were not disclosed in either document, the overall approach would not have appeared speculative or uncertain to the person skilled in the art.

EXTENT AND EFFORT FACTOR

It is our preliminary view that the effort required to achieve the claimed subject-matter would have been routine for the person skilled in the art, who is assumed to be a clinician specializing in pediatric rheumatology with a strong foundation in inflammatory diseases such as JIA. No inventive effort would have been required to design a trial to evaluate intravenous golimumab, as D2 already provides a study protocol, including dosage, administration schedule, and combination with methotrexate. Additionally, golimumab was already commercially available in intravenous form (Simponi^{TM} IV), and its use in adults with similar inflammatory conditions was well known.

The outcome measures recited in the claims—JIA ACR responses, JADAS71 scores, and assessments of inactive disease and remission—are standard and routinely used in clinical research on pJIA, as evidenced by D1. Given the established nature of these measures and the presence of a detailed dosing protocol in D2, it is our preliminary view that the steps required to carry out and evaluate the treatment approach would not have gone beyond what was routine in the field at the relevant time.

MOTIVE FACTOR

D2 discloses a clear plan to investigate intravenous golimumab for the treatment of pJIA, providing a specific dosing regimen, patient population, and concomitant methotrexate treatment. Given the encouraging results from D1 using subcutaneous golimumab, it is our preliminary view that the person skilled in the art would have had a strong motivation to evaluate whether intravenous golimumab would produce similar or improved outcomes. The goal of optimizing treatment delivery, particularly in pediatric patients who may benefit from less frequent dosing schedules associated with intravenous

> therapy, would further support a motive to pursue the intravenous route.
>
> Moreover, as D1 already employs outcome measures such as JIA ACR30/50/70/90, inactive disease and remission, and JADAS71 in evaluating subcutaneous golimumab, there would have been a clear rationale to use the same measures in evaluating intravenous administration, including assessment of sustained response at 52 weeks.
>
> CONCLUSION ON OBVIOUS TO TRY
>
> Therefore, in view of the above analyses of the relevant factors pertaining to an obvious to try analysis, we are of the preliminary view that it was obvious to try to obtain the subject-matter of the claims. The combination of D1 and D2 provides a strong rationale, a reasonable expectation of success, and a clear path for testing the claimed subject-matter, all without requiring inventive effort.
>
> **Conclusion on obviousness**
>
> In light of the above considerations, it is our preliminary view that the claims on file encompass subject-matter that would have been obvious to the person skilled in the art, as of the relevant date, having regard to D2 in view of D1 and their common general knowledge, contrary to section 28.3 of the *Patent Act*.

SELF-EVIDENT FACTOR

[58] In addressing the self-evident factor, the Response to the Preliminary Review letter argued that the prior art would not have provided the person skilled in the art with any reasonable expectation of success. With regard to D1, the Response to the Preliminary Review letter, on page 2, argued that D1 demonstrated that subcutaneous golimumab did not maintain long-term clinical effectiveness:

> D1 only investigates the effect of *subcutaneously* administered golimumab, delivered every 4 weeks, which was shown to not be effective in maintaining long-term clinical effectiveness … the primary endpoint was not met as treatment groups (golimumab vs placebo) had comparable JIA flare rates and the rates of clinical remission were comparable between golimumab vs placebo. [Emphasis in original]

[59] The Response to the Preliminary Review letter further contended that D2 provided no clinical results and that planned Phase III trials did not create a reasonable expectation of success:

> D2 is completely silent as to the recited JIA ACR30/50/70/90 response rates, JADAS71, JIA ACR inactive disease, and JIA ACR clinical remission as no clinical results were published in D2 prior to the priority date of the present application. Furthermore, the fact that a clinical trial is planned (i.e., as is described in D2) provides no reasonable expectation of success. For example, Patel et al. (Journal of Allergy and Clinical Immunology 2017 May;140(3):685-687; provided herein as "Exhibit A") reported that of candidate drugs in a Phase 3 trial, only 49% are ultimately approved and available for treatment. These statistics show that planned studies of a Phase III clinical trial provides no reasonable expectation of success at arriving at the presently claimed anti-TNF antibody and use thereof in treating a pediatric patient having juvenile idiopathic arthritis (JIA), wherein the method comprises administering the recited antibody at the recited dosing regimen, wherein the administration of the recited antibody at the recited treatment regimen results in the specific recited clinical improvement.

[60] The Response to the Preliminary Review letter further asserted that the claimed 52-week outcomes demonstrated a new technical effect not suggested by D1 or D2:

> D1 and D2 do not teach the long-term efficacy, where clinical metrics are reached and retained after 52 weeks of treatment. That is, D1 and D2 do not teach or suggest that after 52 weeks of treatment, a sustained response of JIA ACR30/50/70, JADAS71 for low disease activity, JIA ACR inactive disease or JIA ACR clinical remission was achieved.

[61] The Response to the Preliminary Review letter also emphasized the inherent unpredictability of long-term efficacy, citing Billioud et al. (Am J Gastroenterol, 2011, 106(4):674–84), a systematic review of 39 studies that evaluated loss of response to adalimumab therapy. Billioud et al. reported that the mean percentage of patients who lost response was 18.2%, with an annual risk of 20.3% per patient-year. This unpredictability was attributed to immunogenicity, inter-patient differences in bioavailability and pharmacokinetics, and other factors affecting drug clearance. According to the Response to the Preliminary Review letter, these factors demonstrated that the maintenance of clinical improvement and long-term efficacy of the recited antibodies could not have been easily predicted by the person skilled in the art.

[62] We respectfully disagree. The first Sanofi factor does not require certainty of success or advance knowledge of the exact magnitude or duration of effect. The relevant question is whether it would have been more or less self-evident to the person skilled in the art that intravenous golimumab “ought to work” in treating pediatric JIA (see para [57]).

[63] In our view, D1 and D2, read together with the common general knowledge, provide such an expectation. D1, although its primary endpoint was not met, nonetheless demonstrated that golimumab was well tolerated and produced rapid and clinically meaningful improvements, including substantial JIA ACR responses and achievement of inactive disease. D2 provided a detailed intravenous dosing protocol for the same patient population, and intravenous golimumab was already approved in adults with rheumatoid arthritis at a comparable regimen. These disclosures

would have led the person skilled in the art to reasonably expect that intravenous golimumab could provide clinical benefit in pediatric JIA patients.

[64] While Patel et al. and Billioud et al. highlight the inherent unpredictability of long-term response, this does not negate a reasonable expectation of success. Obviousness does not require foreknowledge of the exact percentages of response or their duration; it requires only that the person skilled in the art would have reasonably expected meaningful clinical improvement without inventive effort. Planned Phase III studies and variability in clinical response are common in drug development, and the person skilled in the art would recognize that a biologic therapy with demonstrated efficacy and tolerability in pediatric and adult populations, combined with a clear and conventional trial design, “ought to work” even in the absence of prior published Phase III results.

[65] The Response to the Preliminary Review letter’s reliance on the sustained efficacy observed for at least 52 weeks does not alter this conclusion. The sustained response outcomes recited in the claims represent normal variability in clinical response rather than a technical effect that would be considered unexpected. The person skilled in the art would understand that biologic therapies administered over extended periods can be expected to maintain clinical improvement, including for at least 52 weeks.

[66] Accordingly, in our view, on the basis of D1, D2 and the common general knowledge, the person skilled in the art would have considered it more or less self-evident that the recited dosing regimen of intravenous golimumab “ought to work” in pediatric JIA, including in achieving the types of outcomes recited in the claims.

EXTENT AND EFFORT FACTOR

[67] With regard to the extent and effort factor, the Response to the Preliminary Review letter submitted that it was not predictable which modifications to

D1, specifically the route of administration, dose, and dosing frequency, would result in long-lasting clinical efficacy:

> In addition, it is not predictable for a skilled artisan to arrive at the specifically recited claimed invention from D1 as the present claims differ from D1 in the (1) manner of administration; (2) dose; and (3) frequency of administration. A skilled artisan, starting from D1 could have many possible “tweaks” to the method of D1. However, a skilled artisan would not have any predictability in what “tweaks” or combination of “tweaks” would result in a long-lasting clinical efficacy prior to actually conducting the studies presented in the present application.

[68] We respectfully disagree. In our view, the effort required to arrive at the claimed subject-matter would not have exceeded routine clinical trial work. D2 provides a detailed protocol specifying the claimed intravenous golimumab dosing, patient population, and concomitant methotrexate use. The clinical endpoints recited in the claims—JIA ACR responses, JADAS71, inactive disease, and remission—were standard efficacy measures already employed in D1 and widely recognized in the art.

[69] The fact that confirmatory clinical trials were required to generate long-term data does not render the claimed subject-matter inventive. Conducting such trials is the ordinary work of the person skilled in the art once preliminary efficacy has been shown. Golimumab was already commercially available in both subcutaneous and intravenous formulations, with intravenous Simponi™ approved in adults at the very regimen proposed in D2. In our view, the steps necessary to evaluate intravenous golimumab in pediatric JIA patients were therefore conventional and predictable, not inventive.

MOTIVE FACTOR

[70] The Response to the Preliminary Review letter does not explicitly discuss motivation. However, it submitted that D1 taught away from the claimed invention because subcutaneous golimumab every four weeks did not maintain long-term clinical effectiveness (see Figure 3 of D1) and the primary endpoint was not met, with comparable JIA flare and clinical remission rates between golimumab and placebo. The Response to the Preliminary Review letter cited *AB Hassle and AstraZeneca AB v Apotex Inc*, 2003 FCT 771 at paras 88 to 89 [*AB Hassle*] to support the position that this taught away from the claimed approach and therefore demonstrated inventiveness.

[71] We respectfully disagree with the Response to the Preliminary Review letter's reliance on *AB Hassle*. In that case, the prior art expressly discouraged the claimed approach, directing the person skilled in the art away from it. While D1 reported that the primary endpoint was not met, it also disclosed positive and clinically meaningful findings, including substantial JIA ACR responses, achievement of inactive disease, and good tolerability. These data would have encouraged further investigation rather than discouraged it. Accordingly, D1 did not "teach away" in the sense contemplated by *AB Hassle*.

[72] Moreover, and independently of the above, D2 demonstrated a clear motivation to pursue intravenous golimumab in pediatric JIA. D2 explicitly disclosed a plan to investigate intravenous administration in pediatric JIA, including the specific dosing regimen, patient population, and combination with methotrexate. The established efficacy of intravenous golimumab in adults with rheumatoid arthritis, coupled with the conventional trial design in D2, would have further encouraged the person skilled in the art to pursue the intravenous route. The outcome measures employed in D1—JIA ACR30/50/70/90, JADAS71, inactive disease, and remission—were conventional and readily transferable to intravenous administration, reinforcing the motivation to carry out the regimen disclosed in D2.

[73] On this basis, we remain of the view that there was an overall motivation to pursue intravenous golimumab in pediatric JIA. The teaching-away arguments from D1 do not negate this motivation, and D2's disclosure of a detailed intravenous trial, combined with established adult efficacy and conventional outcome measures, further reinforces it.

WAS IT OBVIOUS TO TRY TO OBTAIN THE INVENTION?

[74] Taking into account all the above assessments of the relevant factors pertaining to an obvious to try analysis, as well as the submissions and arguments presented in the Response to the Preliminary Review letter, we are of the view that it was obvious to try to obtain the subject-matter of the claims on file. In our view, the combination of D1 and D2 provides a strong rationale, a reasonable expectation of success, and a clear path for testing the claimed subject-matter, all without requiring inventive effort.

Conclusion on obviousness

[75] In light of the above considerations, it is our view that the claims on file encompass subject-matter that would have been obvious to the person skilled in the art, as of the relevant date, having regard to D2 in view of D1 and their common general knowledge, contrary to section 28.3 of the *Patent Act*.

PAGE NUMBERING

Legal principles

[76] Subsection 50(1) of the *Patent Rules* states that:

> The pages of the specification must be numbered consecutively.

Analysis

[77] The Preliminary Review letter, on pages 21 to 22, expressed our preliminary view that the pages of the specification are not numbered consecutively:

> The Final Action, on page 3, identifies the following presentation defect with the specification:
>
> > The pages of the specification are not numbered consecutively and do not comply with subsection 50(1) of the *Patent Rules*. The description ends on page 206 while the claims begin on page 208.
>
> Having reviewed the page numbering of the specification, we preliminarily agree for the same reasons as outlined in the Final Action. Therefore, it is our preliminary view that the specification does not comply with subsection 50(1) of the *Patent Rules*.

[78] The Response to the Preliminary Review letter did not address our preliminary assessment of the page numbering defect with the specification. Accordingly, we adopt the above reasons here. The pages of the specification are not numbered consecutively, contrary to subsection 50(1) of the *Patent Rules*.

THE PROPOSED CLAIMS

[79] In our view, the proposed claims are not a necessary amendment because they would not make the application allowable.

Legal principles

[80] According to subsection 86(11) of the *Patent Rules*, an application that has been rejected in a Final Action can only be amended if the Commissioner

informs the Applicant that certain amendments are necessary to make the application allowable:

> If, after review of a rejected application for a patent, the Commissioner has reasonable grounds to believe that the application does not comply with the Act or these Rules and certain amendments are necessary in order to make the application allowable, the Commissioner must by notice inform the applicant that those amendments must be made not later than three months after the date of the notice.

Analysis

[81] The submissions in the Response to the Preliminary Review letter were focused on addressing the obviousness assessment provided in our Preliminary Review letter, without specifying whether it related to the claims on file or the proposed claims. As indicated above, we understood the submissions to apply equally to both sets of claims.

[82] The Preliminary Review letter, on pages 22 to 23, expressed our preliminary view that there is no meaningful difference between the scope of the proposed claims and the claims on file:

> As indicated above, with the Response to the Final Action the Applicant submitted proposed claims 1 to 32.
>
> A review of the proposed claims indicates that the proposed independent claims have been amended to specify that the use is for the achievement of the recited clinical endpoints.
>
> According to page 2 of the Summary of Reasons, this amendment "merely amounts to semantics rather than any substantial change to the claims." The Summary of Reasons further points out that the proposed claims "are not directed to a new use or a new population to be treated, nor would the achievement of the recited clinical

> endpoints affect how the use is carried out. It is merely a further characterization of that which is inherent to the known use." Consequently, the Summary of Reasons submits that the proposed claims would not overcome the anticipation defect.
>
> Having reviewed proposed claims 1 to 32, we agree that there is no meaningful difference between the proposed claims and the claims on file. Therefore, it is our preliminary view that proposed claims 1 to 32 share the same essential elements and inventive concepts that have already been identified in respect of claims 1 to 32 on file.

[83] The Response to the Preliminary Review letter did not address our preliminary assessment that there is no meaningful difference between the proposed claims and the claims on file. Accordingly, we adopt the above reasons here. It is our view that proposed claims 1 to 32 share the same essential elements and inventive concepts that have already been identified in respect of claims 1 to 32 on file. It follows that, for the same reasons provided for claims 1 to 32 on file, it is our view that proposed claims 1 to 32 would not be anticipated and would comply with paragraph 28.2(1)(a) of the *Patent Act* and that the subject-matter of proposed claims 1 to 32 would be obvious having regard to D2 in view of D1 and the common general knowledge, contrary to section 28.3 of the *Patent Act*.

[84] In addition, page 23 of the Preliminary Review letter also noted that the proposed claims do not remedy the page numbering defect with the specification:

> The Summary of Reasons, on page 2, also notes that contrary to the indication in the Response to the Final Action, the pagination error has not been remedied as the amended claim pages are still not numbered consecutively with the description. Having reviewed the page numbering of the proposed claims, we preliminarily agree for the same reasons as outlined in the Summary of Reasons.

> Therefore, it is our preliminary view that the amended specification would not comply with subsection 50(1) of the *Patent Rules*.

[85] The Response to the Preliminary Review letter did not address our preliminary view with respect to the page numbering defect. Accordingly, we adopt the above reasons here. It is our view that the amended specification would not comply with subsection 50(1) of the *Patent Rules*.

Conclusion on proposed claims

[86] In view of the above, it is our view that the proposed claims do not make the application allowable, and therefore are not considered to be a necessary amendment under subsection 86(11) of the *Patent Rules*.

THE BOARD RECOMMENDS TO REFUSE THE APPLICATION

[87] In view of the above, we recommend that that the application be refused on the grounds that:

- claims 1 to 32 on file are obvious contrary to section 28.3 of the *Patent Act*; and
- the pages of the specification are not numbered consecutively contrary to subsection 50(1) of the *Patent Rules.*

Christine Teixeira	Marcel Brisebois	Mehdi Ghayour
Member	Member	Member

THE COMMISSIONER REFUSES THE APPLICATION

[88] I agree with the Board's findings and its recommendation to refusion the application on the grounds that:

- claims 1 to 32 on file are obvious contrary to section 28.3 of the *Patent Act*; and
- the pages of the specification are not numbered consecutively contrary to subsection 50(1) of the *Patent Rules.*

[89] I therefore refuse, under section 40 of the *Patent Act*, to grant a patent for this application. The Applicant has six months from the mailing of my decision to appeal it to the Federal Court of Canada under section 41 of the *Patent Act*.

Konstantinos Georgaras

Commissioner of Patents
Dated at Gatineau, Quebec
this 14th day of October, 2025.