Citation: Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., 2023 CACP 18
Commissioner's Decision #1651
Décision du commissaire nº 1651
Date: 2023-06-23

TOPIC:	A11	Application for Patent - Amendment to - New Matter
	C00	Disclosure - Adequacy or Deficiency of Description
	G00	Utility
SUJET:	A11	Demande de brevet - Modification - Nouvelle matière
	C00	Divulgation - Caractère adéquat ou inadéquat de la description
	G00	Utilité

Application No. : 2,812,110

Demande nº 2 812 110

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,812,110 having been rejected under subsection 199(1) of the *Patent Rules*, has consequently been reviewed in accordance with paragraph 86(7)(c) of the *Patent Rules*. The recommendation of the Patent Appeal Board and the decision of the Commissioner are to refuse the application.

Agent for the Applicant:

Ledgley Law

724 Annette Street
Toronto, Ontario
M6S 2E2

INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,812,110, which is entitled "Targeted identification of immunogenic peptides". Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. is the sole Applicant. A review of the rejected application has been conducted by a Panel of the Patent Appeal Board pursuant to paragraph 86(7)(c) of the *Patent Rules*.

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

BACKGROUND

The Application

[3] The application is a divisional application of parent application 2,622,036 which was filed under the Patent Cooperation Treaty (PCT) and has an effective filing date in Canada of September 8, 2006. The parent application was laid open to public inspection on March 15, 2007.

[4] The rejected application relates to methods for the targeted identification of immunogenic peptides that may provoke an unwanted immune response in a host. The identification of these peptide sequences, that are involved in antibody binding, is useful for preventing, suppressing and treating immune-related diseases.

[5] The application has 7 claims on file that were received at the Patent Office on October 2, 2017.

Prosecution History

[6] On May 5, 2020, a Final Action was written under subsection 199(1) of the *Patent Rules*. The Final Action states that the subject-matter of the description, sequence listing and drawings contain new matter not reasonably to be inferred from the specification or drawings as originally filed in parent application 2,622,036 contrary

to section 38.2 of the *Patent Act*[1]. As a result of the new matter defect, the Final Action also rejects claims 1 to 7 on file for being directed to subject-matter that lacks utility, contrary to section 2 of the *Patent Act*, for lacking support under section 84 of the former *Patent Rules* (SOR/96-423, now section 60 of the *Patent Rules*) and for lack of proper disclosure and enablement of the claimed subject-matter as required by subsection 27(3) of the *Patent Act*.

[7] The Response to the Final Action dated November 5, 2020, disagrees with this assessment and submits that the contested subject-matter was timely filed in the International Phase in accordance with the provisions of the PCT and/or United States Receiving Office practices and legislation. It further submits that the contested subject-matter can be relied on to establish the utility, support and enablement of the claimed subject-matter.

[8] On June 4, 2021, the application was forwarded to the Patent Appeal Board for review under paragraph 86(7)(c) of the *Patent Rules* along with a Summary of Reasons explaining that the rejection is maintained.

[9] In a letter dated July 8, 2021, the Patent Appeal Board forwarded a copy of the Summary of Reasons to the Applicant and requested that they confirm their continued interest in having the application reviewed.

[10] In a letter dated October 8, 2021, the Applicant confirmed their interest in having the review proceed.

[11] The present Panel was formed to review the rejected application under paragraph 86(7)(c) of the *Patent Rules*. On February 13, 2023, the Panel sent a Preliminary Review letter detailing our preliminary analysis and opinion that the application contains new matter not reasonably to be inferred from the originally filed specification of parent application 2,622,036 contrary to section 38.2 of the *Patent Act*[1].The Preliminary Review letter also expresses the preliminary opinion that as a result of the new matter the claims on file lack utility contrary to section 2 of the *Patent Act*, the claims on file lack support contrary to section 60 of the *Patent Rules* and the specification, insofar as it relates to the claims on file, is insufficient

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[1] *Patent Act* (RSC 1985, c P-4 as amended by Intellectual Property Law Improvement Act: (An Act to amend the Copyright Act, the Industrial Design Act, the Integrated Circuit Topography Act, the Patent Act, the Trade-marks Act and other Acts in consequence thereof, RS 1993, c 15, s 41)

contrary to subsection 27(3) of the *Patent Act*. The Preliminary Review letter also provided the Applicant with an opportunity to make oral and/or written submissions.

[12] The Response to the Preliminary Review letter dated March 28, 2023 included written submissions in support of the timely filing of the contested subject-matter during the International Phase and the patentability of the claims on file. On June 6, 2023 an oral hearing was conducted.

Issues

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

- whether the description, sequence listing, drawings and claims contain new matter contrary to section 38.2 of the *Patent Act*[1];
- whether the claims on file lack utility contrary to section 2 of the *Patent Act;*
- whether the claims on file lack support contrary to section 60 of the *Patent Rules*; and
- whether the specification, insofar as it relates to the claims on file, is insufficient contrary to subsection 27(3) of the *Patent Act*.

PURPOSIVE CONSTRUCTION

Legal Background

[14] 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.

[15] 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

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

[16] The Preliminary Review letter, on page 4, states the following with regard to the identity of the person skilled in the art and their expected common general knowledge:

> Neither the Final Action nor the Response to the Final Action identify the person skilled in the art and the relevant common general knowledge. As indicated above, a purposive construction of the claims is performed from the perspective of the person skilled in the art. We therefore present our preliminary view regarding the identity of the person skilled in the art and the relevant common general knowledge.
>
> Based on the specification of the originally filed parent application 2,622,036, our preliminary view is that the person skilled in the art would be a team comprising an immunologist and a bioinformatician having experience in identifying immunogenic peptides.
>
> Further, in our preliminary view, the common general knowledge of this team would include the following, as taught on pages 1 to 5 of the originally filed description of parent application 2,622,036 (Description of the Background):
>
> - An antigen is a molecule or molecular structure that is processed by the immune system and can trigger an immune response including the production of antibodies that specifically recognize the antigen;
> - Antigens can originate from the external environment or from the host itself;
> - Antigens are processed by antigen-presenting cells and only those fragments of a processed antigen which carry antigenic determinants, referred to as epitopes, are able to bind to antibodies;

- Peptide epitopes represent a promising approach to the production and design of vaccines for the prevention, suppression and treatment of immune-related diseases;

- Conventional methods using biochemical and biophysical properties have attempted to determine the location of probable peptide epitopes, however these methods are both cost and labor intensive; and

- Computer-driven algorithms have been designed that can identify regions of proteins that contain epitopes that are likely to induce an immune response.

[17] The Applicant made no submissions on these characterizations of the person skilled in the art and the relevant common general knowledge in either the Response to the Preliminary Review letter or at the hearing. Accordingly, we adopt the above characterizations for this review.

The claims on file

[18] There are 7 claims on file. Independent claim 1 is taken as being representative of the independent claims and reads as follows:

> 1. A therapeutically effective composition comprising a peptide that represents a portion of the sequence of Her2/neu antigen, wherein the peptide binds to a class I HLA2-A2 molecule and consists of the sequence of SEQ ID NO: 17 (GP2 = IISAVVGIL) or SEQ ID NO: 18 (GP2' = IVSAVVGIL), and further comprising an antibody that binds to the Her2/neu antigen, wherein the antibody is trastuzumab**.**

[19] Independent claims 2 and 3 are composition for use and peptide for use claims, respectively, that refer to the same peptide as claim 1 and specify its use in the treatment of a Her2/neu expressing cancer.

[20] The dependent claims 4 to 7 define further limitations regarding the type of cancer.

[21] The Applicant made no submissions on these characterizations of the claims on file in either the Response to the Preliminary Review letter or at the hearing. Accordingly, we adopt the above identification of claim 1 as being representative of the independent claims. Likewise, we adopt the above characterization of dependent claims 4 to 7 as providing further limitations regarding the type of

cancer.

Essential elements

[22] As stated above, all of the 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. Further, a claim element is essential when it would have been obvious to the person skilled in the art that its omission or substitution would have a material effect on the way the invention works: Free World Trust at para 55.

[23] The Preliminary Review letter, on page 5, 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 7 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, or a preferred embodiment. Although some claims recite a list of alternatives, we consider that the person skilled in the art would understand that the element represented by one of said alternatives is essential. In addition, there is no indication on the record before us that any claim elements are non-essential. Therefore, our preliminary view is that the person skilled in the art would consider all of the elements in the claims to be essential.

[24] The Applicant made no submissions on the identification of the essential elements of the claims on file in either the Response to the Preliminary Review letter or at the hearing. Accordingly, we adopt the above identification of the claim elements that are essential in this recommendation.

NEW MATTER

[25] In the case of a divisional application, new matter is to be evaluated based on the *Patent Act* in force at the date of filing of the divisional and/or at the date(s) of amendment. In the present case, the divisional application was filed on April 5, 2013 and the pending specification and drawings include amendments made on October 24, 2013, June 25, 2014 and October 2, 2017. Accordingly, the assessment of new subject-matter is to be made under section 38.2 of the *Patent*

Act[1].

Legal Background

[26] Section 38.2 of the *Patent Act*[1] sets forth the conditions under which amendments may be made to the specification and drawings of a patent application: [Emphasis in original]

> 38.2 (1) Subject to subsections (2) and (3) and the regulations, the specification and any drawings furnished as part of an application for a patent in Canada may be amended before the patent is issued.
>
> **Restriction on amendments to specifications**
>
> (2) The specification may not be amended to describe matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application.
>
> **Restriction on amendments to drawings**
>
> (3) Drawings may not be amended to add matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application.

[27] The question as to whether matter added to the specification or drawings by amendment complies with section 38.2 of the *Patent Act* is considered from the point of view of the person skilled in the art: Re Uni-Charm Corp's Patent Application 2313707 (2013), CD 1353 (Pat App Bd & Pat Commr) at para 13.

[28] Therefore, assessing whether there is new matter requires a comparison of the pending specification and drawings with the originally filed specification and drawings and a determination as to whether the subject-matter of the amendments would have been reasonably inferable from the original specification or drawings by the person skilled in the art.

Analysis

[29] The Preliminary Review letter, on pages 7 to 8, explains why in our preliminary view the pending specification and drawings contain new matter:

On page 2, the Final Action identifies a new matter defect with the pending description, sequence listing and drawings:

> As detailed in the previous office actions, the subject matter of pages 5, 6, 7, 7a, 7b, 13 and 14 of the description, the Sequence Listing and figures 1-8 of the drawings does not comply with section 38.2 of the Patent Act because it is not reasonably to be inferred from the specification and drawings as originally filed in the parent application CA 2622036 or the instant divisional application. Pages 5, 6, 7, 13 and 14 of the most recent description (2014-06-25), the Sequence Listing and figures 1-8 of the drawings were filed with the divisional application, while pages 7a and 7b (containing SEQ ID NO:17 and 18) were filed on 2013-10-24. In order for an application to be considered a proper divisional, the description and drawings of a divisional application must be the same as those originally filed for the parent application. However, the parent application as originally filed, which serves as the basis for the instant application, does not contain any figures, sequence listings, description of any figures or any examples. As the subject matter of these passages cannot be reasonably inferred from the description of the parent as originally filed, it is considered as new matter and must be removed.

The Final Action on pages 2 to 3 also continues to disagree with the Applicant's arguments in response to the new matter defect identified in previous Office Actions and the admissibility of the matter under Rules 20.6 and 20.7(b) of the Patent Cooperation Treaty. The Response to the Final Action, on page 2, maintains these arguments.

Although the present application is a divisional application of Patent Cooperation Treaty National phase application 2,622,036, the Rules governing the corresponding international application are not within our jurisdiction. Accordingly, we agree with the Final Action that an assessment for new matter must be based on a comparison of the pending specification and drawings to the originally filed specification and drawings of its parent application 2,622,036 on file at the Patent Office as of its National phase entry date, March 10, 2008.

As indicated above, patent application 2,622,036 is based on a previously filed Patent Cooperation Treaty application. Therefore, the originally filed specification of 2,622,036 is the corresponding international application WO2007/030771 as filed on September 8, 2006 and published on March 15, 2007 by the World Intellectual Property

Organization as Initial Publication without ISR [A2 11/2007] and retrieved from:

https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2007030771&_cid=P21-LD21G3-50577-1.

The international application as filed contains 13 pages of description and 17 claims. No sequence listing or drawings were present in the international application as filed.

The amended claims received by the International Bureau on March 14, 2008 under Article 19 of the Patent Cooperation Treaty are not considered to be part of the application as filed.

Having compared the pending specification and drawings of the present divisional application to the originally filed specification of its parent application 2,622,036, it is our preliminary view that the content of both the specification and the drawings of the pending divisional application contain substantial amendments over the originally filed parent application. For example, the originally filed specification of the parent application describes in general terms a method for the targeted identification of immunogenic peptides with no identification of any immunogenic peptides and no examples. The originally filed parent application also did not contain a sequence listing or any drawings.

In contrast, the pending specification and drawings of the present divisional application introduce experimental results identifying specific immunogenic peptides of Her2/neu in the description, claims and drawings—details that were not present in the originally filed specification of its parent application 2,622,036. In addition, it is our preliminary view that the person skilled in the art would not have reasonably inferred these details based on the general methods disclosed in the originally filed specification of parent application 2,622,036.

Therefore, it is our preliminary view that the introduction of the description of Figures 1 to 8 on page 5, line 12 to page 6, line 4 of the description, the introduction of the embodiments on page 7, line 21 to page 7b, line 30 of the description, the introduction of a reference to Figure 1 on page 9, line 15 of the description, the introduction of the example on page 13, line 23 to page 14, line 22 of the description, the Sequence Listing, claims 1 to 7 on file and Figures 1 to 8 of the drawings constitute new matter not reasonably to be inferred from the originally filed specification of parent application 2,622,036, contrary to section 38.2 of the *Patent Act* and must be removed.

[30] The Applicant in both the Response to the Preliminary Review letter and at the hearing continued to argue that the originally filed application included the

submission under Rule 20.6 of the PCT as well as the Article 19 claim amendments. In particular, the Applicant explains that both the Notice Under Rule 20.6 of Incorporation by Reference, as well as the Article 19 amendment of the claims, were timely filed during the International Phase at the Receiving Office in the United States on March 7, 2008.

[31] Regarding the Notice Under Rule 20.6 of Incorporation by Reference, the Applicant argues that the submission was recognized by the World Intellectual Property Office (WIPO) as there is no indication that the Receiving Office refused the submission, which was timely filed in compliance with the time limits set out in Rule 20.7 of the PCT Rules. Further, the Rule 20.6 submission has been identified as a related document on file at the International Bureau and is published on Patentscope with the title "Confirmation of Incorporation by Reference of Element or Part (Rule 20.6)" at the International Bureau[2]. In addition, the Receiving Office accepts this submission for all designated states as evidenced by United States Patent No. 8945573 which issued with the very same claims that the Applicant is seeking in the present application.

[32] Regarding the timeliness of the submission, the Applicant submits that Rule 20.7(b) permits a late submission of the Rule 20.6 Incorporation by Reference implicitly and expressly and this is stated in PCT Newsletter 05/2007[3]:

> If a notice confirming the incorporation by reference of an element is received by the receiving Office after the expiration of the applicable time limit under PCT Rule 20.7(a) but before that Office notifies the applicant under PCT Rule 20.4(i) that the application will not be treated as an international application, that applicant's notice will be considered to have been received within that time limit (PCT Rule 20.7(b)).

[33] At the hearing the Applicant also referred to PCT Newsletter 07-08/ 2015[4] which states that the reason for the provisions of PCT Rules 4.18 (Statement of Incorporation by Reference), 20.5 (Missing Parts) and 20.6 (Confirmation of Incorporation by Reference of Elements and Parts) is to provide a safeguard for applicants in cases where any of the following are not contained in the international application: the entirety of the description or the entirety of the claims;

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[2] WO2007030771 TARGETED IDENTIFICATION OF IMMUNOGENIC PEPTIDES (wipo.int)

[3] PCT Newsletter No. 05/2007 (May 2007) (wipo.int)

[4] PCT NEWSLETTER No. 07-08/2015 (July-August 2015) (wipo.int)

or, part of the description, claims or the entirety or part of the drawings and where the element or part of the element concerned is completely contained in the earlier application the priority of which is being claimed. Regarding the Rules concerning incorporation by reference, the Applicant noted that although some Designated Offices have submitted notifications of incompatibility between their national law and the Rules concerning incorporation by reference, the Canadian Intellectual Property Office has never submitted such a notice under PCT Rule 20.8.

[34] Further, Canada is a Member of the Patent Law Treaty which provides another opportunity for the correction of mistakes under Rule 18. Given that the PCT regulations were complied with before the application entered the national phase and these corrections were made in the international application the disputed subject-matter should be permitted.

[35] In the alternative, the Applicant requests that the documents submitted under the Rule 20.6 Notice be accepted by way of an amendment because the priority document was incorporated by reference. In addition, the priority document was available to the public so there is no harm to third parties.

[36] Finally, at the hearing, the Applicant noted that the issue of new matter was not raised until examination had gone on for two or three years raising a question of procedural fairness.

[37] Firstly, although the new matter defect was not raised from the outset of the prosecution of the present application, the principle of procedural fairness has been followed. Prior to the issuance of the Final Action, the new matter defect was raised in three Office Actions. In addition the Applicant was provided opportunities to respond to the Preliminary Review letter and to participate in a hearing.

[38] Secondly, as we explained in the Preliminary Review letter, the present application is a divisional application of PCT National phase application 2,622,036 and the Rules governing the corresponding international application are not within our jurisdiction. Therefore, our assessment for new matter must be based on a comparison of the pending specification and drawings to the originally filed specification and drawings of its parent application 2,622,036 on file at the Patent Office as of its National phase entry date, March 10, 2008.

[39] The originally filed specification of parent application 2,622,036 consists of 13

pages of description and 17 claims which are identical to what was published on March 15, 2007 at WIPO in respect of corresponding international application WO2007/030771[2]. No sequence listing or drawings were present in the international application as originally filed. Likewise, the Article 19 claim amendments were also not present in the international application as originally filed as they are a replacement of the claims originally filed: PCT Applicant's Guide[5]

> 9.005
>
> Rule 6.1, Rule 46.5, Section 205
> When filing amendments to the claims under Article 19, the applicant is required to file a sheet or sheets containing a complete set of claims in replacement of the claims originally filed.

[40] Thirdly, there are no provisions in our *Patent Act* to include the matter that the Applicant has tried to incorporate by reference during the International Phase. In fact, section 57(1) of the *Patent Rules* explicitly does not permit the incorporation by reference of documents:

> [Emphasis in original] No incorporation by reference
>
> **57 (1)** The description must not incorporate any document by reference.

[41] In view of the foregoing, we maintain that the introduction of the description of Figures 1 to 8 on page 5, line 12 to page 6, line 4 of the description, the introduction of the embodiments on page 7, line 21 to page 7b, line 30 of the description, the introduction of a reference to Figure 1 on page 9, line 15 of the description, the introduction of the example on page 13, line 23 to page 14, line 22 of the description, the Sequence Listing, claims 1 to 7 on file and Figures 1 to 8 of the drawings constitute new matter not reasonably to be inferred from the originally filed specification of parent application 2,622,036.

[42] Although we consider that the above analysis is determinative of the new matter assessment in this case, we offer the following views regarding the applicability and timeliness of the Rule 20.6 submission during the International Phase. Notably, the corresponding international application WO2007/030771 was filed on

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[5] PCT Applicant's Guide Introduction to the International Phase

September 8, 2006. At this date, Rule 4.18 was entitled Additional Matter and did not permit requests for the inclusion of additional matter such as matter incorporated by reference. The provisions allowing for the inclusion of matter through a Statement of Incorporation by Reference under Rule 4.18 and subject to confirmation under Rule 20.6 did not come into effect until April 1, 2007[6],[7]. As explained in PCT Newsletter 05/2007[3], PCT Rule 20.6 does not apply to the corresponding international application WO2007/030771:

> [Emphasis added] Following the recent entry into force of amendments to the PCT Regulations concerning the incorporation by reference of missing elements or parts of the international application, it is possible for you to submit the missing pages of the description without affecting your international filing date, provided that certain conditions are met (further details follow). Amended PCT Rule 20 enables the inclusion of accidentally omitted *elements* of the international application referred to in PCT Article 11(1)(iii)(d) or (e) (that is, the whole of the description or the whole of the claims) or *parts* of the international application (that is, part of the description, part of the claims or part or all of the pages of drawings) that were completely contained in an earlier filed application, the priority of which is claimed in the international application, without affecting the international filing date. **Those amendments entered into force on 1 April 2007** and are applicable in respect of international applications filed on or after that date **(hence they will not apply to international applications in respect of which one or more elements referred to in PCT Article 11(1)(iii) were first received by the receiving Office before 1 April 2007)**.

[43] This is consistent with the lack of any statement of incorporation by reference in the request submitted with international application WO2007/030771 filed on September 8, 2006[2]. The required statement of incorporation by reference under PCT Rule 4.18 was only preprinted in the request form dated 1 April 2007: PCT Newsletter 05/2007[3].

[44] Further, even if the provisions under Rule 4.18 and Rule 20.6 were in force at the time the corresponding international application WO2007/030771 was filed, it appears that the time limit for submission of an incorporation by reference expired before the Applicant filed a Notice under Rule 20.6 to include the contents of the priority document on March 7, 2008.

[45] Rule 20.7 is the relevant provision for time limits and reads as follows:

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[6] History of the PCT Regulations (June 19, 1970n - July 1, 2022) (wipo.int)

[7] FAQs: Amendments to the PCT Regulations (April 1, 2007) (wipo.int)

20.7 *Time Limit*

(a) The applicable time limit referred to in Rules 20.3(a) and (b), 20.4, 20.5(a), (b) and (c), 20.5*bis*(a), (b) and (c), and 20.6(a) shall be:

(i) where an invitation under Rule 20.3(a), 20.5(a) or 20.5*bis*(a), as applicable, was sent to the applicant, two months from the date of the invitation;

(ii) where no such invitation was sent to the applicant, two months from the date on which one or more elements referred to in Article 11(1)(iii) were first received by the receiving Office.

(b) Where neither a correction under Article 11(2) nor a notice under Rule 20.6(a) confirming the incorporation by reference of an element referred to in Article 11(1)(iii)(d) or (e) is received by the receiving Office prior to the expiration of the applicable time limit under paragraph (a), any such correction or notice received by that Office after the expiration of that time limit but before it sends a notification to the applicant under Rule 20.4(i) shall be considered to have been received within that time limit.

[46] The Applicant argues that Rule 20.7(b) is the relevant provision for international application WO2007/030771 and, because there was no notice under Rule 20.4(i) sent by the Receiving Office to the Applicant, their Notice under Rule 20.6 should be considered to have been timely filed. We respectfully disagree with the Applicant's interpretation of Rule 20.7 as it applies to international application WO2007/030771 for the following reasons: [Emphasis added]

a. It is not a reasonable interpretation because it would effectively nullify the clear time limit provision under Rule 20.7(a)(ii).

b. We consider that a more reasonable interpretation of Rule 20.7 as a whole is:

   i. Rule 20.7(a)(ii) governs time limits of cases where no invitation by the Receiving Office has been sent to submit missing or correct elements or parts, as it is the case for international application WO2007/030771. In such cases, the time limit to confirm the incorporation by reference is two months from the date on which papers were first received by the Receiving Office.

   ii. Rule 20.7(b) governs time limits of cases covered by 20.7(a)(i) that would

be the subject of a negative determination under Article 11(1) in absence of a timely response before the two month time limit to an invitation under Rule 20.3(a), 20.5(a) or 20.5bis(a). Simply put, Rule 20.7(b) allows a late response to an invitation to be considered to have been received in time as long as the late response is received before the Receiving Office could notify the applicant under Rule 20.4(i) of a negative determination under Article 11(1).

c. We consider that our interpretation is aligned with the information provided in the PCT Applicant's Guide[5]:

> 6.029. What is the time limit for confirming the incorporation by reference of missing or correct elements or parts?
>
> Rule 20.7
> Where no invitation by the receiving Office has been sent to submit missing or correct elements or parts (Form PCT/RO/103 or PCT/RO/107), the time limit to confirm is two months from the date on which papers were first received by the receiving Office.

[47] In view of the foregoing, we consider that the time limit applicable to international application WO2007/030771 for confirming the incorporation by reference of missing elements under Rule 20.6 was two months from the date on which papers were first received by the Receiving Office. For international application WO2007/030771, the time limit to confirm was two months from the filing date of September 8, 2006. However, a Notice under Rule 20.6 to include the contents of the priority document was not made until March 7, 2008.

[48] Finally, contrary to the Applicant's submissions, we do not agree that the issuance of United States Patent 8945573 or the identification of the Notice under Rule 20.6 as a related document on Patentscope is evidence that the Receiving Office accepted the Notice under Rule 20.6 for all designated states. Regarding issued United States Patent 8945573, we note that it has a filing date of March 10, 2008 and not September 8, 2006 which is the filing date of the present application. No corresponding United States Patent containing the disputed subject-matter was granted with a filing date of September 8, 2006. Regarding the publication of the Notice under Rule 20.6, the contents of this submission do not appear to have been considered to have been contained in the international application at filing as they were never published as part of the international application and only appear as a related document[2].

[49] In view of the above analysis, we conclude that the pending specification and drawings contain new matter not reasonably to be inferred from the originally filed specification of parent application 2,622,036, contrary to section 38.2 of the *Patent Act*[1].

UTILITY

Legal Background

[50] Utility is required by section 2 of the *Patent Act*:

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

[51] In AstraZeneca Canada Inc v Apotex Inc, 2017 SCC at paras 54 to 55 [AstraZeneca], the Supreme Court of Canada outlines the approach to follow to determine whether a patent discloses an invention with sufficient utility under section 2 of the *Patent Act*:

> [54] To determine whether a patent discloses an invention with sufficient utility under s. 2, courts should undertake the following analysis. First, courts must identify the subject-matter of the invention as claimed in the patent. Second, courts must ask whether that subject-matter is useful—is it capable of a practical purpose (i.e., an actual result)?
>
> [55] The Act does not prescribe the degree or quantum of usefulness required, or that every potential use be realized—a scintilla of utility will do. A single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date (*AZT,* at para 56).

[52] As indicated above, the inventor must either have demonstrated the utility of the invention, or have been capable of soundly predicting its utility as of the filing date. Utility cannot be supported by evidence and knowledge that only became available after this date: Apotex Inc v Wellcome Foundation Ltd, 2002 SCC 77 at para 56 [AZT], cited in the passage above.

[53] In AZT, at paras 70 to 71, the Supreme Court of Canada lists the requirements to

be met for a sound prediction of utility:

- there must be a factual basis for the prediction;
- the inventor must have, at the date of the patent, an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis; and
- there must be proper disclosure of the factual basis and line of reasoning.

[54] These requirements are assessed from the perspective of the person skilled in the art to whom the patent is directed, considering the relevant common general knowledge. Further, with the exception of the common general knowledge, the factual basis and sound line of reasoning must be included in the patent application: Bell Helicopter Textron Canada Ltée v Eurocopter SAS, 2013 FCA 219 at paras 152 to 153 [Bell Helicopter].

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

Analysis

[56] The Preliminary Review letter, on pages 10 to 13, explains why in our preliminary view the claims on file encompass subject-matter for which utility has not been established by demonstration or sound prediction:

> [Bolding indicates date corrected from Preliminary Review letter]
> According to page 4 of the Final Action, the claimed subject-matter has not been established by demonstration or sound prediction essentially because there is no evidence in the parts of the pending specification that correspond to the originally filed specification of parent application 2,622,036 “for the utility of a composition or combination comprising a peptide comprising a sequence as set forth in SEQ ID NO: 17 or 18 and an antibody that binds to an immunogenic region of Her2/neu”.
>
> The Response to the Final Action, on page 3, disagrees with this assessment and submits that the arguments presented for the new matter defect also apply to this defect. It further submits that the subject-matter on pages 5, 6, 7, 7a, 7b, 13 and 14 of the Description, the

Sequence Listing and Figures 1 to 8 of the drawings can be relied on to establish the utility of the claimed subject-matter.

As indicated above, utility must be established by either demonstration or sound prediction as of the filing date: AZT at para 56. Further, there is no requirement to disclose the utility of the invention to satisfy the requirements of section 2 of the *Patent Act*: AstraZeneca at para 58.

A review of the prosecution history of parent application 2,622,036 reveals that the United States Provisional application 60/714,865 filed on September 8, 2005 contains Attachment A which demonstrates the enhanced lysis of various Her2/neu expressing tumor cell lines treated with a combination comprising a sequence as set forth in SEQ ID NO: 17 (referred to therein as GP2) and the antibody trastuzumab. Further, during the prosecution of the present application, the Applicant indicates in the response dated January **14, 2016** that Attachment A provides support for the subject-matter of pages 5, 6, 7, 7a, 7b, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings.

Therefore, given that it appears that the subject-matter of pages 5, 6, 7, 7a, 7b, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings contains information that is relevant to the demonstration of utility that existed prior the filing date of the present application, as evidenced by Attachment A of United States Provisional application 60/714,865, it is our preliminary view that this information can be relied on to establish demonstrated utility.

However, Attachment A does not provide any demonstration of the utility of a peptide comprising a sequence as set forth in SEQ ID NO: 18 and the antibody trastuzumab. Therefore, what must be considered is whether the utility of this peptide was soundly predicted at the filing date. Although the subject-matter on pages 5, 6, 7, 7a, 7b, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings and in Attachment A of United States Provisional application 60/714,865, may provide a factual basis for the utility of a composition or combination comprising a peptide comprising a sequence as set forth in SEQ ID NO: 18 and the antibody trastuzumab, we disagree that this subject-matter can be relied on to establish whether the utility of this claimed subject-matter was soundly predicted. As explained above, with the exception of common general knowledge, only information that is contained in the parts of the pending specification that correspond to the originally filed specification of parent application 2,622,036 can be used to establish whether the requirements for a sound prediction of this claimed subject-matter have been met: Bell Helicopter para 153.

As indicated above, we have already presented our preliminary view that the information on pages 5, 6, 7, 7a, 7b, 9, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings contain new

matter that the person skilled in the art would not have reasonably inferred based on the originally filed specification of parent application 2,622,036. This means that this information cannot be relied on to establish the utility of a composition or combination comprising a peptide comprising a sequence as set forth in SEQ ID NO: 18 and the antibody trastuzumab by sound prediction.

What is the subject-matter of the invention as claimed?

In our preliminary view the subject-matter of the invention relates to methods of identifying immunogenic peptides that may provoke an unwanted immune response in a host. The identification of these peptide sequences, that are involved in antibody binding, is useful for preventing, suppressing and treating immune-related diseases. Page 8 of the originally filed description refers to a preferred embodiment wherein a unique immunogenic region of the Her2/neu protein was identified. Therefore, the subject-matter of the invention as claimed that must be useful is a peptide consisting of the sequence of SEQ ID NO: 17 or 18 and the antibody trastuzumab to treat a Her2/neu expressing cancer.

Is that subject-matter useful?

As indicated above, at the time the application was filed, a peptide consisting of the sequence of SEQ ID NO: 17 and the antibody trastuzumab had been demonstrated to treat a Her2/neu expressing cancer. Although, there is no indication in the parts of the pending specification that correspond to the originally filed specification of parent application 2,622,036 that states a peptide consisting of the sequence of SEQ ID NO: 17 will be useful to treat a Her2/neu expressing cancer, as explained in AstraZeneca, there is no requirement to disclose the utility of the invention to satisfy the requirements of section 2 of the *Patent Act* (para 58).

Therefore, in our preliminary view the demonstration, before the filing date, that a peptide consisting of the sequence of SEQ ID NO: 17 would be useful to treat a Her2/neu expressing cancer is appropriately related to the subject-matter of the present application and meets the requirements of utility under section 2 of the *Patent Act*.

However, we have also established that at the time the application was filed, the utility of a peptide comprising a sequence as set forth in SEQ ID NO: 18 and the antibody trastuzumab had not been demonstrated. Further, there is no indication in the parts of the pending specification that correspond to the originally filed specification of parent application 2,622,036 that discloses a peptide consisting of the sequence of SEQ ID NO: 18 and its use to treat a Her2/neu expressing cancer.

> In our preliminary view, in the absence of the disclosure of a peptide consisting of the sequence of SEQ ID NO: 18 and its use to treat a Her2/neu expressing cancer, the person skilled in the art would consider that there is no factual basis or sound line of reasoning to support a sound prediction for the therapeutic utility of a peptide consisting of the sequence of SEQ ID NO: 18 and the antibody trastuzumab to treat a Her2/neu expressing cancer.
>
> Therefore, it is our preliminary view that claims 1 to 7 on file encompass subject-matter for which utility has not been established by demonstration or sound prediction, contrary to section 2 of the *Patent Act*.

[57] In the Response to the Preliminary Review letter and at the hearing the Applicant submitted that the arguments presented in respect of the new matter defect also apply to this defect. However, as explained above in the new matter assessment, we do not agree with the submissions in the Response to the Preliminary Review letter and at the hearing that the information on pages 5, 6, 7, 7a, 7b, 9, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings can be reasonably inferred based on the originally filed specification of parent application 2,622,036.

[58] Therefore, we maintain the foregoing reasoning and conclude that claims 1 to 7 on file encompass subject-matter for which utility has not been established by demonstration or sound prediction, contrary to section 2 of the *Patent Act*.

LACK OF SUPPORT

Legal Background

[59] Section 60 of the *Patent Rules* (equivalent to section 84 of the former *Rules*) requires that the claims be fully supported by the description:

> The claims must be clear and concise and must be fully supported by the description independently of any document referred to in the description.

[60] Section 16.05 of the Manual of Patent Office Practice (Canadian Intellectual Property Office, October 2019) provides the following guidance on the requirements of section 60 of the *Patent Rules*:

A claim must be fully supported by the description as required by section 60 of the *Patent Rules*. All the characteristics of the embodiment of the invention which are set forth in the claim must be fully set forth in the description (Section 60 of the *Patent Rules*). However, since any claims included in the application at the time of filing are part of the specification (see subsection 27(4) of the *Patent Act* and the definition of "description" in section 2 of the *Patent Rules* subsection 1(1) of the *Patent Rules*), any matter in the originally filed claims that was not included in the description as filed may be added to the description (except for divisional applications which have further requirements regarding new subject-matter see section 20.04 for more details).

A claim is objected to for lack of support by the description if the terms used in the claim are not used in the description and cannot be clearly inferred from the description. Terms used in the claims and in the description must be used in the same sense.

Analysis

[61] The Preliminary Review letter, on pages 14 to 15, explains why in our preliminary view the claims on file lack support:

> According to page 4 of the Final Action, there is no support in the description as originally filed in the parent application 2,622,036 for the subject-matter of the claims on file:
>
> > In the parts of the description that were originally filed, or which can be inferred from the originally filed specification, there is no support for the utility of a peptide (or composition comprising said peptide) comprising a sequence as set forth in SEQ ID NO: 17 or 18 and an antibody that binds to an immunogenic region of Her2/neu to treat cancer. […] As Applicant has not disclosed a peptide comprising an amino acid sequence as set forth in SEQ ID NO: 17 or 18 and an antibody that binds to an immunogenic region of Her2/neu, claims 1-7 are regarded as being directed to speculative subject matter.
>
> The Response to the Final Action, on page 4, disagrees with this assessment and submits that the arguments presented for the new matter defect also apply to this defect. It further submits that the subject-matter on pages 5, 6, 7, 7a, 7b, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings can be relied on in establishing support in the description of the claimed subject-matter.

Although the subject-matter on pages 5, 6, 7, 7a, 7b, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings may provide support for the utility of a peptide comprising a sequence as set forth in SEQ ID NO: 17 or 18 and the antibody trastuzumab to treat a Her2/neu cancer, we disagree that this subject-matter can be relied on to establish support in the description of the claimed subject-matter.

As indicated above, we have already presented our preliminary view that the information on pages 5, 6, 7, 7a, 7b, 9, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings contain new matter that the person skilled in the art would not have reasonably inferred based on the originally filed specification of parent application 2,622,036. This means that this information cannot be relied on to establish support in the description of the claimed subject-matter.

As explained in section 16.05 of the Manual of Patent Office Practice, section 60 of the *Patent Rules* requires that all the characteristics of the embodiment of the invention which are set forth in a claim must be fully set forth in the description. Therefore, a claim will lack support in the description if the terms used in the claim are not used in the description and cannot be clearly inferred from the originally filed specification.

We agree with the Final Action, there is no support in the parts of the pending specification that correspond to the originally filed specification of parent application 2,622,036 for the utility of a peptide consisting of the sequence of SEQ ID NO: 17 or 18 to treat a Her2/neu expressing cancer.

In addition, we agree with the Final Action that the originally filed specification of parent application 2,622,036 simply teaches general methods of identifying immunogenic peptides. Although page 8 of the originally filed description refers to a preferred embodiment wherein a unique immunogenic region of the Her2/neu protein was identified, this region is neither disclosed, nor shown to be therapeutically effective.

In our preliminary view, in the absence of the disclosure of a peptide consisting of the sequence of SEQ ID NO: 17 or 18 and its use treat a Her2/neu expressing cancer, the person skilled in the art would not infer the therapeutic utility of a peptide consisting of the sequence of SEQ ID NO: 17 or 18 and the antibody trastuzumab to treat a Her2/neu expressing cancer from the originally filed specification of parent application 2,622,036.

Therefore, it is our preliminary view that the subject-matter of claims 1 to 7 on file lack support in the description, contrary to section 60 of the *Patent Rules*.

[62] In the Response to the Preliminary Review letter and at the hearing the Applicant

submitted that the arguments presented in respect of the new matter defect also apply to this defect. However, as explained above in the new matter assessment, we do not agree with the submissions in the Response to the Preliminary Review letter and at the hearing that the information on pages 5, 6, 7, 7a, 7b, 9, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings can be reasonably inferred based on the originally filed specification of parent application 2,622,036.

[63] Therefore, we maintain the foregoing reasoning and conclude that claims 1 to 7 on file lack support in the description, contrary to section 60 of the *Patent Rules*.

SUFFICIENCY OF DISCLOSURE

Legal Background

[64] Subsection 27(3) of the *Patent Ac*t requires, among other things, a specification of a patent to correctly and fully describe an invention, and to enable its practice:

> 27(3) The specification of an invention must:
>
> (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
>
> (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
>
> […].

[65] A determination of whether the specification complies with paragraphs 27(3)(a) and 27(3)(b) of the *Patent Act* requires that three questions be answered: What is the invention? How does it work? Having only the specification, can the person of skill in the art produce the invention using only the instructions contained in the disclosure?: Teva Canada Ltd v Novartis AG, 2013 FC 141 citing Teva Canada Ltd v Pfizer Canada Inc, 2012 SCC 60 [Teva] and Consolboard v MacMillan Bloedel (Sask) Ltd, [1981] 1 SCR 504 at 520 [Consolboard].

[66] With respect to this third question, "it is necessary that no additional inventive ingenuity be required in order to make the patent work": Aventis Pharma Inc v Apotex Inc, 2005 FC 1283 at para 172. A patent will not be invalid for insufficient disclosure where routine experimentation is required of the skilled person, but the Supreme Court of Canada has held that a disclosure is insufficient if the specification "necessitates the working out of a problem": Idenix Pharmaceuticals, Inc v Gilead Pharmasset LLC, 2017 FCA 161 at para 19, citing Pioneer Hi-Bred v Canada [1989] 1 SCR 1623 at 1641.

[67] In Consolboard, at page 517, the Supreme Court of Canada referred to the textbook Canadian Law and Practice Relating to Letters Patent for Inventions (1969, 4th edition) from which it quoted H.G. Fox as saying "the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired".

[68] Further, "it is not enough for the disclosure to teach how to make the preferred embodiment. The disclosure must teach the skilled person to put into practice all embodiments of the invention, and without exercising inventive ingenuity or undue experimentation": Seedlings Life Science Ventures, LLC v Pfizer Canada ULC, 2021 FCA 154, at para 68.

Analysis

[69] The Preliminary Review letter, on pages 17 to 18, explains why in our preliminary view the specification, insofar as it relate to the claims on file, is insufficient:

> Pages 4 to 5 of the Final Action explain why, in view of the new matter defect, the specification does not correctly and fully describe the invention and its operation or use, so as to enable any person skilled in the art to practice the invention:
>
> > In the parts of the specification that were originally filed, or which can be inferred from the originally filed application, Applicant has not disclosed any peptide that represents a portion of the sequence of Her2/neu, nor how to use said peptide to treat cancer.
>
> The Response to the Final Action, on page 4, disagrees with this assessment and submits that the arguments presented for the new

matter defect also apply to this defect. It further submits that the subject-matter on pages 5, 6, 7, 7a, 7b, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings can be relied on in establishing enablement of the claimed subject-matter.

Although the subject-matter on pages 5, 6, 7, 7a, 7b, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings may provide sufficient disclosure of a peptide comprising a sequence as set forth in SEQ ID NO: 17 or 18 and the antibody trastuzumab to treat a Her2/neu cancer, we disagree that this subject-matter can be relied on to establish enablement of the claimed subject-matter.

As indicated above, we have already presented our preliminary view that the information on pages 5, 6, 7, 7a, 7b, 9, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings contain new matter that the person skilled in the art would not have reasonably inferred based on the originally filed specification of parent application 2,622,036. This means that this information cannot be relied on to establish sufficient disclosure of the claimed subject-matter.

We agree with the Final Action, there is no disclosure in the parts of the pending specification that correspond to the originally filed specification of parent application 2,622,036 of any peptide that represents a portion of the sequence of Her2/neu, nor of how to use said peptide to treat cancer.

The reference in the originally filed specification of parent application 2,622,036 to a preferred embodiment wherein a unique immunogenic region of the Her2/neu protein was identified does not provide a correct and full description of a peptide consisting of the sequence of SEQ ID NO: 17 or 18 and its use treat a Her2/neu expressing cancer.

Further, in the absence of the disclosure of a peptide consisting of the sequence of SEQ ID NO: 17 or 18, the person skilled in the art would require inventive ingenuity to solve the problem of identifying peptides that represent a portion of the sequence of Her2/neu, are therapeutically effective to treat a Her2/neu expressing cancer and can be used in combination with the antibody trastuzumab.

Therefore, it is our preliminary view that the specification does not correctly and fully describe the invention, nor does it enable its use insofar as it relates to claims 1 to 7 on file, contrary to paragraphs 27(3)(a) and (b) of the *Patent Act*.

[70] In the Response to the Preliminary Review letter and at the hearing the Applicant submitted that the arguments presented in respect of the new matter defect also apply to this defect. However, as explained above in the new matter assessment,

we do not agree with the submissions in the Response to the Preliminary Review letter and at the hearing that the information on pages 5, 6, 7, 7a, 7b, 9, 13 and 14 of the Description, the Sequence Listing and Figures 1 to 8 of the drawings can be reasonably inferred based on the originally filed specification of parent application 2,622,036.

[71] Therefore, we maintain the foregoing reasoning and conclude that the specification does not correctly and fully describe the invention, nor does it enable its use insofar as it relates to claims 1 to 7 on file, contrary to paragraphs 27(3)(a) and (b) of the *Patent Act*.

CONCLUSIONS

[72] We have determined that the description, sequence listing, drawings and claims contain new matter contrary to section 38.2 of the *Patent Act*[1].

[73] We have also determined that claims 1 to 7 on file encompass subject-matter for which utility has not been established by demonstration or sound prediction, contrary to section 2 of the *Patent Act*, that claims 1 to 7 on file lack support contrary to section 60 of the *Patent Rules* and that the specification, insofar as it relates to claims 1 to 7 on file, is insufficient contrary to subsection 27(3) of the *Patent Act*.

RECOMMENDATION OF THE BOARD

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

- the description, sequence listing, drawings and claims contain new matter contrary to section 38.2 of the *Patent Act*[1];
- claims 1 to 7 encompass subject-matter that lacks utility contrary to section 2 of the *Patent Act*;
- claims 1 to 7 lack support contrary to section 60 of the *Patent Rules*; and
- the specification, insofar as it relates to claims 1 to 7, is insufficient contrary to subsection 27(3) of the *Patent Act*.

Christine Teixeira	Marcel Brisebois	Ian de Belle
Member	Member	Member

DECISION OF THE COMMISSIONER

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

- the description, sequence listing, drawings and claims contain new matter contrary to section 38.2 of the *Patent Act*[1];
- claims 1 to 7 encompass subject-matter that lacks utility contrary to section 2 of the *Patent Act*;
- claims 1 to 7 lack support contrary to section 60 of the *Patent Rules*; and
- the specification, insofar as it relates to claims 1 to 7, is insufficient contrary to subsection 27(3) of the *Patent Act*.

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

Konstantinos Georgaras
Commissioner of Patents

Dated at Gatineau, Quebec

this 23rd day of June, 2023