Citation: Bioatla, LLC (Re), 2023 CACP 14

Commissioner's Decision #1647
Décision du commissaire nº 1647
Date: 2023-04-17

TOPIC:	F00	Novelty
	B00	Ambiguity or indefiniteness
SUJET:	F00	Nouveauté
	B00	Caractère ambigu ou indéfini

Application No. : 3,021,086

Demande nº 3 021 086

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 3,021,086 having been rejected under subsection 199(1) of the *Patent Rules* (SOR/2019-251), 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 withdraw the rejection and allow the application.

Agent for the Applicant:

MBM INTELLECTUAL PROPERTY LAW LLP
275 Slater Street, 14th floor
Ottawa, Ontario
K1P 5H9

INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 3,021,086, which is entitled “Anti-Axl antibodies, antibody fragments and their immunoconjugates and uses thereof” and owned by Bioatla, LLC (the 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, the Panel’s recommendation is that the Commissioner of Patents withdraw the rejection and that the application be allowed.

BACKGROUND

The Application

[3] The application was filed under the *Patent Cooperation Treaty* and has an effective filing date in Canada of April 13, 2017. It was laid open to public inspection on October 19, 2017.

[4] The rejected application relates to conditionally active anti-Axl antibodies that have a higher binding affinity to Axl in a tumor microenvironment in comparison with their binding affinities to Axl in a non-tumor environment. This may also permit administration of higher dosages of the anti-Axl antibodies or more frequent treatment.

[5] The claims under review are claims 1 to 26 dated August 6, 2021 (the claims on file) that were rejected in the Final Action.

Prosecution history

[6] On September 24, 2021, a Final Action was written pursuant to subsection 199(1) of the *Patent Rules*. The Final Action states that the subject-matter of claims 1 to 26 is anticipated contrary to paragraph 28.2(1)(a) of the *Patent Act*. The Final Action also indicates that claim 26 is ambiguous and therefore non-compliant with subsection 27(4) of the *Patent Act.*

[7] In the Response to the Final Action dated January 24, 2022, the Applicant expressed general disagreement with the positions laid out in the Final Action, provided specific submissions as to why the claims on file are compliant with paragraph 28.2(1)(a) of the *Patent Act* and proposed an amended claims set (the proposed claims) containing amended claim 26 to address the clarity defect noted in the Final Action.

[8] On March 11, 2022, 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 as the Applicant's arguments presented in the Response to the Final Action are not persuasive and that the proposed amendments presented in the Response to the Final Action do not overcome all of the defects identified in the Final Action.

[9] In a letter dated March 15, 2022, 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 April 8, 2022, the Applicant confirmed their interest in having the review proceed.

Issues

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

- whether the subject-matter of claims 1 to 26 is anticipated, contrary to paragraph 28.2(1)(a) of the *Patent Act*; and
- whether claim 26 is ambiguous and does not comply with subsection 27(4) of the *Patent Act.*

[12] In light of our recommendation that the rejection be withdrawn and the application allowed, we have not reviewed the proposed claims.

FOLLOWING A PURPOSIVE CONSTRUCTION, WHICH CLAIMED ELEMENTS ARE ESSENTIAL?

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

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 of ordinary skill in the art (POSITA) in light of the relevant common general knowledge (CGK) 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 POSITA 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 of the claims on file

The POSITA and the relevant CGK

[16] In our view, the POSITA is a person practising in the fields of immunology and cancer therapy.

[17] For the present purpose and with respect to the CGK possessed by the POSITA, it is sufficient to say that the POSITA has CGK and technical experience for the production of therapeutic monoclonal antibodies of different types and knowledge of general conditions of tumor microenvironments versus non-tumor microenvironments.

The claims on file

[18] There are 26 claims on file. It is our view that independent claims 1, 2, 18, 23, 25 and 26 are independent claims and read as follows:

> 1. An antibody or antibody fragment that specifically binds to Axl protein, said antibody or antibody fragment comprising a heavy chain variable region including three heavy chain complementarity determining regions and a light chain variable region including three light chain complementarity determining regions, said three heavy chain complementarity determining regions having H1, H2, and H3 sequences, wherein:
>
> (a) the H1 sequence is $X_1GX_2X_3MX_4$ (SEQ ID NO: 1);
>
> (b) the H2 sequence is $LIKX_5SNGGTX_6YNQKFKG$ (SEQ ID NO: 2); and
>
> (c) the H3 sequence is $GX_7X_8X_9X_{10}X_{11}X_{12}X_{13}X_{14}DYX_{15}X_{16}$ (SEQ ID NO: 3),
>
> wherein
>
> X_1 is T or W,
>
> X_2 is H or A,
>
> X_3 is T,
>
> X_4 is N,
>
> X_5 is P,
>
> X_6 is S,
>
> X_7 is H,
>
> X_8 is Y,
>
> X_9 is E,
>
> X_{10} is S,
>
> X_{11} is Y,
>
> X_{12} is E,
>
> X_{13} is A,
>
> X_{14} is M,
>
> X_{15} is W, and
>
> X_{16} is G, and
>
> said three light chain complementarity determining regions having L1, L2, and L3 sequences, wherein:
>
> (d) the L1 sequence is $KASQDX_{17}X_{18}SX_{19}VX_{20}$ (SEQ ID NO: 4);

(e) the L2 sequence is $X_{21}X_{22}X_{23}TRX_{24}T$ (SEQ ID NO: 5); and

(f) the L3 sequence is $QEX_{25}X_{26}SX_{27}X_{28}X_{29}X_{30}$ (SEQ ID NO: 6), wherein

X_{17} is V,
X_{18} is S or V,
X_{19} is A,
X_{20} is A,
X_{21} is W,
X_{22} is Q,
X_{23} is D,
X_{24} is H,
X_{25} is H,
X_{26} is F,
X_{27} is T or P,
X_{28} is P,
X_{29} is L, and
X_{30} is T or R.

2. An antibody or antibody fragment that specifically binds to Axl protein, comprising a heavy chain variable region encoded by a DNA sequence selected from sequences of SEQ ID NOS: 11-13, and a light chain variable region encoded by a DNA sequence selected from SEQ ID NOS: 7-10.

18. An immunoconjugate comprising the antibody or antibody fragment of any one of claims 1-17.

23. A pharmaceutical composition comprising:
the antibody or antibody fragment of any one of claims 1-17, or the immunoconjugate of any one of claims 18-22; and
a pharmaceutically acceptable carrier.

25. Use of the pharmaceutical composition of any one of claims 23-24 to treat cancer.

26. A kit comprising the antibody or antibody fragment of any one of claims 1-17, or the immunoconjugate of any one of claims 18-22, or the pharmaceutical composition of any one of claims 23-24 and instructions for using the antibody or antibody fragment for a therapeutic and/or

> diagnostic assay, the immunoconjugate and/or the pharmaceutical composition.

[19] The dependent claims 3 to 17, 19 to 22 and 24 define further limitations with regard to: the heavy or light chain DNA sequence (claims 3 to 8), the complementarity determining regions amino acid sequences (claims 9 to 12), the relative affinity of the encompassed antibody for Axl under different microenvironment conditions (claims 13 and 16), the microenvironment condition (claims 14 and 15), the type of antibody (claim 17), the presence of one or more additional agents (claims 19, 20, 22 and 24), and the presence of a linker molecule between the antibody or antibody fragment and the additional agent(s) (claim 21).

Essential elements

[20] We consider that the POSITA reading claims 1 to 26 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 POSITA would understand that the element represented by one of said alternatives is essential. Further, there is no indication on the record before us that any claim elements are non-essential. It is therefore our view that the POSITA would consider all of the elements of claims 1 to 26 as essential.

IS THE SUBJECT-MATTER OF CLAIMS 1 TO 26 ON FILE ANTICIPATED?

[21] It is our view that the subject-matter of claims 1 to 26 is novel.

Legal background

[22] Paragraph 28.2(1)(a) of the *Patent Act* sets out the requirement that the subject-matter of a claim must be novel in view of a disclosure by the applicant itself:

> 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;
>
> […].

[23] There are two separate requirements to show that prior art anticipates a claimed invention: there must be a prior disclosure of the claimed subject-matter and the prior disclosure must enable the claimed subject-matter to be practised by the POSITA (*Apotex Inc v Sanofi–Synthelabo Canada Inc*, 2008 SCC 61 [Sanofi] at paras 24 to 29 and 49).

[24] "Prior disclosure" means that the prior art must disclose subject-matter which, if performed, would necessarily result in infringement of the patent. The POSITA looking at the disclosure is "taken to be trying to understand what the author of the description [in the prior patent] meant" (see Sanofi at para 32). At this stage, there is no room for trial and error or experimentation by the POSITA. The prior art is simply read "for the purposes of understanding it": see Sanofi, at paragraph 25, citing *Synthon B.V. v SmithKline Beecham plc*, [2006] 1 All ER 685, [2005] UKHL 59.

[25] The enablement requirement means that the prior art reference enables the POSITA to make and perform the invention, allowing for some trial and error experimentation to make it work (see Sanofi at paras 26 to 27).

[26] We understand from para 37 of Sanofi that the following (non-exhaustive) factors should be considered:

- Enablement is to be assessed having regard to the prior art reference as a whole including the specification and the claims (in the case of a prior patent). There is no reason to limit what the POSITA may consider in the prior art reference in order to discover how to perform or make the invention of the subsequent patent. The entire prior art reference constitutes prior art.

- The POSITA may use his or her CGK to supplement information contained in the prior art reference.

- The prior art reference must provide enough information to allow the subsequently claimed invention to be performed without undue burden. When considering whether there is undue burden, the nature of the invention must be taken into account. For example, if the invention takes place in a field of technology in which trials and experiments are generally carried out, the threshold for undue burden will tend to be higher than in circumstances in which less effort is normal. If inventive steps are required, the prior art will not be considered as enabling. However, routine trials are acceptable and would not be considered undue burden. But experiments or trials and errors are not to be prolonged even in fields of technology in which trials and experiments are generally carried out. No time limits on exercises of energy can be laid down; however, prolonged or arduous trial and error would not be considered routine.

- Obvious errors or omissions in the prior art reference will not prevent enablement if reasonable skill and knowledge in the art could readily correct the error or find what was omitted.

[27] The determinations as to disclosure and enablement must be made on the usual civil burden of balance and probabilities, and not to any more exacting standard such as quasi-criminal (*Abbott Laboratories v Sandoz Canada Inc,* 2008 FC 1359 aff'd 2009 FCA 94, at para 69).

Analysis of the claims

[28] We must determine if the subject-matter of claims 1 to 26 on file is anticipated by the disclosure of WO 2016/033331 [D2], a patent application with a publication date of March 3, 2016. D2 and the instant application have Short, J.M. as a listed inventor and Bioatla, LLC as the Applicant.

[29] According to page 1 of the Final Action, D2 discloses "antibodies, several of which are identical to those disclosed in the instant application (Table 3). D2 does not disclose that the antibodies bind Axl, but simply that they bind to "drug target X". D2 also discloses immunoconjugates, pharmaceutical compositions, methods of treating and diagnosing cancer, and associated kits".

[30] With regard to the disclosure requirement, page 2 of the Final Action essentially

submits the following:

> Specifically, D2 discloses the same antibodies or antibody fragments that specifically bind the Axl protein, as disclosed in the instant application. D2 does not disclose that the antibodies bind Axl, but simply that they bind to “drug target X”. However, based upon the fact that the antibodies have the same name and various kinetic parameters as those of the instant application (compare Table 3 of D2 with Table 5 of the instant application), it is clear that the antibodies are identical. D2 also discloses associated immunoconjugates, pharmaceutical compositions, use of the composition to treat cancer, and kits for diagnosis or treatment.

[31] In response, the Response to the Final Action submits on page 2 that the reasons stated in the Final Action “do not rely on the disclosure of D2, but require one skilled in the art to consult the disclosure of the present application *in addition* to the disclosure of the cited prior art D2, in order for one skilled in the art to have allegedly understood that the antibodies of D2 are the same as those disclosed in the instant application”. [emphasis in the original]

[32] Given that the issue is focused directly on the antibodies that appear in Table 3 of D2 and Table 5 of the instant application, both tables are reproduced below.

Table 3 - Summary of the conditionally active antibodies

Clone	CAB scFv	mg/ml	Aggregation (PBS,pH7.4)	Thermostability (1 h 60 °C)	increased binding at pH7.4 after heat treatment	Ka [M-s]	Kd[s^{-1}]	KD[M] pH6.0	SPR activity pH 6.0	SPR activity pH 7.4
BAP063.6-hum10F10-FLAG		7	No	100%	No	5.14E+06	8.38E-04	1.63E-10	100%	100%
BAP063.6-HC-H100Y-FLAG		6.6	N.D.			2.41E+06	5.12E-03	2.12E-09	80%	40%
BAP063.9-13-1-FLAG		5.3	No	100%	Yes	1.98E+06	2.88E-03	1.46E-09	100%	75%
BAP063.9-29-2-FLAG		4.9	No	100%	Yes	1.19E+06	2.14E-03	1.79E-09	90%	50%
BAP063.9-45-2-FLAG		5.4	No	reduced	Yes	1.53E+06	2.31E-03	1.51E-09	75%	25%
BAP063.9-13-3-FLAG	Yes	5.9	No	100%	Yes	1.42E+06	1.82E-03	1.28E-09	75%	0%
BAP063.9-21-3-FLAG		5.3	No	100%	No	1.53E+06	4.13E-03	2.69E-09	50%	25%
BAP063.9-21-4-FLAG		7	No	100%	No	1.03E+06	3.26E-03	3.16E-09	50%	0%
BAP063.9-29-4-FLAG		6.2	No	100%	(yes)	1.40E+06	2.21E-03	1.58E-09	75%	0%
BAP063.9-48-3-FLAG	Yes		<5%	reduced	Yes	8.92E+05	2.33E-03	2.61E-09	90%	0%

Table 5 - Summary of the conditionally active anti-Axl antibodies

Clone	mg/ml	estimated yield	actual yield	Aggregation (PBS,pH7.4)	Thermostability (1 h 60 °C)	Ka [M-s]	Kd[s^{-1}]	KD[M] pH6.0
BAP063.1-01-10	7	150	294	No	100%	5.14E+06	8.38E-04	1.63E-10
BAP063.6-01-05	6.6	150	238	N.D.		2.41E+06	5.12E-03	2.12E-09
BAP063.9-13-01	5.3	50	123	No	100%	1.98E+06	2.88E-03	1.46E-09
BAP063.9-29-02	4.9	50	102	No	100%	1.19E+06	2.14E-03	1.79E-09
BAP063.9-45-02	5.4	50	129	No	reduced	1.53E+06	2.31E-03	1.51E-09
BAP063.9-13-03	5.9	50	123	No	100%	1.42E+06	1.82E-03	1.28E-09
BAP063.9-21-03	5.3	50	117	No	100%	1.53E+06	4.13E-03	2.69E-09
BAP063.9-21-04	7	50	176	No	100%	1.03E+06	3.26E-03	3.16E-09
BAP063.9-29-04	8.2	50	196	No	100%	1.40E+06	2.21E-03	1.58E-09
BAP063.9-48-03	7	50	125	<5%	reduced	8.92E+05	2.33E-03	2.61E-09
BAP063.9-49-04	5.3	50	126	No	100%	2.35E+06	3.42E-03	1.45E-09
BAP063.9-61-01	5.1	50	97	<10%	100%	n.d.	n.d.	
BAP063.9-61-02	7	50	91	<10%	100%	1.72E+06	2.85E-03	1.66E-09

[33] On the basis of our understanding of the case law of the meaning of “prior disclosure”, it is our view that one relevant question is whether D2 discloses subject-matter which, if performed, would necessarily result in infringement of the claims on file if granted. It is our view that the POSITA who is looking at the disclosure of D2 and trying to understand what the author of the description meant, would consider that Example 7 on pages 96 and 97 and corresponding Table 3 disclose conditionally active biological antibodies with various physical properties and characteristics which serve to characterize said antibodies to some extent. What cannot be understood by the POSITA from a fair reading of D2 is the identity of the antigen(s) targeted by the antibodies of Table 3 as D2 discloses that they bind to “drug target X”.

[34] Determining if the antibodies of Table 3 of D2 would necessarily infringe the claims on file is a fact driven inquiry that requires *comparing* what is encompassed by the claims on file and the pertinent D2 disclosure detailed above. Therefore, it is our view that it is reasonable to consult the specification of the present application *and* the disclosure of the D2 to gather the relevant facts required. However, and in accordance with paragraph 28.2(1)(a) of the *Patent Act*, the disclosure analysis must start with the essential elements of the claims on file. Then, it must proceed to examine if the essential elements have been disclosed in D2.

[35] It is our view that the POSITA would not readily understand from a fair reading of

the instant description that the conditionally active anti-Axl antibodies described in Example 1, and corresponding Table 5 on pages 86 to 89, necessarily possess all the essential elements of the anti-Axl antibodies recited in the claims on file which includes the specified sequences. The description does not indicate which clones of Table 5 possess the complementarity determining regions encompassed by the scope of the claims. In that regard, the description only states at para [0112] that anti-Axl antibodies comprising heavy chain variable regions encoded by the DNA sequences of SEQ ID NOS: 11-13 and light chain variable regions encoded by the DNA sequences of SEQ ID NOS: 7-10 have been found to have a higher binding affinity to Axl at a pH found in the tumor microenvironment than at a pH in a non-tumor microenvironment.

[36] Once compared, it is apparent that the ten antibodies of Table 3 of D2 share the exact same kinetic binding constant values with ten antibodies of Table 5 of the instant application, a highly unlikely coincidence in the context of the respective documents that both relate to conditionally active biological antibodies and their use for the treatment of cancer. However, we have already found above that the antibodies of Table 5 of the instant application do not necessarily possess all the essential elements of the anti-Axl antibodies recited in the claims on file. Moreover, we consider that the POSITA would not readily understand from a fair reading of D2 that the antibodies of Table 3 of D2 necessarily possess the essential complementarity determining regions recited in the claims on file. Therefore, it is our view that the antibodies described in Table 3 of D2 are not necessarily encompassed by the claims on file.

[37] In any case, had we found that antibodies encompassed by the claims on file have been disclosed in Table 3 of D2, it would not have been the end of the inquiry. In accordance with the facts of the instant case, the phrase “if performed” in our introductory question at para [33] above bears weight and brings us directly to the second requirement of an anticipatory document: the prior disclosure must enable the claimed subject-matter to be practised by the POSITA without undue burden.

[38] The Final Action does not set forth the reasons for considering that the disclosure of D2 is, in fact, enabling when it comes to the antibodies that bind to “drug target X” listed in Table 3 beyond a mere statement that the antibodies “were available to practice the invention” found on page 3:

> The examiner disagrees with the applicant's assertion that the claimed subject matter was not fully disclosed and enabled by D2. D2 discloses the exact same antibodies and this would have been clear to a skilled worker. Defining the antibodies in a different manner does not change the fact that the antibodies were known in the art and were available to practice the invention. [emphasis added]

[39] In contrast, the Response to the Final Action offers on page 4 a reasoned argument and relevant facts as to why the disclosure of D2 is not enabling with regard to the antibodies listed in Table 3 of D2:

> Although, Example 7 of D2 discloses a method of producing a conditionally active antibody that binds to target "X" - D2 does not provide direct and unambiguous disclosure that such target "X" is Axl, much less the sequences of the present claimed antibodies or antibody fragments, in order to enable one skilled in the art to make the presently claimed antibodies. [emphasis in the original]

[40] Having in mind the factors that should be considered, and in accordance with the evidence of the instant case, it is our view that D2 does not provide enough information to allow the POSITA to produce and use the antibodies of Table 3 without undue burden. In absence of any information with regard to the target antigen, their antigen binding regions and/or their encoding nucleic acid sequence, it is our view that the D2 disclosure is not sufficient to enable the POSITA to make or use the antibodies of Table 3.

[41] In view of the foregoing, it also follows that the antibodies of Table 3 of D2 cannot be enabled without access to the antibodies *per se*. Contrary to the position expressed in the Final Action, we are not of the view that D2 made available the antibodies of Table 3. D2 does not suggest that said antibodies are commercially available and D2 does not provide a reliable access to said antibodies through deposits of these biological materials or otherwise. According to the *Manual of Patent Office Practice* (CIPO) at 23.06.06, revised on October 2019, a section which relates to considerations respecting anticipation in the context of biological material, the D2 disclosure would not be not anticipatory because of that consideration:

> Where an invention cannot be enabled without requiring access to a biological material associated with the invention, a description may lack sufficiency unless a

> deposit of this material was made [see 23.06.01]. This requirement extends to an allegedly anticipatory disclosure relevant under section 28.2 of the *Patent Act* [see Chapter 18 for further guidance]. Consequently, if a prior art disclosure requires access to a biological material in order for the matter described therein to be practised, the biological material must necessarily have been reliably available to the person skilled in the art before the claim date in order for the disclosure to be anticipatory.

[42] Therefore and in view of the above, we conclude that the subject-matter of claims 1 to 26 is not anticipated by the disclosure of D2 and complies with paragraph 28.2(1)(a) of the *Patent Act*.

IS CLAIM 26 AMBIGUOUS AND/OR UNCLEAR?

[43] In our view, claim 26 on file defines distinctly the subject-matter of the invention and complies with subsection 27(4) of the *Patent Act*.

Legal Background

[44] Subsection 27(4) of the *Patent Act* states that "[t]he specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed".

[45] In *Minerals Separation North American Corp v Noranda Mines Ltd*, [1947] Ex CR 306 at 352, 12 CPR 99, the Court emphasized the obligation of an applicant to make clear in the claims the ambit of the monopoly sought and the requirement that the terms used in the claims be clear and precise:

> By his claims the inventor puts fences around the fields of his monopoly and warns the public against trespassing on his property. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own. The terms of a claim must be free from avoidable ambiguity or obscurity and must not be flexible; they must be clear and precise so that the public will be able to know not only where it must not trespass but also where it may safely go.

Analysis of the claim

[46] According to the Final Action on page 4, the phrase "instructions for using the

antibody or antibody fragment for a therapeutic and/or diagnostic assay, the immunoconjugate and/or the pharmaceutical composition" is ambiguous since it is unclear to what the immunoconjugate and/or the pharmaceutical composition are meant to relate. In that regard, the Final Action suggests that the phrase "instructions for using the antibody or antibody fragment, the immunoconjugate and/or the pharmaceutical composition for a therapeutic and/or diagnostic assay" may have been intended instead.

[47] The Final Action further submits that the purpose of the therapeutic and/or diagnostic assay is not adequately defined as it is unclear if the assay is limited to a therapeutic and/or diagnostic assay for cancer.

[48] The Response to the Final Action does not contest or otherwise comment on the above views but nevertheless proposes amendments to amend claim 26 on file.

[49] Having reviewed claim 26 on file, we are of the view that, although claim 26 "is not a model of concision and lucidity" (*Letourneau v Clearbrook Iron Works Ltd*, 2005 FC 1229, at para 37), it can be given a reasonable interpretation by the POSITA with a mind willing to understand. We consider that the kit of claim 26 can be reasonably interpreted as comprising broad instructions for using the immunoconjugate and/or the pharmaceutical composition, not necessarily in a therapeutic and/or diagnostic assay.

[50] We are also of the view that claim 26 is clear with regard to the intended scope; it is not limited to a therapeutic and/or diagnostic assay for cancer.

[51] We are therefore of the view that claim 26 on file defines distinctly the subject-matter of the invention and complies with subsection 27(4) of the *Patent Act*.

CONCLUSIONS

[52] We have determined that:

- the subject-matter of claims 1 to 26 on file is not anticipated by the disclosure of D2 and complies with paragraph 28.2(1)(a) of the *Patent Act*; and
- claim 26 defines distinctly the subject-matter of the invention and complies with subsection 27(4) of the *Patent Act*.

RECOMMENDATION OF THE BOARD

[53] In light of the above, we are of the view that the rejection is not justified on the basis of the defect indicated in the Final Action notice and have reasonable grounds to believe that the instant application complies with the *Patent Act* and the *Patent Rules*. We recommend that the Applicant be notified in accordance with subsection 86(10) of the *Patent Rules* that the rejection of the instant application is withdrawn and that the instant application has been found allowable.

[54] As we consider the application in its present form to be allowable, we have not reviewed the proposed claims. In accordance with paragraph 86(7)(b) of the *Patent Rules*, these proposed amendments are considered not to have been made.

Marcel Brisebois	Ryan Jaecques	Christine Teixeira
Member	Member	Member

DECISION OF THE COMMISSIONER

[55] I concur with the conclusions and recommendation of the Board. In accordance with subsection 86(10) of the *Patent Rules*, I hereby notify the Applicant that the rejection of the instant application is withdrawn, the instant application has been found allowable and I will direct my officials to issue a Notice of Allowance in due course.

Konstantinos Georgaras
Commissioner of Patents

Dated at Gatineau, Quebec

this 17 day of April, 2023.