

# Patenting antibodies in Canada? Don't forget claims to competitive antibodies

September 27, 2021

Those seeking patent protection for immune-based therapeutic innovations in Canada should be aware that claims to antibodies defined by competitive binding (herein termed “competitive antibodies”) may be available, even in the absence of working examples or literal support. The availability of these claims contrasts favourably with past practice in Canada, and could provide innovators with important protection for key epitopes that is not otherwise available.

## CIPO's revised guidelines

Following a 2016 decision of the Patent Appeal Board (the Board)<sup>1</sup>, the Canadian Intellectual Property Office (CIPO) revised section 23 of its Manual of Patent Office Practice (MOPOP)<sup>2</sup> to update examination practices for claims to antibodies. These changes relaxed historically strict written description and enablement requirements and provided guidance for the examination of claims to subclasses of antibodies. Some of these changes were directly related to the humanized antibody claims upheld by the Board, while others were a consequence of the Board's wider acknowledgment of the evolving state of the art.

In the latter category, a lesser-known change is the availability of claims to competitive antibodies, even in cases in which no such competitive antibody has been produced or experimentally tested.

## Sufficiency, enablement, and clarity requirements

Example 2 of subsection 23.07 provides the following fact scenario relevant to competitive antibodies:

**“The description discloses the production of murine monoclonal antibody, M1, specific for the RF protein for use in diagnosing Rheumatoid arthritis. Also disclosed are details of a biological deposit of the hybridoma that produces the antibody. A further embodiment includes monoclonal antibodies that compete with M1 although a working example of competing antibodies is not disclosed. A search of the prior art identified the murine RF protein and its full amino acid sequence.”<sup>3</sup>**

Claim 3 of Example 2 reads as follows:

**“3. An antibody that competes for specific binding to RF with monoclonal antibody M1 produced by the hybridoma having accession number IDAC 022612-11.”**

The analysis provided for Example 2 states that claim 3 meets clarity, enablement, and written description requirements:

**“In claim 3, the antibody is distinctly and explicitly defined as one that competes with monoclonal antibody M1 for specific binding to the RF protein and, thus, satisfies subsection 27(4) of the Act. As noted above, the M1 antibody produced by the hybridoma having accession number IDAC 022612-11 is novel and non-obvious and it follows that an antibody that competes for specific binding with that particular antibody is also novel and non-obvious. Appreciating that the person skilled in the art could identify competing antibodies without undertaking undue experimentation or the need to exercise inventive ingenuity (e.g., by using routine competition binding assays), the subject-matter of claim 3 is enabled. Assuming that the hybridoma which produces M1 was deposited in accordance with the Patent Rules, the provision of the deposited hybridoma serves to provide a correct and full description of the M1 antibody and antibodies in general that specifically bind the same epitope, i.e., competing antibodies. Therefore, the claim is supported by a specification that satisfies subsection 27(3) of the Patent Act and complies fully with the Patent Act and Rules.”**

Thus, a claim to an antibody that competes with an antibody produced by a hybridoma cell line meets enablement and written description requirements, even when no such competitive antibody has been made. The sequence of the specific epitope within the target is not required. This mode of claiming is thus well suited to situations in which the epitope is not yet known, or in which the epitope defies conventional description as a linear sequence.

It is also possible to obtain claims to antibodies that compete for binding with a reference antibody defined by sequence. Minimally, the complementarity-determining region (CDR) sequences of the reference antibody must be defined in the claim. For both modes of claiming, it is necessary to stipulate that the competition involves “specific binding” to the same target.

## **Novelty and inventiveness requirements**

The availability of claims to competitive antibodies also depends on meeting novelty and inventiveness requirements. The analysis provided for claim 3 indicates that prior disclosure of a full-length target sequence does not adversely impact subsequent claims to competitive antibodies that bind to a specific epitope. Because the reference antibody functionally conveys information about the epitope, claims to competitive antibodies will tend to rise or fall with the novelty and inventiveness of the reference antibody itself. **CIPO’s treatment of claims to competitive antibodies is thus consistent with its treatment of claims to other types of antibodies.**

## **Summary**

The availability of claims to competitive antibodies is relatively new in Canada, and **contrasts markedly with CIPO's ongoing strict treatment of other aspects of antibody claims** during examination. For example, variation in CDR sequences may not be claimed unless exemplified, and, even then, claims will be strictly limited to the scope of what has been tested. With these restrictive elements of examination still in effect, claims to competitive antibodies provide an attractive alternative to secure additional coverage for key epitopes that cannot otherwise be protected.

<sup>1</sup> Re Chugai Seiyaku and Kabushiki Kaisha (CD 1398).

<sup>2</sup> [Manual of Patent Office Practice](#), online: The Canadian Intellectual Property Office s. 23.07.

<sup>3</sup> Ibid s. 23.07.02c, Example 2.

By

[Graeme Boocock](#)

Expertise

[Intellectual Property, Patents](#)

---

## **BLG | Canada's Law Firm**

As the largest, truly full-service Canadian law firm, Borden Ladner Gervais LLP (BLG) delivers practical legal advice for domestic and international clients across more practices and industries than any Canadian firm. With over 725 lawyers, intellectual property agents and other professionals, BLG serves the legal needs of businesses and institutions across Canada and beyond – from M&A and capital markets, to disputes, financing, and trademark & patent registration.

[blg.com](http://blg.com)

### **BLG Offices**

#### **Calgary**

Centennial Place, East Tower  
520 3rd Avenue S.W.  
Calgary, AB, Canada  
T2P 0R3

T 403.232.9500  
F 403.266.1395

#### **Ottawa**

World Exchange Plaza  
100 Queen Street  
Ottawa, ON, Canada  
K1P 1J9

T 613.237.5160  
F 613.230.8842

#### **Vancouver**

1200 Waterfront Centre  
200 Burrard Street  
Vancouver, BC, Canada  
V7X 1T2

T 604.687.5744  
F 604.687.1415

#### **Montréal**

1000 De La Gauchetière Street West  
Suite 900  
Montréal, QC, Canada  
H3B 5H4

T 514.954.2555  
F 514.879.9015

#### **Toronto**

Bay Adelaide Centre, East Tower  
22 Adelaide Street West  
Toronto, ON, Canada  
M5H 4E3

T 416.367.6000  
F 416.367.6749

The information contained herein is of a general nature and is not intended to constitute legal advice, a complete statement of the law, or an opinion on any subject. No one should act upon it or refrain from acting without a thorough examination of the law after the facts of a specific situation are considered. You are urged to consult your legal adviser in cases of specific questions or concerns. BLG does not warrant or guarantee the accuracy, currency or completeness of this publication. No part of this publication may be reproduced without prior written permission of Borden Ladner Gervais LLP. If this publication was sent to you by BLG and you do not wish to receive further publications from BLG, you may ask to remove your contact information from our mailing lists by emailing [unsubscribe@blg.com](mailto:unsubscribe@blg.com) or manage your subscription preferences at [blg.com/MyPreferences](http://blg.com/MyPreferences). If you feel you have received this message in error please contact [communications@blg.com](mailto:communications@blg.com). BLG's privacy policy for publications may be found at [blg.com/en/privacy](http://blg.com/en/privacy).

© 2025 Borden Ladner Gervais LLP. Borden Ladner Gervais LLP is an Ontario Limited Liability Partnership.