Patenting antibodies in Canada? Don’t forget claims to competitive antibodies

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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)[1], the Canadian Intellectual Property Office (CIPO) revised section 23 of its Manual of Patent Office Practice (MOPOP)[2] 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."[3]

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.

[1] *Re Chugai Seiyaku and Kabushiki Kaisha* (CD 1398).

[2] Manual of Patent Office Practice, online: The Canadian Intellectual Property Office s. 23.07.

[3] *Ibid* s. 23.07.02c, Example 2.

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