BULLETIN
Life Sciences

FASKEN MARTINEAU
www.fasken.com

April 18, 2011

Monoclonal Antibodies Now Patentable in Canada Without Working Example

By: Serge Lapointe, Ph.D. | Montréal

In a recently published decision[1], the Canadian Patent Appeal Board endorsed the principle established in other jurisdictions that in cases where an antigen is a novel polypeptide and has been fully characterized, a pioneering applicant can claim monoclonal antibodies that are immunoreactive with the polypeptide without the applicant actually having made or deposited a specific embodiment of such antibody. Prior to that decision, the Canadian Intellectual Property Office (CIPO) followed and relied upon a previous decision where claims to a monoclonal antibody were not enabled when the application failed to set out a detailed protocol or when the specification did not provide evidence of enablement in the form of the actual preparation of a monoclonal antibody[2].

In arriving at its decision, the Board referred to relevant case law from the United States and the United Kingdom where it has been recognized that it generally does not require undue effort to make and identify monoclonal antibodies that are capable of specifically binding to a novel and defined polypeptide. In the present case, the Board found that anti-Type I IL-1R monoclonal antibodies were properly enabled because the specification of the patent application provided a full description of novel Type I IL-1 receptors and of the DNA sequences encoding such receptors, thereby allowing for their production in high quantities through recombinant means. The Board also considered a post-filing document establishing that it is possible to generate anti-Type I IL-1R monoclonal antibodies as an indicator that the specification was enabling, even as early as the filing date, since there was no indication that the post-filing work involved undue experimentation or undue adaptation of methods already known to the skilled person.

The Board acknowledged that broad claims can be envisioned and that such claims could embrace antibodies implicitly or explicitly defined in relation to well-known monoclonal antibody production methods and that the claims would not necessarily need to be restricted to any one species of monoclonal antibody since there is neither commonality amongst the particular structures of the monoclonal antibodies' binding regions (CDRs) nor a predictable structural relationship between such binding regions and their target epitopes.

The Board also addressed an objection concerning lack of support for the utility of the claimed monoclonal antibodies. The Board concluded that the skilled person would appreciate that the monoclonal antibodies have at least one utility and as long as utility is apparent to that skilled person, neither the description nor the claims need explicitly mention the utility of these novel antibodies.

The conclusion of the Board that the application met the requirements of enablement, sufficiency and utility was confirmed for Type I IL-1 receptors only. Since the claims covered both Type I and Type II IL-1R polypeptides, the Board invited the Applicant to limit the claims to the Type I IL-1 receptors for enabling allowance of the application.

Comment: *This decision is a significant change in CIPO's previous rigid position on the patenting of monoclonal antibodies. Applicants will welcome the fact that actual physical preparation of monoclonal antibodies is no more a strict requirement for patentability and that the criteria of sufficiency of description of monoclonal antibodies in Canada is being aligned with that of other countries. It remains to be seen how this decision will impact examination of other types of antibodies, such as chimeric or humanized antibodies.*

---

[1] Immunex Corp. Patent Application No. 583,988 (Re), (Patent Appeal Board File No. 1302); 89 CPR 9 (4th), 34-64.

[2] Institut Pasteur Patent Application (Re) (1995), 76 C.P.R. (3d) 206.

FASKEN MARTINEAU
www.fasken.com

For more information on the subject of this bulletin, please contact the author:

Serge Lapointe, Ph.D.
514 397 5219
slapointe@fasken.com

Contacts

VANCOUVER

Susan Ben-Oliel
604 631 3162
sbenoliel@fasken.com

TORONTO

Kevin E. Holbeche
416 868 3404
kholbeche@fasken.com

Mark D. Penner
416 868 3501
mpenner@fasken.com

MONTRÉAL

Janique Forget
514 397 4332
jforget@fasken.com

Serge Lapointe, Ph.D.
514 397 5219
slapointe@fasken.com

Philip Swain
514 397 4360
pswain@fasken.com

David Turgeon
514 397 5222
dturgeon@fasken.com