Commissioner=s Decision # 1314
Décision du Commissaire # 1314

TOPIC: B20, C00
SUJET: B20, C00

Application No. : 2,407,304
Demande n^{o}. : 2,407,304

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,407,304 having been rejected under subsection 30(3) of the *Patent Rules*, has consequently been reviewed in accordance with subsection 30(6) of the *Patent Rules* by the Patent Appeal Board and the Commissioner of Patents. The findings of the Board and the ruling of the Commissioner are as follows:

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INTRODUCTION

[1] A review of the rejection of patent application number 2,407,304 resulted in the decision in *Re Application of Genentech Inc.* (2010), Commissioner=s Decision No.1307 (*Genentech*) dated November 1, 2010. Subsequent to that decision, the Applicant alleged that he had not been given a fair opportunity to address two issues. Accordingly, the Patent Appeal Board agreed to reconvene in order to ensure that the Applicant was fully heard on the two issues.

[2] The questions of double patenting and support for monoclonal antibodies B apart from the two specific issues discussed below B that were at issue in *Genentech* have been resolved and will not be considered any further.

[3] Our findings and recommendation in relation to the two issues are set out below.

BACKGROUND

[4] The Applicant is Genentech, Inc., the inventors are William I. Wood and James Lee and the invention is entitled AHUMAN PF4A RECEPTORS AND THEIR USE.@

[5] The application is concerned with human receptors of the so-called Aplatelet factor 4 superfamily@ (PF4A), antibodies capable of specifically binding to said receptors and the use of said antibodies as anti-inflammatory agents. According to the description, the platelet factor 4 superfamily includes ACXC@ polypeptides and AC-C@ polypeptides and comprises ten or more pro-inflammatory cytokines, including the cytokine interleukin-8 (IL-8).

PROCEDURAL HISTORY BEFORE THE BOARD

[6] The Board has reviewed the rejected application and submitted a recommendation which resulted in the decision *Genentech*. Part of that recommendation was to make two claim amendments.

[7] In letters dated November 16, 2010 and November 30, 2010, the Applicant alleged that the decision made apparent, for the first time, two issues that factored in the decision in *Genentech*. The Applicant indicated that he had not been given a fair opportunity to respond to, or be heard or make submissions on these two particular issues. Those issues relate to the two claim amendments called for in the *Genentech* decision. More particularly, one issue relates to the scope of a broad claim in relation to target polypeptides, and the other issue relates to a claim concerning therapeutic uses for antibodies.

[8] The Board therefore offered to reconvene for the limited purpose of hearing supplemental submissions on the two issues outlined in the Applicant=s correspondence. An invitation dated January 4, 2011 was sent to the Applicant and it reads:

> While we do not necessarily agree with the Applicant=s position, the panel is prepared to reconvene for the limited purpose of hearing supplemental submissions on two distinct issues: (i) the scope of claim 1 in relation to the target polypeptides encompassed by the claim; and (ii) lack of support for claim 7 in relation to therapeutic antibodies (whether they be poly- or monoclonal antibodies).

[9] The Applicant accepted the offer. Written submissions and proposed new claims were provided to the Board in advance of the second hearing which was held via teleconference on January 26, 2011. Two questions raised by the Board at the second hearing were addressed by the Applicant through correspondence received the day after the hearing.

THE ISSUES

[10] Having regard to *Genentech*, the two issues identified above, and the arguments submitted in regard to these issues, the Board is faced with two questions:

(1) Is the scope of claim 1, in relation to the target polypeptides, too broad?

(2) Does the instant specification provide sufficient support for claim 7 in relation to therapeutic antibodies?

CLAIMS UNDER REVIEW

[11] In advance of the hearing the Applicant voluntarily proposed an amended claim set. The Applicant was advised at the hearing that, according to section 31 of the *Patent Rules*, an application that has been rejected cannot be voluntarily amended after the expiry of the time to respond to a Final Action. Therefore, the proposed amendments could not be formally entered into the application.

[12] Nonetheless, subsection 31(*c*) of the *Patent Rules* does allow the Commissioner to direct the Applicant to make claim amendments that would bring the application into conformance with the *Patent Act* and *Patent Rules*. This means that, although the present recommendation is based on the claims submitted in response to the Final Action, the Applicant=s newly proposed claims have been considered by the Board in both its conclusions and recommendations to the Commissioner.

[13] The claims under review that are pertinent to this recommendation and which were submitted in response to the Final Action read:

1. An antibody that is capable of specifically binding an isolated platelet factor 4 superfamily receptor PF4AR polypeptide having at least an 85% amino acid sequence identity with the translated amino acid sequence of figures 2, 4 or 5.

2. An antibody that is capable of specifically binding the PF4AR polypeptide of figures 2, 4 or 5.

5. The antibody of any one of claims 1 to 4 which is a monoclonal antibody.

6. A composition comprising the antibody of any one of claims 1 to 5 and a

pharmaceutically acceptable carrier.

7. An antibody of any one of claims 1 to 5 for use as an anti-inflammatory agent.

ISSUE (1): SCOPE OF CLAIM 1 IN RELATION TO THE TARGET POLYPEPTIDES

[14] According to the Applicant=s submission dated January 25, 2011, the Board indicated in *Genentech* that the scope of claim 1 was not supported by the specification contrary to subsection 27(3) of the *Patent Act* and subsection 138(2) of the *Patent Rules*. The Applicant asserted that the Board had confused the requirement of support for monoclonal antibody claims with support for general or polyclonal antibody claims. Finally, the Applicant submitted that the instant specification is sufficient to support the polyclonal antibody claims regardless of whether it is necessary or not to have a fully characterized antigen to support monoclonal antibody claims.

[15] The broader question we were faced with in *Genentech* asked whether the specification provides adequate support for the claimed monoclonal antibodies themselves. In addressing this question it is important to bear in mind the scope of the claims in relation to the target polypeptide. This has necessarily brought into question the scope of claim 1 in relation to the target polypeptides. That concern was also expressed in *Genentech*.

[16] Claim 1 refers, in the alternative, to receptor polypeptides defined by the translated amino acid sequences of Figures 2, 4 or 5. Claim 1 can be broken into three parts, each referring to a different family of polypeptides with each family defined as having at least 85% amino acid sequence identity to one of three target receptor polypeptides whose amino acid sequences are given in Figures 2, 4 or 5. The three families of polypeptides are related in that they all bind members of the so-called APF4A@ superfamily of polypeptides.

[17] Some members of the PF4A superfamily make up a subset referred to as ACXC@ peptides which possess neutrophil agonist activity, while other members, termed AC-C@ peptides, possess no such activity. Beyond that, the activity of a APF4A@ receptor is very generally described in the specification as being one of three possibilities:

> PF4AR qualitative biological activity is defined as any one of (1) immunological cross-reactivity with at least one epitope of a polypeptide set forth in Figs. 2, 4, or

> 5: (2) the ability to specifically bind to a member of the PF4 superfamily; or (3) any effector or functional activity of the Figs. 2, 4 or 5 polypeptides as found in nature, including their ability to bind any ligands other than superfamily members.

[18] The latter two of these three activities make reference to ligand binding activity. While the specific polypeptide of Figure 2 is described as an IL-8 receptor, the same is not true of the polypeptides of Figures 4 and 5. The identity of the latter polypeptides= ligands is not disclosed. This makes a functional description of all the polypeptides of claim 1 rather troublesome and means that claim 1 refers to a family of IL-8 receptors (those related to the polypeptide of Figure 2) and two other PF4AR-like polypeptide families of unknown ligand binding activity (those related to the polypeptides of Figures 4 and 5).

[19] One type of biological activity for the polypeptides is that recited in part 1 of the definition: immunological cross- reactivity. Claim 1 can therefore be read as:

> An antibody that is capable of specifically binding an isolated platelet factor 4 superfamily receptor PF4AR polypeptide having at least an 85% amino acid sequence identity with the translated amino acid sequence of Figs. 2, 4 or 5, wherein the polypeptide is immunologically cross-reactive with at least one epitope of a polypeptide set forth in Figs. 2, 4, or 5.

[20] Claim scope at this point appears appropriate since, although the starting material may be a variant PF4AR polypeptide (one at least 85% identical to the non-variant reference polypeptides of Figures 2 , 4 or 5), the resultant antibodies of claim 1 still must cross-react with one of the non-variant target polypeptides. In this way a degree of integrity is maintained across the scope of the claim.

[21] However, one begins to lose sight of reasonable claim scope if the following passage from the description, found on page 5, lines 33 to 35, is considered:

> Immunologically cross-reactive as used herein means that the candidate polypeptide is capable of competitively inhibiting the binding of a PF4AR to polyclonal antibodies or antisera raised against a PF4AR.

[22] This means claim 1 can be read as:

> An antibody that is capable of specifically binding an isolated platelet factor 4 superfamily receptor PF4AR polypeptide having at least an 85% amino acid sequence identity with the translated amino acid sequence of Figs. 2, 4, or 5, wherein the polypeptide is capable of competitively inhibiting the binding of a PF4AR to polyclonal antibodies or antisera raised against a PF4AR.

[23] It should also be remembered that PF4AR biological activity can include Aany effector or functional activity of the Figs. 2, 4 or 5 polypeptides as found in nature, including their ability to bind any ligands other than superfamily members@. When this definition is incorporated into claim 1, its scope becomes incredibly vast and encompasses receptor polypeptides that may, for example, bind unknown non-PF4A ligands. In other words, the Applicant=s circular and expansive definitions ultimately generate a claim that is far broader than what has been enabled and described.

[24] This was explained in *Genentech* at paragraphs 59 to 62 and 67 to 70.

[25] In *Genentech*, we recommended that the Applicant limit claim 1 to antibodies that are cross- reactive with any one of the three PF4AR polypeptide species defined in Figures 2, 4 or 5. What this means is that, although variability is permissible in respect of the target polypeptide, the scope of claim 1 should be limited to antibodies that at least maintain cross- reactivity with the target polypeptides of Figure 2, 4 or 5. This would restore claim scope to what we see as subject matter that has been described and enabled.

[26] The Applicant now submits, with reference to the description, that variant sequences coding for variant PF4A receptor polypeptides can be cloned using nucleic acid sequence probes Ato screen for [variant] receptors as described in claim 1@. The best probes are described as Along sequences greater than 100 bases to represent sequences which are highly homologous among the exemplified human receptors [of Figures 2, 4 or 5]@. Variant PF4A receptor polypeptides can also be prepared through substitution, insertion or deletion

or amino acid residues in the exemplified human receptors. We do not necessarily disagree with these assertions but hasten to point out the following:

$ The description states on page 10 at lines 24 to 26, in relation to regions of PF4A receptor polypeptides suitable for alteration, that:

> In general, the regions of the PF4AR molecule preferred for alterations are non-hydrophobic regions or regions that are not highly conserved.

$ The description states on page 11, lines 10 to 12, in relation to deletion mutants, that:

> However, any sequence which is capable of raising an antibody that will cross-react with the intact receptor, or which will bind a member of the PF4A superfamily, is useful.

$ The description indicates on page 31 at lines 28 to 30 that monoclonal antibodies are preferably:

> [S]pecific for each target PF4AR polypeptide, and will not cross-react with . . . other members of the PF4AR family.

[27] Considered as a whole, the description indicates a theme of conservation of structural and functional attributes amongst the target PF4AR polypeptides. These indications are consistent with our reasoning that either the generic antibodies of claim 1, or the monoclonal antibodies of claim 5, should be still be capable of cross-reacting with the particular target PF4AR polypeptides of Figure 2, 4 or 5 even though the PF4AR polypeptide used to generate either antibody can be a variant of any one of these three particular PF4AR polypeptides.

[28] The Applicant also submits that subgenus, or dependent, claims may be formulated, as they have been in this case, to more specific subject matter. The more specific subject matter can refer to a subgenus of polypeptides, e.g. the specific polypeptides referred to in Figure 2, 4 or 5, or can refer to a more specific subgenus of antibody, e.g. monoclonal antibodies

that are reactive with any one of the generic polypeptides. Still more specific subject matter can be claimed through a combination of different aspects (subgenera), e.g. specific monoclonal antibodies that are reactive with a species of polypeptide. The Applicant concludes that:

> While the Board and Commissioner may question whether the subgenus of monoclonal antibodies directed to a polypeptide having 85% sequence identity to the polypeptides of figures 2, 4 or 5 is properly supported in the disclosure, this does not affect the patentability of the genus claim, namely the general antibody claim to the polypeptides having 85% sequence identity to the polypeptides of figure 2, 4 or 5. The patentability of such a claim, like any other, is to be determined on the principle of whether the claim is adequately supported by the disclosure addressed to one of ordinary skill in the art.

[29] The gist of this argument is that an antibody claim can be made more specific in one or more of its aspects. We agree. This follows general principles of claim drafting. The Applicant then seems to say that if a more specific claim is considered too broad, that is no reason to conclude that a more general claim is also too broad.

[30] Dependent claim 5 has been narrowed to refer to a monoclonal antibody, but neither it nor its parent claim (i.e. claim 1) have been limited in respect of the target polypeptide. In *Genentech*, we recommended that the Applicant limit claim 1 to antibodies that are reactive with any one of the three PF4AR polypeptide species defined in Figures 2, 4 or 5. What this means is that, although variability is permissible in respect of the target polypeptide, the scope of claim 1 should still be limited to antibodies that are at least capable of specifically binding the target polypeptide of Figure 2, 4 or 5.

[31] The intended purpose of the amendment of claim 1 recommended in *Genentech* was to properly limit the scope of the antibody claims with respect to the target polypeptides. In other words, the amendment was determined to be necessary so the application becomes compliant with the *Patent Act* and the *Patent Rules* as stipulated by subsection 31(*c*) of the *Patent Rules*. We remain unconvinced that the Applicant may validly claim antibodies that are not so limited.

We therefore stand by the recommendation as it was in *Genentech* in respect of this issue.

ISSUE (2): SUPPORT FOR THE UTILITY OF THE CLAIMED ANTIBODIES AS ANTI-INFLAMMATORY AGENTS

[32] To begin with, we reiterate that therapeutic utility for any type of anti-PF4AR antibody had not been demonstrated by the Applicant as of the filing date. Thus, the Applicant must rely on a sound prediction in order to support claims related to antibodies having a therapeutic utility.

[33] According to *Apotex Inc. v. Wellcome Foundation Ltd*, 2002 SCC 77 at para 71, the soundness of a prediction is a question of fact:

> It bears repetition that the soundness (or otherwise) of the prediction is a question of fact. Evidence must be led about what was known or not known at the priority date, as was done here. Each case will turn on the particularities of the discipline to which it relates.

[34] We would add that a balanced and thorough factual inquiry considers all relevant facts, not just those that support one conclusion over another.

[35] Although the Applicant has argued with reference to the newly proposed claims, rather than to the claims that were submitted in response to the Final Action, the Board considers that the Applicant=s arguments are applicable to both claim sets. We also consider that the analysis, findings and reasons presented in *Genentech* at paragraph 71 to paragraph 90 remain entirely relevant. For the sake of conciseness, the Board will not repeat the entire passage but will clarify its reasons in relation to the Applicant=s arguments.

[36] The Applicant has argued that the prediction is sound and has focused on antibodies specific for a particular PF4AR polypeptide whose amino acid sequence is set out in Figure 2. The Applicant submitted the specification provides a proper disclosure such that the person skilled in the art, given that disclosure, would have understood that the antibodies of claim 7 would block the binding of a cytokine ligand to its corresponding PF4A receptor, that they would have antagonistic activity towards their targets, and that such antibodies would be useful as anti-inflammatory agents once reduced to practice. The Applicant submitted that the factual basis consists of three elements:

> The factual basis for the prediction is:
>
> 1. The disclosure of the full amino acid sequence of the receptor given in figure 2 as well as the identification of the extracellular regions of the receptor as described in the brief description of figure 2. These extracellular regions would be involved in the binding of the cytokine ligand to the receptor and as described in both *Holmes et al* and *Murphy and Tiffany* referred to in the application, the N-terminal region was expected to play a role in this binding.
>
> 2. The application also describes the assay methods for identifying antibodies which block the binding of the cytokine ligand to the receptor as well as assay method for assaying the biological effect of the binding of the cytokine ligand to the receptor,

> namely the determination of the intracellular Ca^{++} response of the transfected cell to binding of the cytokine ligand.
>
> 3. The application also describes antagonist antibodies as being for use in treating inflammation on pages 31 and 32.
>
> From these facts, with their specific reference to utility in treating inflammation, one of skill in the art would readily predict that such antibodies would be useful in anti-inflammatory therapy. This clearly represents an Aarticulable and sound@ line of reasoning from which the desired result can be inferred.
>
> The application provides a proper disclosure of the invention through the description of the antibodies, the antagonistic antibodies and their use in therapy on pages 31 to 33.
>
> It is therefore submitted that it was soundly predictable that one of skill in the art utilizing this teaching and their common general knowledge would have no difficulty preparing antibodies to the PF4AR polypeptide which will be useful in anti-inflammatory therapy such that a person skilled in the art, given that disclosure, could have, as the inventors did, soundly predicted that the invention of the use of an antagonistic antibody in anti-inflammatory therapy would work once reduced to practice.

[37] The Applicant also identified the person skilled in the art and we agree with that characterization:

> [T]he present application would be directed to a molecular immunologist with experience in monoclonal antibody production, immunoassays and a clinical immunologist specializing in inflammation.

[38] The Applicant relies on the disclosure of two scientific papers published before the filing date of the instant application as a factual basis for identifying the N-terminal region of the PF4AR polypeptide of Figure 2 as a binding region for the ligand (i.e. IL-8). The Applicant argues that the binding site itself is predictable and, based on that premise, further argues that the utility ultimately promised is also soundly predictable.

[39] The pertinent passages of *Holmes et al.* and *Murphy and Tiffany* referred to by the Applicant are almost identical and read, respectively:

> Like the C5a receptor (*19*), the NH_2-terminal extracellular region of the IL-8 receptor has several acidic residues. These amino acids <u>may participate</u> in the binding of IL-8, which is quite basic (pI –9.5), to the receptor. [Emphasis added]

and

> As with the C5a receptor (*21*), the NH_2-terminal segment is rich in acidic residues and <u>may form</u> the binding site for IL-8, which is basic (pI –9.5). [Emphasis added]

[40] These particular passages merely predict a hypothetical binding site for IL-8 in the N-terminal region of the receptor rather than factually identifying the N-terminal region as such. It follows that the actual binding site of IL-8 on the PF4AR polypeptide of Figure 2 was not

known at the filing date. A factual basis, by definition, is restricted to established facts and the specification does not establish, as fact, the identity of the IL-8 binding site.

[41] Moreover, although the IL-8 receptor of *Holmes et al.* appears to be the same as the PF4AR polypeptide of Figure 2, it is clear from both publications that the IL-8 receptor of *Murphy and Tiffany* is different from the IL-8 receptor of *Holmes et al.* and, by extension, the PF4AR polypeptide of Figure 2. We noted another passage of *Murphy and Tiffany* which stipulates that, although both IL-8 receptor forms share 77% amino acid identity, most of the differences between the two forms are found in the NH_2-terminal region. The relevant passage reads as follows:

> In the accompanying paper, a cDNA from human neutrophils is described that encodes a high affinity IL-8 receptor (*24*). This receptor has 77% amino acid identity with the low affinity IL-8 receptor and is more closely related to F3R (79% versus 69% amino acid identity). Neither human IL-8 receptor interacts with N-formyl peptides. The low affinity form diverges most extensively from the other two sequences in the NH_2-terminal segment, although the acidic character of this region is conserved. [Emphasis added]

[42] It follows that what could allegedly serve as part of the factual basis for the IL-8 receptor of *Murphy and Tiffany* has a very limited applicability with regard to the PF4AR polypeptide of Figure 2.

[43] In view of the above, the Board finds that the factual basis with respect to a binding region for IL-8 on the PF4AR polypeptide of Figure 2 is limited to the identification of extracellular regions of the PF4AR polypeptide of Figure 2 without precise and factual information regarding the actual binding site of IL-8.

[44] The Applicant further submits that the N-terminal domain and the four extracellular loops found on the surface of the PF4AR polypeptide of figure 2 have been characterized. Given that the N-terminal domain is expected to comprise the binding site for IL-8 (i.e. based on the submitted references), an antibody which recognizes an epitope on these regions would also be expected to block or interfere with the binding of the IL-8 ligand.

[45] The person skilled in the art would understand that an antibody which recognizes an epitope in these regions could, as asserted by the Applicant, bind and block an epitope that is critical to the binding of IL-8 (i.e. an antagonistic antibody). However, the same person would also recognize that said antibody could also; i) bind and block an epitope that is not required for the binding of IL-8 (i.e. a simple binding antibody) or ii) bind an epitope that is critical to the binding of IL-8 but instead triggers the *activity* of the receptor (i.e. an agonistic antibody). These potential capabilities of an antibody are also identified in the description on page 31, lines 31 to 33. Therefore, an antibody which recognizes an epitope on these regions would not necessarily be expected to block or interfere with the binding of the IL-8 ligand.

[46] The second element of the factual basis presented by the Applicant establishes that methods for identifying antibodies which block the binding of a ligand to a receptor, as well as assay

methods for assaying the biological effect of the binding of a ligand to a receptor are described in the specification and/or were known in the art at the filing date. Although the Board agrees with the Applicant that such methods and assays were available at the filing date of the instant application, it is not clear how this supports a predicted antagonistic activity for the recited antibodies. The existence of testing means is perhaps relevant once the determination of the soundness of a prediction regarding a promised activity is achieved, but not necessarily before.

[47] Turning now to the third element of the factual basis presented by the Applicant, wherein it is submitted that the application describes the intended use of antagonistic antibodies. Given that it has been established that antagonistic antibodies, antibodies that block the binding of a cytokine ligand to the corresponding receptor or antibodies with anti-inflammatory activity have not actually been prepared by the Applicant as of the filing date of the instant application, it is not clear how the literal description of the predicted antagonistic antibodies and their predicted utility in treating inflammation could be part of the factual basis for the prediction that such antibodies would actually possess antagonistic and anti-inflammatory activities.

[48] The factual basis regarding the prediction of antibodies capable of blocking the binding of a ligand to its receptor presented by the Applicant did not take into account pertinent factual considerations introduced by the Board in *Genentech*. The same is true for the factual considerations relating to the prediction that such antagonistic antibodies would be effective as anti-inflammatory agents.

[49] The following list summarizes the Board=s findings in *Genentech* with regard to the factual basis that were not mentioned or specifically addressed by the Applicant. In our opinion, these findings are relevant to the prediction that the encompassed antibodies would have blocked the binding of a cytokine ligand to its receptor, would have antagonistic activity towards their target, and would be useful as anti-inflammatory agents once reduced to practice:

- The principle of immunodominance that would have been known to the skilled person as that person has been defined by the Applicant (outlined at para. 81 of *Genentech*).

- The relevance of presence or absence of factual data regarding epitopes essential to the function(s) of a target polypeptide (para. 82 of *Genentech*).

- The existence of a second high affinity receptor for IL-8 (paras. 84 and 85 of *Genentech*).

- The biological functions and the ligands of the PF4AR polypeptides of Figures 4 and 5 are unknown (paras. 86 and 87 of *Genentech*).

[54] Having considered the Applicant=s further submissions and arguments, the Board finds as in *Genentech*, that the factual basis is limited to antibodies that simply possess the ability to bind to the target antigen. This supports only limited utility for said antibodies, e.g., as reagents for detecting or purifying PF4AR polypeptides.

[55] The factual basis in the specification does not provide the information that would allow the skilled person to accept that the encompassed antibodies would antagonize the activity of their respective targets. Moreover, the factual basis would not lead the skilled person to conclude

that the blocking of the PF4AR polypeptide of Figure 2 with a specific antibody would, on its own, result in an inhibition of inflammation. The same applies to the subject matter of the proposed claims and to the PF4AR polypeptides of Figures 4 and 5, given that the ligands and biological functions of these polypeptides are even less characterized (see paragraph 18 above).

[56] We conclude that the factual basis in the specification as of the filing date is insufficient to substantiate an articulable and sound line of reasoning that would support the promised utility of an antibody specific for the PF4AR polypeptide of Figure 2, 4 or 5 for use as an anti-inflammatory agent as defined in claim 7 currently on file. This finding also applies in respect of the promised utility of an antibody specific for the PF4AR polypeptide of Figure 2 as defined in the proposed claims 9 to 12.

[57] It also follows that the instant specification does not provide a sufficient disclosure with regard to the utility promised and consequently the requirements of the test for sound prediction have not been met.

RECOMMENDATION

[58] The Board considers that the proposed claims would not render the application compliant with the Act and Rules for the reasons already set forth in *Genentech* and the reasons found herein. Therefore, we cannot recommend that they be introduced into the application.

[59] The Board recommends that:

The Applicant be informed in accordance with paragraph 31(*c*) of the *Patent Rules*, that the following amendments, and only the following amendments, of the application are necessary for compliance with the *Patent Act* and *Patent Rules*:

a) deletion of claim 7, and

b) amendment of claim 1 to incorporate the restriction of claim 2 with respect to the target polypeptide, i.e., amendment of claim 1 to further indicate that the claimed antibody is capable of specifically binding the PF4AR polypeptide of Figure 2, 4 or 5.

Marcel Brisebois	Ed MacLaurin	Serge Meunier
Member	Member	Member

COMMISSIONER=S DECISION

[60] I concur with the findings and recommendation of the Patent Appeal Board. Accordingly, I invite the applicant to make the above amendments, and only the above amendments, within three months from the date of this decision, failing which I intend to refuse the application.

Mary Carman
Commissioner of Patents

Dated at Gatineau, Quebec
this 13th day of April, 2011