Commissioner=s Decision #1294

Décision de la Commissaire #1294

TOPIC: A20

SUJET: A20

Application No. : 2,388,770

Demande no. : 2,388,770

COMMISSIONER=S DECISION SUMMARY

C.D. 1294, Application No. 2,388,770

The subject application is a divisional application of Canadian Patent 2,059,124, relating to peptide platelet aggregation inhibitors. In the Final Action, the examiner rejected the application for not being patentably distinct from what was claimed in the parent patent. The Board recommended that the rejection be affirmed.

The Commissioner of Patents agreed with the Board, and the application was refused.

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

The rejection of patent application number 2,388,770 under subsection 30(4) of the *Patent Rules* was reviewed. The rejection has been considered by the Patent Appeal Board and by the Commissioner of Patents. The findings of the Board and the decision of the Commissioner are as follows:

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INTRODUCTION

1. This Decision deals with a review by the Commissioner of Patents of the examiner=s Final Action dated August 23, 2007, on application 2,388,770 (the >subject application=), entitled >PLATELET AGGREGATION INHIBITORS=. The inventors on record are Robert M. Scarborough, David L. Wolf and Israel F. Charo, and the current owner is MILLENNIUM PHARMACEUTICALS.

2. The application is a divisional of patent 2,059,124 (the >parent patent=), which was filed on June 15, 1990 and issued on August 20, 2002. The subject application was given divisional status on July 16, 2002.

3. The claimed invention relates to peptide platelet aggregation inhibitors (PAIs) that are, or are related to, naturally-occurring peptides isolated from snake venom that function by blocking receptors for adhesive proteins involved in platelet adherence and aggregation. The PAIs are taught for use in treating and preventing platelet aggregation, making them useful in treating platelet-associated ischemic disorders as well as related conditions. The peptides are also claimed for use in preventing platelet loss and consumption during extracorporeal circulation of blood by reducing the tendency of the platelets to aggregate; embolisation due to such aggregates is also claimed to be prevented or avoided as a result.

PROSECUTION HISTORY

4. When the divisional application was filed, it contained a single claim directed to a Aplatelet aggregation inhibitor (PAI) polypeptide@. Prior to any examination, a voluntary amendment dated August 21, 2003 was filed, increasing the number of claims to 42. An Office Action of April 4, 2006, raised a single issue: the claims on file were alleged to not be patentably distinct from the claims of the parent patent. With the applicant=s response of December 10, 2006, the claims were amended, reducing the number of claims on file to 40, and the objection traversed. A subsequent Office Action reapplying and further elaborating upon the original objection was issued August 23, 2007, and made Final. In the February 19, 2008 response to the Final Action, the applicant did not amend any of the claims, but again traversed the objection via written argumentation. The response failed to satisfy the examiner and, consequently, a Summary of Reasons was forwarded to the Board on April 1, 2008, a copy of which was sent to the applicant. On December 10, 2008, a Hearing via teleconference was held between the members of the Board and the applicant=s representative, Michael R. Williams. Representing the Office was Nicholas Ohan, Section Head; the examiner, Christiane Hansen, was unable to attend.

SUMMARY OF THE GROUNDS FOR REJECTION

5. The sole issue to be addressed is whether the claims of the subject application are patentably distinct from those of the parent patent; i.e. whether they define a separate invention from what was claimed in the parent. The impetus for the objection is that, if the claims of the divisional are not directed to a different invention from what was claimed in the parent, then there is potential double patenting if those claims were to issue.

CLAIM OVERVIEW

6. The divisional application contains 40 claims, 11 of which are independent. The independent claims can be summarised as being directed to: a genus of PAIs (claim 1); compositions comprising one of those PAIs (claim 11); compositions comprising a particular PAI (claims 14 and 15); uses of that particular PAI (claims 17, 28 and 29); and uses of a peptide selected from a specified group (claims 16 and 38B40).

7. The parent patent contains 70 claims, all of which are implicated by the examiner in the double patenting objection raised against the claims of the divisional. It includes a number of independent claims, broadly directed to: methods for determining whether a PAI is present in a biological fluid (claim 1); PAIs *per se* (claims 2, 12, 14 and 21); PAI purification methods (claim 6); compositions comprising PAIs (claims 8B11, 36 and 37); recombinant systems for expressing DNA encoding PAIs, and host cells containing same (claims 18, 19, 48, 49, 68 and 69); PAI production methods (claims 20, 50 and 70); and DNA molecules deduced from the amino acid sequences of specific PAIs (claims 47 and 51B67).

SUMMARY OF THE RELEVANT CASE LAW

8. The prohibition against double patenting is judge made law which originated under the preB1989 provisions of the *Patent Act* to address the concern of >evergreening= and patent term extension in situations where the same parties, such as inventors or applicants, are involved. Notwithstanding the postB1989 provisions of the *Patent Act* in which patent protection begins at the date of filing rather than the date of issue, the prohibition against double patenting remains (*GlaxoSmithKline Inc. v. Apotex Inc.*, 2003 FCT 687, 27 C.P.R. (4th) 114 (*GSK*) at paras. 89B91).

9. *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067 (*Whirlpool*) is frequently cited as the leading authority for the prohibition. In *Whirlpool*, the Supreme Court noted that there are two branches to the test for double patenting, each of which is to be evaluated in determining whether one claim-set defines a separate invention from another. The first branch, termed >same invention double patenting=, applies in situations where the claims are identical or conterminous (*Xerox of*

Canada Ltd. v. IBM Canada Ltd. (1978), 33 C.P.R. (2d) 24; *Beecham Canada Ltd. v. Procter & Gamble Co.* (1982), 61 C.P.R. (2d) 1 at p. 22).

10. The second branch of the test, outlined at paragraph 66 of *Whirlpool*, is termed >obviousness double patenting= and is somewhat broader:

> There is, however, a second branch of the prohibition which is sometimes called Aobviousness@ double patenting. This is a more flexible and less literal test that prohibits the issuance of a second patent with claims that are not Apatentably distinct@ from those of the earlier patent.

11. Although there are limitations insofar as what can be considered, obviousness double-patenting is assessed conceptually in the same way as determining obviousness under subsection 28.3 of the *Patent Act*; *viz.*, viewed from the perspective of a person skilled in the art: *Bayer AG v. Novopharm Ltd.*, 2006 FC 379, 48 C.P.R. (4th) 46 at paras. 40B63 (*Bayer*); *Aventis Pharma Inc. v. Pharmascience Inc.*, 2005 FC 340, 38 C.P.R. (4th) 441, aff=d 2006 FCA 229, 53 C.P.R. (4th) 453 at para. 63 (*Aventis*). The assessment is limited in that it is the claims in one patent which are compared against those in another (*Whirlpool* at para. 63). The test may take into account common general knowledge but not particular pieces of prior art.

12. In *Bayer* and *Aventis* it was the traditional test for obviousness outlined in *Beloit Canada Ltd. v. Valmet Oy* (1986), 8 C.P.R. (3d) 289 at 294 (F.C.A) (*Beloit*) that was considered. Recently, the approach to obviousness has been updated with the decision of the Supreme Court in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, 69 C.P.R. (4th) 251 (*Sanofi*), which stepped away from the strict test defined in *Beloit*, and introduced a four-step approach to assessing obviousness. It is this approach that is the current standard for determining obviousness and is likewise the one to be applied in the conceptual assessment of obviousness double patenting.

13. A further consideration within the ambit of the obviousness enquiry is whether different claim-types define different inventions or are merely different aspects of the same invention (*Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49 (*Hoechst*); *Libbey-Owens-Ford Glass Company v. Ford Motor Company of Canada, Ltd.*, [1970] S.C.R. 833; and *Ciba-Geigy AG v. Commissioner of Patents* 65 C.P.R. (2d) 73). Different categories of invention are not necessarily indicative of distinct inventive concepts; inventive ingenuity is still required to support a second patent (see *GSK* at para. 89). However, claims ostensibly overlapping in scope with claims of another patent may in fact be patentably distinct. For example, claims defining a sub-genus or species are not considered obvious over claims defining the broader genus in a separate patent where the criteria for a proper selection are met (*Sanofi* at para. 113; *Aventis* at paras. 46 and 64).

14. The foregoing jurisprudence sets forth the requirements to support a second patent in the situation of an application divided from a parent patent and in the case of a copending application

filed by the same applicant. It is clear from the case law that in order for the claims of the divisional to be considered directed towards a second invention the subject-matter must not be conterminous with or >obvious= in view of the claims of the parent.

15. The language of the Final Action indicates that it is the >second branch= of the prohibition which the examiner believes to be the relevant consideration: the claims are not alleged to be identical or conterminous, but rather not patentably distinct from those of the parent. For this reason, it is this branch of the prohibition that will be the focus of the analysis in this Decision.

THE APPLICANT=S POSITION

16. In the response to the Final Action, the applicant raised a number of arguments in support of the claims of divisional application 2,388,770. These were repeated during the Hearing, and can be paraphrased as follows:

1. The claims of the divisional differ from those of the parent:
    a. claim 1 of the divisional is directed to different subject-matter than claim 2 of the parent patent.
    b. claim 12 of the divisional is directed to different uses than in the parent patent.
    c. claims 16B40 of the divisional are directed to uses of peptides, which are not claimed in the parent patent.

2. Claims to methods of manufacture of medicaments are not present in the parent patent, but protection for these is being sought in the divisional, and should be allowed, in order to protect against potential infringers.

3. Different International Patent Classifications (IPCs) for the subject-matter would necessitate a different search by the examiner over the claims of the parent patent, suggesting that there are in fact two inventions.

4. There is a lack of clear rules as to how >invention= is defined in such cases, since section 2 of the *Patent Act* only broadly defines the term.

17. Although no new arguments were presented at the Hearing, the point was made by Mr. Williams that the divisional and parent will expire at the same time according to the postB1989 provisions of the *Patent Act*. That is, there would be no extension of monopoly in issuing the divisional. This point was addressed above, *en passant*, where it was noted that, according to *GSK*, the prohibition still exists, the absence of monopoly extension notwithstanding. Each of the

arguments presented by the applicant will be addressed in the order given, above

ANALYSIS

APPLICANT=S FIRST ARGUMENT: CLAIM DIFFERENCES

18. The first argument involved the direct comparison of the claims in the divisional to those of the parent, to show that the claimed subject-matter differs between the two.

19. In the Final Action, an analysis was performed by the examiner to show that the claims of the divisional are not patentably distinct from those of the parent. An excerpt from the expository portion of the Final Action reads:

> As outlined in the previous office action dated April 4, 2006, the present application and its parent (2059124) both define compositions of matter consisting of platelet aggregation inhibitor (PAI) polypeptides having the same functional limitations. Both claim 1 of the present application and claim 21 of the parent define a Acomposition of matter consisting essentially of a specific platelet aggregation inhibitor (PAI) capable of inhibiting binding of Fg or vWF to GP Ilb-Illa with substantially more potency than of inhibiting binding with vitronectin to vitronectin receptor or fibronectin to fibronectin receptor@ of the general formula defined in claim 1 of the present application.
>
> While the formula of claim 1 of the present application is limited to the situation where n2= 1-3
> (amended in the claims submitted with Applicant=s communication dated October 4, 2006) and n3=1, n2 in the parent (claim 21) may be 0-3 and n3 in the parent (claim 21) may be 0 or 1. The parent also includes a proviso to overcome prior art. This proviso is not needed in claim 1 of the present application due to the limitation put on n3 (i.e n3=1 rather than 0 or 1). In addition, AA_2 in the parent patent is defined as a neutral, non-polar large (aromatic or non aromatic) or a polar aromatic amino acid whereas AA_2 in the present claims submitted with Applicant=s correspondence dated October 4, 2006 is now limited to the amino acids tryptophan, phenylalanine, leucine, tyrosine or valine. These amino acids are, however, encompassed by the definition of AA_2 found in claim 27 of the parent patent. The aforementioned differences between the claims of the present application and its parent therefore represent minor variations. Consequently, the formulae define a subset of polypeptides and compositions of matter which are not patentably distinct from one another.

In his response to the Final Action, the applicant stated:

> It is respectfully requested that the examiner reconsider this position [on the double patenting objection] in view of the differences between the claims of the instant application and Canadian Patent 2,059,124.
>
> Specifically, applicant again notes that submitted claim 1 of the instant application differs from claim 2 of Canadian Patent 2,059,124 in that claim 2 of >124 refers to detecting a decrease or lack of decrease in binding of fibrinogen or von Willebrand Factor to GP IIb-IIIa in the presence or absence of snake venom whereas claim 1 of the instant application refers to a platelet aggregation inhibitor capable of inhibiting binding of fibrinogen or von Willebrand Factor to GP IIb-IIIa more than inhibiting binding of vitronectin to vitronectin receptor or fibronectin to fibronectin receptor.
>
> Thus, claim 2 of >124 compares effectiveness between a PAI-containing sample and an untreated control whereas submitted claim 1 of the instant application compares effectiveness of PAI on inhibiting binding of Fg or vWF to GP IIb-IIIa to inhibition of binding

of fibronectin to fibronectin receptor or vitronectin to vitronectin receptor.

20. As the applicant has noted, the claims of the divisional differ from those of the parent patent, but this is only relevant in >same invention= double patenting, which is not at issue. The examiner explained in the Final Action that the objection is that the claims of the divisional are not *patentably distinct* from those of the parent, since there is a single inventive concept shared between the two claim-sets. Although the claims may differ in scope and form, what needs to be determined is whether this difference actually amounts to a separate invention being claimed. In order to determine this, the scope of the claims of the parent and divisional need to be compared.

21. Since the objection raised pertains to the obviousness double patenting provisions, what has to be established is whether the claims of the divisional are patentably distinct from those of the parent patent. To facilitate the analysis, each independent claim of the divisional will be compared to the claim in the parent that most closely resembles it, regardless of claim-type. This claim-by-claim analysis is one that was endorsed by *Whirlpool* for assessing double patenting. Claims in the parent patent which differ more substantially from the divisional claims (such as those directed to methods of producing, identifying and expressing PAIs, in addition to DNA encoding same) can subsequently be considered if deemed necessary. For clarity, the following table has been produced to show which of the parent patent claims will serve as the basis for the comparison.

	Subject-Matter	Claims of Divisional (2,388,770)	Claims of Parent (2,059,124)
Group A	PAIs, *per se*	1B10	21B35
Group B	PAI Compositions	11B15	21B35
Group C	Use of a PAI	16 and 38B40	21B35, 38, 39 and 41B46
Group D	Use of a specific PAI	17B37	32

GROUP A CLAIMS

22. Group A consists of claims directed to PAIs themselves, and includes claims 1B10 of the subject application. The claims referred to in the passages reproduced from the Final Action and the applicant=s response (paragraph 19) fall within this group. Claim 1 is the sole independent

claim in Group A, and forms the basis for the initial comparison to the parent claims. The claim reads:

> 1. A composition of matter which consists essentially of a specific platelet aggregation inhibitor (PAI) capable of inhibiting binding of Fg or vWF to GP IIb-IIIa with substantially more potency than of inhibiting binding with vitronectin to vitronectin receptor or fibronectin to fibronectin receptor, which PAI has the formula
>
> [wherein the groups are as defined].

Of the claims in the parent patent directed to PAIs (claims 2, 12, 14 and 21), it is independent claim 21 that will be compared as it most closely resembles claim 1 of the divisional. This is in contrast to the applicant=s response, which compared claim 1 to claim 2 of the parent patent. Claim 2 of the parent is substantially different in form and scope than claim 1 of the divisional, insofar as it is directed to a purified and isolated PAI that is characterised by function and from where it was obtained (but with no structural limitations defined) as well as by how its activity can be identified. Owing to the significant differences between divisional claim 1 and claim 2 of the parent, the Board has determined that it is claim 21 that serves as a more appropriate basis for the initial comparison.

23. As presented by the examiner in the Final Action, parent claim 21 is identical to claim 1 of the divisional with certain exceptions. In the definition of the radical groups, AA_2 is defined in the parent patent as being a Aneutral, nonpolar large (aromatic or nonaromatic) or a polar aromatic amino acid and n2 is an integer of 0-3@. In claim 1 of the divisional, AA_2 is defined as being Atryptophan (W), phenylalanine (F), leucine (L), tyrosine (Y) or valine (V) and n2 is an integer from 1-3@. The second difference lies in the definition of n3, which dictates the number of AA_3 groups; the parent patent claim 21 defines it as Aan integer of 0-1@, while claim 1 of the divisional restricts it to An3=1@. As a result of this restriction, the proviso present in the parent patent does not apply, and thus is not included in the claims of the divisional.

24. According to pages 30B31 of the originally-filed parent description, tryptophan and phenylalanine are examples of neutral, nonpolar, large aromatic amino acids; tyrosine is a neutral, polar, large aromatic amino acid; and valine and leucine are neutral, nonpolar, large, nonaromatic amino acids. The amino acids defined in claim 1 of the divisional application therefore represent a restriction of those allowed for by claim 21 of the parent patent. That restriction was mentioned by the examiner to be the subject-matter of claim 27 of the parent patent, further reducing the differences between claim 1 of the divisional and the claims of the parent patent.

25. The Board notes that the peptides of claims 1B10 and those in independent claim 21 and

dependent claims 22B35 of the parent patent appear to be identical in function (as evidenced by the identical language in the claims prior to the peptide being defined), no use *per se* is defined in those claims, and there is no distinction made in the description about their utility. More specifically, there is nothing which suggests that any of the restrictions present in claim 1, or dependent claims 2B10, were recognised as being a separate invention over the broader genera defined in the parent patent claims, at least insofar as no separate utility for these peptides is taught.

26. Aside from the possibility of the sub-genera defined in the claims being patentably distinct from the claims of the parent patent by virtue of having a unique utility, the restrictions could be considered to represent a separate, patentable invention over the parent claims where the subject-matter defined fulfils the requirements of being a proper selection. The courts have ruled that a proper selection will not be found to be obvious in light of the claims from which the selection was made; the claims will be considered patentably distinct (*Sanofi*). Therefore, in order to determine whether the claims of Group A actually define a separate invention, this avenue must be explored.

27. The requirements for a selection were recapitulated in *Sanofi*, citing *In re I.G. Farbenindustrie A.G.=s Patents* (1930), 47 R.P.C. 289 (Ch. D.) (*Farbenindustrie*), where the principles were originally set forth. These are quoted at paragraph 10 of *Sanofi*:

> 1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members.
>
> 2. The whole of the selected members (subject to Aa few exceptions here and there@) possess the advantage in question.
>
> 3. The selection must be in respect of a quality of a special character peculiar to the selected group.

In addition to these three criteria, there is an additional requirement: Ait is necessary that the specification of the selection patent define in clear terms the nature of the characteristic which the patentee alleges to be possessed by the selection for which he claims a monopoly@ (*Sanofi*, para. 114). The Board notes that there is no disclosure in the originally-filed parent application of any such characteristic.

28. Besides this lack of disclosure, there are also no indications in the specification that any substantial advantage has been secured (or any substantial disadvantage avoided) by the use of these members, and therefore no such advantage can be said to be possessed by all the selected members. Possible advantages that selected species could be expected to exhibit over the broader genera are recited in the original description from page 7, line 34 to page 8, line 12, and include increased potency, greater specificity, decreased immunogenicity, increased stability and improved ease of administration. There is, however, nothing that suggests that any such advantage was recognised at the time of filing. It is also noted that there were never any claims directed to the

sub-genus of claim 1 in the parent. Therefore, applying these criteria, the Board has concluded that the claims of Group A do not represent a proper selection from the parent patent.

29. In sum, the claims to the PAI peptides of claims 1B10 (Group A) cannot be considered patentably distinct over the parent patent claims (claims 21B35 in particular).

GROUP B CLAIMS

30. Next to be considered are the composition claims of the divisional; Group B, comprising claims 11B15. This group includes independent claims 11, 14 and 15. Claim 11 reads:

> 11. A pharmaceutical composition which comprises a platelet aggregation inhibitor polypeptide according to any one of claims 1 to 10 with a pharmaceutically acceptable carrier.

The claim is thus directed to compositions of the peptides of claims 1B10, which were themselves found to not be patentably distinct from those claimed in the parent patent (see the analysis of Group A). The fact that simply diluting a compound to form a composition, absent any inventive contribution, does not constitute a separate invention over the compound itself has been well established through the jurisprudence, where the following from *Hoechst* at page 53 was originally noted, and continues to be cited by the courts:

> A person is entitled to a patent for a new, useful and inventive medicinal substance but to dilute that new substance once its medical uses are established does not result in further invention. The diluted and undiluted substance are but two aspects of exactly the same invention. In this case, the addition of an inert carrier, which is a common expedient to increase bulk, and so facilitate measurement and administration, is nothing more than dilution and does not result in a further invention over and above that of the medicinal itself .

Claim 12 depends from claim 11, only specifying the amount of peptide present; i.e. an amount Aeffective to inhibit platelet aggregation@. This is not claimed in the parent as noted by the applicant:

> Regarding submitted claim 12 of the instant application, it is again noted that this claim states that the effective amount is sufficient to inhibit platelet aggregation. This is in contrast with claims 8, 10 and 36 of >124 which are directed to preventing thrombus formation and claims 9, 11 and 37 of >124 which are directed to treating or preventing platelet associated ischemic syndrome.

While the claims of the parent patent do not include this subject-matter, no actual use is claimed here so >an amount effective to= is considered to simply direct the concentration of the peptide in the composition by specifying the amount present; i.e., the composition contains an amount of PAI that would have this effect. As this limitation is ultimately a matter of uninventive dilution, it does not constitute a second invention.

31. Claim 13 also depends from claim 11, but restricts the peptide such that it is effectively the same as claims 14 and 15; *viz.* directed to compositions comprising the peptide identified in the parent patent as PAI 60. The claim in the parent which most closely resembles claims 13B15 of the divisional is parent claim 32, because the peptide PAI 60 itself is being claimed. For identical reasons, claims to compositions comprising this peptide are not considered patentably distinct over claims to the molecule itself.

32. In light of the above, composition claims 11B15 (Group B) are not considered to be patentably distinct from the claims of the parent patent.

GROUP C CLAIMS

33. The next group of claims to be compared to the parent are identified in the table as Group C, consisting of independent claims 16 and 38B40 of the subject application, relating to uses of PAI peptides selected from a defined group. The claims are reproduced below:

> 16. The use of a platelet aggregation inhibitor polypeptide according to any one of Claims 1 to 10 for the manufacture of a medicament suitable for inhibiting platelet aggregation or the treatment or prevention of platelet-associated ischemic disorders.
>
> 38. The use of a polypeptide comprising a sequence selected from the group consisting of:
>
> [list of peptides]
>
> or a pharmaceutically acceptable salt thereof for the manufacture of a medicament suitable for treating or preventing platelet aggregation or a platelet-associated ischemic disorder, wherein the polypeptide is in cyclic form through formation of disulfide linkages.
>
> 39. The use of a polypeptide comprising a sequence selected from the group consisting of:
>
> [list of peptides]
>
> or a pharmaceutically acceptable salt thereof for the manufacture of a medicament suitable for preventing platelet loss during extracorporeal circulation of blood involving the contact of said blood with an effective amount of said polypeptide, wherein the polypeptide is in cyclic form through formation of disulfide linkages.
>
> 40. The use of a polypeptide comprising a sequence selected from the group consisting of:
>
> [list of peptides]
>
> or a pharmaceutically acceptable salt thereof for the manufacture of a medicament suitable for preventing platelet aggregation, embolization or consumption of extracorporeal circulation, wherein the polypeptide is in cyclic form through formation of disulfide linkages.

At the outset, it should be noted that the peptides listed in claims 38B40 are also found in one or more of claims 30B35, 38, 39 and 41B46 of the parent patent, while those of claim 16 were discussed in relation to Group A. In the parent, however, the claims are directed to the peptides *per se*, no claims are directed to the uses thereof.

34. This absence of use claims in the parent was dismissed in the Final Action, where it was determined that the claims are nevertheless directed to the same inventive concept:

> The present application includes claims directed towards the use of the PAI polypeptides for the manufacture of a medicament suitable for inhibiting platelet aggregation or the treatment or prevention of platelet-associated ischemic disorders. While uses of the specific PAI polypeptides making up the composition of matter according to claim 21 of the parent were not claimed in the parent, the use of these specific PAI polypeptides in the manufacture of a medicament or in treating conditions relating to platelet aggregation or the treatment or prevention of platelet-associated ischemic disorders as claimed in the present application relate to the same general inventive concept. . . . Furthermore, the polypeptide in the composition of matter claimed in claim 21 of 2059124 is specifically defined as being Aa specific platelet aggregation inhibitor (PAI)@ thus indicating its usefulness for the inhibition of platelet aggregation or in the treatment or prevention of platelet-associated ischemic disorders.

35. Although the uses are not claimed in the parent patent, the ultimate patentability of the peptides requires that there be some associated utility. This utility is not considered a separate invention from the peptides themselves or the compositions comprising them, and therefore cannot be separately patented.

36. This concept was applied in *Re: Application 207,229*, Commissioner=s Decision 332 (1976), to a similar fact situation, where the parent patent claimed a product (antibiotic), and the divisional claim sought protection for the intended use of it. In that Decision, the Board took the position:

> The claims in our view, though independent of one another, cannot be read apart from the description of the invention in the specification. The applicant has in no way shown that the present claims are directed to a separate invention distinct from the product (antibiotic) claims. It is clear that the present claims are directed to the intended use of the anti-biotic which was allowed in the parent application in 1974. The present utility is the same as that upon which the patentability of the antibiotic was predicated.We are therefore satisfied that there is no further invention in the present application in having claims Adirected to the intended use of the antibiotic,@ beyond that protected in the patent which claims the antibiotic. That is, the present claims are merely directed to a different aspect of the same invention as that of the parent.

37. More recently, a similar conclusion was drawn in *Merck & Co. v. Apotex Inc.*, 59 C.P.R. (3d) 133. This conclusion was raised as part of the appeal in *Apotex Inc. v. Merck & Co.*, [1995] 2 FC 723, 60 C.P.R. (3d) 356 (*Merck*); however, the Federal Court of Appeal agreed with the Trial Judge on this point. From paragraph 37 of that Decision:

> In my view, the appellant was in error in contending that the invention was simply chemical molecules of enalapril. Chemically speaking, that was so. But the specification of the patent, properly construed, asserts more than that. In this respect, the Trial Judge was entirely right when he wrote (at page 156):

> . . . the patent . . . claims more than a molecule with a chemical formula. **Rather, the claims describe several or many compounds, and several compositions, and specific uses for them, all aspects of the same invention. Enalapril may be the essence of each claim, but the claims, and the patent for the invention, are more than the chemical molecule of enalapril or of enalapril maleate.**
>
> **Inherent in the compound, and indeed in the patent, is the purpose and utility of the compound of enalapril.** [*emphasis added*]

Following this reasoning, the utility of the peptides is but an aspect of the same invention as the peptides themselves, as are the compositions comprising them.

38. On the topic of utility, the applicant states in his response to the Final Action:

> Regarding claims 16-40, it is again noted that none of the claims of the parent are directed toward the use of PAI polypeptides . . . .
>
> Specifically, applicant notes that the method of manufacture of a medicament is not subject matter of the claims of the parent application . . . .

It appears that what the applicant is referring to in regard to claims being directed to methods of manufacturing medicaments, are the Swiss-type claims 16B40.

39. The claim format known as >Swiss-type claims= was adopted by the European Patent Office in 1984 to circumvent the restrictions imposed by the European Patent Convention for claiming of second or subsequent medical uses of a known substance or composition. No comparable restrictions exist in Canadian law. Claims of the form AUse of a substance [or composition] for the manufacture of a medicament for [a specified therapeutic application]@ were accepted as appropriate means for claiming such uses. Swiss-type claims have since been construed by the Canadian courts, and are considered to be an alternative format for claiming uses of a medicine, rather than methods of manufacture as suggested by the applicant (see *GD Searle & Co. v. Canada (Minister of Health)*, 2008 FC 437, 65 C.P.R. (4th) 451, aff=d 2009 FCA 35, at para. 46; *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406 (paras. 20-23) and *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 971, aff=d 2009 FCA 8, at paras. 32B35.) In light of how these claims are construed by the courts, and for simplicity, subsequent reference will be made to them as being uses.

40. One minor difference is noted in the language of Group C claims 16 and 38B40 when compared to typical Swiss-type claim language; *viz*. the inclusion of >suitable= in AThe use of . . . in the manufacture of a medicament <u>suitable</u> for . . . .@ The Board is of the opinion that the claims

should nevertheless be viewed as medical uses per the courts= construction of Swiss-type claims, rather than as methods of manufacture as suggested by the applicant. This is despite marginally departing from the form these claims normally take. The suitability of the peptides, or of the manufactured medicament, for the specified medical therapy is implicit, since they must be suitable in order to be applied to the defined medical therapies. The presence of >suitable= in these claims is therefore viewed as being redundant, and the claims are taken to be Swiss-type claims that amount to claims to medical uses.

41. Even if the claims were interpreted as being directed to methods of manufacturing pharmaceuticals as the applicant suggests, claims 16 and 38B40 would not be directed to a separate invention from what was claimed in the parent patent. The methods involved with the claims are not defined in the claims, so the steps necessary to manufacture the medicament must be common general knowledge to a person skilled in the relevant art. The claims would therefore be considered common methods applied to make compositions of the PAIs, which could be used (i.e. are suitable for use) in the therapeutic treatment defined. If compositions are not considered patentably distinct from claims to the peptides (compounds) contained in them, absent any inventive contribution (*cf. Hoechst*), then it follows that common methods for making said compositions are also not patentably distinct from the relevant compounds or compositions, as any invention lies not in the method, but in the peptides. This view is supported in *Apotex Inc. v. Merck* & C*o. Inc.*, 2006 FCA 323, 55 C.P.R. (4th) 1, at para. 32 and *Ciba-Geigy Ag. v. Commissioner of Patents*, [1982] 65 C.P.R. (2d) 73 at p. 79. The peptides defined in these Group C claims were already established to have been claimed in the parent (see Group A analysis), so the Board would not view claims to methods of manufacturing medicaments of these peptides as being directed to a separate invention.

42. As mentioned, however, the Board has interpreted these claims as being Swiss-type claims. The following analysis will continue based on this understanding; i.e. with these claims being treated as being directed to medical uses.

43. Turning back to Group C, claim 16 is directed to uses of peptides shown in the analysis of Group A to not be patentably distinct from the parent, so it can be concluded that the uses defined in this claim are also not patentably distinct from the peptides, in accordance with *Merck* (para. 36, *supra*). Similarly, the peptides listed in claim 38 are all present in one or more of the claims of the parent patent (i.e., in Group A), and therefore the same conclusion must be drawn.

44. With respect to claims 39 and 40, where extracorporeal uses are defined: according to pages 46B47 of the original description two different utilities are ostensibly defined, relating to the prevention of thrombus formation, and to the use of the peptides in preventing platelet aggregation, so as to be useful in extracorporeal treatments.

45. It is evident that the use of PAI peptides *in vivo* as well as *ex vivo* to prevent platelet aggregation was known in the art. This is evidenced from PCT publication 89/07609, published August 24, 1989, which was cited at line 9 of page 4 in the description in the >Background Art= section of the original parent description. The publication date of this document predates the claim date of the parent (2,059,124), so it is to be understood that its disclosure formed part of the state of the art, which the applicant has tacitly acknowledged. This prior art describes homoarginine-based PAI peptides, teaching that they are useful in preventing thrombi formation as well as being useful in extracorporeal applications. From page 9 of that document:

> These compounds are useful whenever it is desired to inhibit platelet aggregation, reduce the adhesive character of platelets, and remove or prevent the formation of thrombi in mammals, including man, rabbits, dogs and rats. For example, these compounds are useful in the treatment and prevention of myocardial infarcts, to treat and prevent post-operative thrombosis . . . .
>
> These compounds are further useful as additives to blood, blood products, blood substitutes or other fluids which are used in artificial extracorporeal circulation or perfusion of isolated body portions, e.g., limbs and organs, whether attached to the original body, detached and being preserved or prepared for transplant or attached to a new body. During these circulations and perfusions, aggregated platelets tend to block the blood vessels and portions of the circulation apparatus.

The commonality between these uses is that platelets are being aggregated, the difference resides in the environment in which the aggregation takes place: *in vivo* or *ex vivo*. It is therefore platelet aggregation that is the utility, *in vivo* and *ex vivo* merely indicate where it is practised. Since there is no reason to believe that it would be expected that the present PAIs would behave any differently than those mentioned in this document, the same conclusions can be drawn: the seemingly different uses in actuality relate to the same utility.

46. The claimed peptides have already been determined to not be patentably distinct from the claims of the parent. Since it has also been established that there is only a single utility taught, which is itself an aspect of the same invention as the peptides themselves, it follows that none of claims 16 and 38B40, relating to uses of PAI peptides selected from provided groups (Group C), are patentably distinct from the claims of the parent patent.

GROUP D CLAIMS

47. Claims 17B37 (Group D) are directed to uses of the peptide identified in the parent as PAI 60. The independent claims in this group (claims 17, 28 and 29), otherwise define uses identical to those of Group C (claims 38, 39 and 40, respectively). Applying reasoning analogous to that used in the analysis of Group C, bearing in mind that PAI 60 itself is not patentably distinct in light of the fact that it was specifically claimed as parent claim 32 (see Group B analysis, *supra*), the uses are found to be an aspect of the same invention as the peptide and compositions comprising it. For the same reason then, claims 17B37 cannot be considered patentably distinct from those of the parent patent.

APPLICANT=S SECOND ARGUMENT: CLAIMS DIFFER TO PROTECT AGAINST INFRINGEMENT

48. In reference to the second argument, the applicant states in response to the Final Action:

> [A]pplicant notes that the method of manufacture of a medicament is not subject matter of the claims of the parent application. Consequently, a third party who obtained the purified material from one company and manufactured pharmaceuticals for sale by another entity would avoid infringement of the claims of the parent.

The reference to >methods of manufacture of a medicament= was discussed previously in this Decision (para.39), in relation to construing Swiss-type claims as uses.

49. Although it is acknowledged that protection against possible infringers is an important consideration in corporate patent strategy, such factors do not weigh into the determination of the propriety of a divisional application. The authority for the voluntary division of subject-matter is subsection 36(2) of the *Patent Act*, reproduced below:

> 36. (2) Where an application (the Aoriginal application@) describes more than one invention, the applicant may limit the claims to one invention only, and any other invention disclosed may be made the subject of a divisional application, if the divisional application is filed before the issue of a patent on the original application.

50. The *Patent Act* therefore contemplates voluntary division of subject-matter from an original application (parent) where that original application describes more than one invention. There is no provision in the *Patent Act* for divisional applications to be filed for the same invention as claimed in the parent, simply to cover claim-types that were not included in the parent but perhaps ought to have been.

APPLICANT=S THIRD ARGUMENT: DIFFERENT IPCS MEANS DIFFERENT INVENTIONS

51. The third line of argumentation involved trying to distinguish the claims of the divisional from those of the parent on the ground that the subject-matter claimed in the divisional should properly have been assigned a different IPC symbol from the parent. From the applicant=s response to the Final Action:

> It is again noted that methods of manufacture of a pharmaceutical should be classified as A61P and not C07K using the PCT classification scheme. Given the fact that these claims would be assigned to different classes, different searches would have to be carried out.

The implication is that, since the matter belongs in different classifications, a separate search would need to be carried out, which suggests a separate invention is being claimed. It should be noted that the reasoning provided by the applicant does not appear to have been intended to apply to all the claims of the divisional, but rather only to the Swiss-type use claims as suggested by

Amethods of manufacture of a pharmaceutical@.

52. The Board does not find this argument convincing since classification considerations are not determinative as to whether there are indeed two inventions being claimed. The intent of assigning IPCs is not for the purposes of signifying different inventions claimed in an application, but rather to aid in the sorting of applications and facilitation of searching and retrieval. The following is taken from: *WIPO Intellectual Property Handbook: Policy, Law and Use*, second edition, Geneva: WIPO publication No. 489(E), 2004, para. 5.427 on the topic of the purpose behind patent classification:

> On the other hand, patent applications also have to be provided with special symbols which relate to the technical field or fields to which the patent application relates. These symbols are required to assist the public concerned, for example industry, and also to facilitate the orderly and classified arrangement of patent documents in order to permit searching and thereby the retrieval of documents relating to distinct technical subject matter.

The IPC assigned to a particular subject-matter is therefore not necessarily a factor in deciding whether there are two or more inventions, as this is not its direct purpose. By way of example, claims to a peptide may be classified in C07K, while claims to compositions comprising that peptide, and uses thereof, may be classified in A61K, yet these were previously-shown to be aspects of the same invention (*cf.* paras. 30 and 37). The classification scheme allows for the sorting, search and retrieval of this information, but does not dictate whether there is one or more inventions embodied. While a different IPC symbol assigned to particular subject-matter may reflect that a separate invention is present, this alone cannot be relied upon to make that determination.

APPLICANT=S FOURTH ARGUMENT: NO CLEAR DEFINITION OF >INVENTION=

53. The final point raised by the applicant related to the definition of >invention= in the *Patent Act*. Specifically, from the applicant=s response to the Final Action:

> [T]he concept of what constitutes an >invention= is only broadly defined in three lines in Section 2 of the Patent Act. Specifically, there is a lack of clear rules on how an >invention= is defined and accordingly Canadian applicants have limited means to argue with the determination made by a Canadian patent examiner.

The case law cited in paragraphs 8B13, above, establishes what is considered a separate patentable invention in cases where the double patenting provisions may apply. Although the language of section 2 of the *Patent Act* is not detailed in its explanation of what constitutes an invention, double patenting was noted to be a judge-made prohibition; it is the jurisprudence that must be consulted for elaboration. For the purposes of double patenting, the question is not whether there is an invention in the divisional, *per se*, but whether the invention claimed is different from what is claimed in the parent patent. This point has been addressed by this Decision.

RECOMMENDATIONS OF THE BOARD

54. The Board has found that none of claims 1B40 in divisional application 2,388,770 define subject-matter that is patentably distinct over the claims of the parent patent 2,059,124. It is therefore recommended that the examiner=s objection to these claims be upheld, and that the decision in the Final Action to reject the application be affirmed.

Ryan Jaecques	Nicole Harris	Ed MacLaurin
Member	Member	Member

COMMISSIONER=S DECISION

55. I concur with the findings and the recommendation of the Patent Appeal Board. Accordingly, I refuse to grant a patent on this application. Under section 41 of the *Patent Act*, the applicant has six months within which to appeal my decision to the Federal Court of Canada.

Mary Carman
Commissioner of Patents

Dated at Gatineau, Quebec,
this 25 day of June, 2009