Commissioner's Decision # 1299

Décision du Commissaire # 1299

TOPIC: A20, D02

SUBJECT: A20, D02

Application No : 2,425,101

Demand no : 2,425,101

COMMISSIONER'S DECISION SUMMARY

C.D. 1299 Application No. 2,425,101

The subject application is a divisional application of Canadian Patent 2,050,300, relating to the use of tumor necrosis factor (TNF-α) binding proteins (BPs), purification and use in treating diseases in which the concentration of TNF-α in the body fluids is elevated. In the Final Action, the Examiner rejected the application for being directed towards the same invention as the Applicant's issued patent. The Board recommended that the rejection of the application be affirmed.

The Commissioner of Patents agreed with the Board=s recommendation and the application

was refused.

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent Application number 2,425,101 having been rejected under Subsection 30(4) of the Patent Rules, the Final Action 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:

Agent for the Applicant

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INTRODUCTION:

(1) This decision deals with a review of the Examiner's Final Action on patent application number 2,425,101 entitled **"TNF-INHIBITING PROTEINS AND THE PREPARATION THEREOF"**. The Applicant is Basf AG and the inventors are Hans-Georg Lemaire, Heinz Hillen, Achim Moeller, Lothar Daum, Thomas Doerper and Thomas Subkowski. Examiner C. MacFarlane issued a Final Action on April 10, 2007 rejecting the application for obviousness double-patenting and non-compliance with subsection 36(2) of the *Patent Act*.

(2) The subject application is a divisional of patent Application 2,050,300 filed on November 15, 1990, which issued to patent on April 8, 2003. The subject application was given provisional divisional status on April 3, 2003.

(3) The invention claimed in the pending application relates to the use of Tumor Necrosis Factor (TNF) binding protein (BP), deglycosylated TNF-BP, exchange, deletion, addition muteins thereof for producing drugs for treating diseases with elevated TNF-α.

BACKGROUND:

Prosecution History

(4) Divisional application 2,425,101 was originally filed with 4 claims; claims 1 and 2 were directed towards TNF-BPs and claims 3 and 4 were directed towards the use of the proteins for producing drugs for treating diseases in which TNF-α in body fluids is elevated. The first Office Action was dated March 21, 2006, and alleged that claims 1 to 4 were not patentably

distinct from that of the claimed subject matter of claims 1 to 3 of the parent patent 2,050,300. In addition, the Examiner referred the Applicant to an Office Action issued against the parent application dated July 4, 2001 in which the claimed TNF-BPs were anticipated by several prior art disclosures. In the Applicant's response of September 21, 2006, the claims were amended, reducing the number of claims to 2 which were directed towards the use of the TNF-BPs for producing drugs for treating diseases and not towards the proteins *per se.* The next Office action was a Final Action dated April 10, 2007. The Final Action raised the same objection with further elaboration. In response, the Applicant traversed the objection but did not amend the claims.

(5) A Summary of Reasons was sent to the Patent Appeal Board on December 4, 2007. The Applicant declined the opportunity to be heard at an oral hearing. The review of the rejection therefore proceeded on the basis of the documents on record.

Grounds for Rejections (the Examiner's Position)

(6) Claims 1 to 2 of application 2,425,101 were formally objected to in the Final Action under Subsection 36(2) of the *Patent Act* for not being patentably distinct from the subject matter of claims 1 to 3 of the parent patent 2,050,300. The arguments presented by the Examiner related to >obviousness' double-patenting.

(7) With respect to the TNF-BPs the Examiner stated in the Final Action that:

> ...the peptide of the divisional application differs from that of the parent only in the possible (undefined) exchanges or deletions of amino acids. However, such muteins are not

patentably distinct from the parent peptides as they would have to be considered as conservative modifications of the peptides so as to maintain its TNF- alpha inhibiting function as stipulated in the claims, thus requiring no inventive step. Indeed, no specific chemical structure of such muteins are set forth and no unexpected advantages over the parent peptides are mentioned.

(8) Further, with respect to the intended use of the proteins, the Examiner stated in part that:

...the claimed use in the divisional application is the same as the intended use of the parent peptide, not a new, unexpected or different use. Both claim 1 of the parent 2,050,300 and instant claim 1 stipulate that the peptide must inhibit TNF-α. The description (at page 3, lines 22-29) states:

> The novel proteins display good TNF-α inhibiting actions and can therefore be used for the treatment of disease in which the concentrations of the TNF-α in body fluids is elevated, such as septic shock. They can also be used for the following disorders: allergies, autoimmune diseases, rheumatic disorders, shock lung, inflammatory bone disorders, disturbances of blood clotting, burns and complications following transplantations.

Clearly, the ultimate point of the parent peptide is its use to prepare drugs to treat TNF-α related diseases due to its TNF-α inhibiting function and, because the structure and intended use of the divisional peptide are the same as those of the parent, an inventive step cannot be acknowledged. Formulating the parent peptide into a pharmaceutically acceptable drug and using the peptide in the manner for which it was intended do not require an inventive step for the skilled person. Further, there is no support in the description for any other uses of the parent peptide other than treating TNF-α related diseases (as stated in page 3 of the description). Indeed, admitting that the use of the instant peptide is a distinct invention over

> that of the parent would call into question the utility of the parent peptide, if not to treat TNF-α related diseases, thereby questioning the validity of the parent patent.

(9) Moreover, with respect to the Applicant's assertion that the claimed use is inventive and that the decision in *Bayer AG vs. Novopharm Ltd.* 2006 FC 379, 48 CPR (4th) 46 supports the notion that ingenuity negates an allegation of obviousness double-patenting the Examiner stated that:

> [the] Applicant is reminded that the test for ingenuity is rooted in the inventiveness or unexpected biological advantages that the peptide would demonstrate over that of the parent peptide and not in unexpected subsequent economic success of the product. In other words, the extent to which a product is successful in the manner that it was intended to function, in this case, its use to prepare drugs to treat TNF-α related diseases, is not a measure of ingenuity and cannot form the basis of inventiveness.

(10) After considering the Applicant's submissions in response to the Final Action, the Examiner maintained the objection to claims 1 to 2 as not being patentably distinct from claims 1 to 3 of the parent patent 2,050,300.

The Applicant's Position

(11) In response to the Final Action the Applicant presented reasons as to why the subject matter claimed in claims 1 and 2 of the divisional application were patentably distinct from the subject matter claimed in claims 1 to 3 of the parent patent. The Applicant argued that the claims belonged to different claim categories and that the economic success and phenomenal utility of the TNF-BPs supported the inventiveness of the subject matter of the divisional claims. The

reasons given were an elaboration of those given with the Applicant's response dated September 21, 2006 relating to the first Office Action dated March 21, 2006.

(12) Firstly, the Applicant argued that the category of the claims of the divisional application differed from the category of the claims issued for the parent and concluded that the claims were directed to a different invention. The Applicant stated in part [emphasis in original]:

> ....it is clear from the wording of claims 1 and 2 that they are directed towards the use of a tumor necrosis factor binding protein for producing drugs for treating diseases in which TNF-α in the body fluids is elevated. Thus it is clear from the claims that the instant application the Applicant wishes to obtain protection on the use of the peptide and not the peptide itself.

(13) The Applicant also referred to the Manual of Patent Office Practice (*MOPOP*) Chapter 11 to define the various categories of claims (product claims, process and method claims and method of use and use claims) to support their position.

(14) Further, with respect to the allegation that the claimed use of the divisional proteins was the same as the intended use of the parent proteins, the Applicant stated in part [emphasis in original]:

> ...TNF alpha inhibition is a function of the protein claimed in claim 1 of CA2,050,300 and that claim 1 of the instant application is directed to the use of the protein of the present application for producing a drug for treating diseases in which the concentration of TNF alpha in body fluid is elevated.

(15) To support their position that the divisional claims were inventive, the Applicant referred to a statement made by Hughes J. in *Merck & Co. v. Apotex Inc*. 2006 FC 524, paragraph 213, 53 C.P.R (4th) 323; (*Merck*):

> I have found that lisinopril and enalapril are separate inventions...they are "patentably distinct" they are not "identical or coterminous". Being separate inventions, one is not obvious in view of the other...

(16) In view of *Merck*, the Applicant concluded that since the subject matter of divisional claims 1 to 2 was not identical or conterminous with that of the claimed subject matter of the parent patent, they should be considered inventive.

(17) Lastly, to establish ingenuity of the proteins, the Applicant referred to statements made by Hughes J. in *Janssen-Ortho Inc. and Daiichi Pharmaceutical Co. Ltd v. Novopharm Limited*, 2006 FC 1234, to the effect that economic success is a secondary factor to be considered on a principled and objective basis during a determination of obviousness. The Applicant alleged that the Examiner erred in dismissing the Applicant's showing of economic success of the protein and its use to treat various arthritic diseases.

(18) In response to the Examiner=s allegation that ingenuity was not rooted in subsequent economic success, the Applicant again submitted that the economic success of a related product was proof of the inventiveness of the subject matter of the divisional claims and stated that:

> ...The phenomenal and unexpected success of Etanercept7 to treat TNF-α related diseases

> should direct one skilled in the art to conclude that the claims directed to the use of novel protein to treat TNF-α related disorders are inventive over the parent application. This success was unexpected at the filing date of the parent application as clinical trials began in 1992 and the use of Etanercept7 was approved first in 1998.

(19) The Applicant thus contended that the divisional claims were inventive over the parent claims and that the divisional status of the present application was therefore merited.

SUMMARY OF THE RELEVANT CASE LAW:

(20) In respect of double-patenting, *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. 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). The second branch of the test, outlined in *Whirlpool* at paragraph 66, is termed >obviousness double-patenting' and is somewhat broader:

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

(21) A summary of the relevant case law has also been provided in *Re: Orasure Technologies Inc.* (2009), Commissioner's Decision 1291, and *Re: Millenium Pharmaceuticals*

(2009), Commissioner's Decision 1294.

(22) Recently, in the decision in *Bayer Schering Pharma AG v. Canada (Attorney General),* 2009 FC 1249, the Court reaffirmed that even when claims of a pending application are not considered >identical= or >precisely conterminous= with the claims of an issued parent patent, inventive ingenuity would still be required for the divisional claims to be considered >patentably distinct= from those of the issued parent.

ANALYSIS:

(23) During the prosecution of 2,425,101, the Applicant noted in the response dated September 21, 2006 that the claims of the two applications were neither identical nor conterminous and that the first branch, >same invention' approach to double-patenting, did not apply. Further, the Applicant discounted the relevance of obviousness double-patenting as the two applications shared the same filing date. Again, in the response to the Final Action, the Applicant stated that the "subject matter of the instant application is not identical nor conterminous with that of claims 2,050,300" and hence "the subject matter of the instant claims should be considered inventive" yet provided no further arguments pertaining to obviousness double-patenting.

(24) Irrespective of the arguments presented by the Applicant, at no time during the prosecution of the divisional application was non-compliance with the first branch of double-patenting alleged by the Examiner. In the Final Action, the Examiner, rejected claims 1 and 2 of divisional application 2,425,101 as not being patentably distinct from the subject matter of claims 1 to 3 of the parent patent 2,050,300. This objection by the Examiner corresponds to the second branch of the double-patenting test noted in *Whirlpool*, termed

>obviousness double-patenting' which requires inventive ingenuity to warrant the issuance of a second patent. Therefore, it is the second branch of the enquiry that will be considered by the Board.

Claims at Issue

(25) To assess whether the issuance of application 2,425,101 to patent raises the possibility of double-patenting, the claims of 2,425,101 must be compared with the claims of the parent patent 2,050,300. The claims of the divisional application 2,425,101 read as follows [emphasis added]:

> 1. Use of Tumour Necrosis Factor binding protein which has a molecular weight of about 42,000 daltons as determined by SDS gel electrophoresis having at the N terminus the amino acid sequence:
>
> Xaa Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg
>
> where:
>
> Xaa is hydrogen,
>
> a phenylalanine residue (Phe) or the amino acid sequences
>
> Ala Phe,
>
> Val Ala Phe,
>
> Gln Val Ala Phe,
>
> Ala Gln Val Ala Phe,
>
> Pro Ala Gln Val Ala Phe or
>
> Leu Pro Ala Gln Val Ala Phe;

and the muteins thereof produced by suitable exchange, deletion or addition of amino acids or peptides or by modification of the glycoside residue without the TNF-alpha inhibiting effect of the protein being greatly diminished thereby, for producing drugs for treating diseases in which the concentration of TNF alpha in body fluids is elevated.

2. The use as claimed in claim 1, wherein the disease is an allergy, autoimmune disease, rheumatic disease, shock lung, inflammatory bone disease, disturbance of blood clotting or complication after transplantations.

(26) The claims of the issued parent patent 2,050,300 are directed towards TNF-BPs (claims 1 and 2) and processes for their purification (claim 3). Although in the Final Action the Examiner objected to divisional claims 1 and 2 as not being patentably distinct in view of claims 1 to 3 of the parent patent, claims 1 and 2 of the parent patent (product claims) are considered the most relevant claims and therefore, will be used for the claim comparison. In particular, claim 1 of 2,050,300 defines the same TNF-BP as those defined in claim 1 of 2,425,101 but limit the muteins to addition muteins. Claims 1 and 2 of the parent patent read as follows [emphasis added]:

1. A Tumour Necrosis Factor binding protein which has a molecular weight of about 42,000 daltons as determined by SDS gel electrophoresis having at the N terminus the amino acid sequence:

Xaa Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg

where:

Xaa is hydrogen,

a phenylalanine residue (Phe) or the amino acid sequences

Ala Phe,

Val Ala Phe,

Gln Val Ala Phe,

Ala Gln Val Ala Phe,

Pro Ala Gln Val Ala Phe or

Leu Pro Ala Gln Val Ala Phe;

and the muteins thereof produced by suitable addition of amino acids or peptides or by modification of the glycoside residue without the TNF-alpha inhibiting effect of the protein being greatly diminished thereby.

2. A protein as claimed in claim 1, in deglycosylated form.

Muteins of TNF-BP

(27) To address the differences between the muteins claimed in the divisional application and those that issued in the parent patent, the Examiner in the Final Action stated that:

> ...the peptide of the divisional application differs from that of the parent only in the possible (undefined) exchanges or deletions of amino acids. However, such muteins are not patentably distinct from the parent peptides as they would have to be considered as conservative modifications of the peptides so as to maintain its TNF-α inhibiting function as stipulated in the claims, thus requiring no inventive step.

(28) During the prosecution of the parent application, exchange and deletion muteins were deemed anticipated by several prior art disclosures (see Office Action dated July 4, 2001). In the response to the Final Action, the Applicant did not refute or challenge the Examiner=s

assertion that the exchange and deletion muteins were not inventive. The Board finds no reason to disagree with the Examiner=s conclusion that the muteins lack ingenuity.

Commercial Success as Support for Ingenuity

(29) The Applicant alleges that the Examiner erred in dismissing the Applicant's showing of the phenomenal and unexpected economic success of Etanercept7 to treat TNF-α related diseases as proof of the inventiveness of the subject matter of the divisional claims:

> ...The phenomenal and unexpected success of Etanercept7 to treat TNF-α related diseases should direct one skilled in the art to conclude that the claims directed to the use of the novel proteins to treat TNF-α related disorders are inventive over the parent application. This success was unexpected at the filing date of the parent application as the clinical trials began in 1992 and the use of Etanercept7 was approved first in 1998.

(30) The Applicant refers to *Janssen-Ortho Inc. and Daiichi Pharmaceutical Co. Ltd v. Novopharm Limited* 2006 FC 1234, as support for the proposition that economic success is a secondary factor to consider when determining obviousness. As noted by Hughes J. in *Janssen*, at paragraph 113, economic success is only one of a number of factors to consider [emphasis added]:

> ...A determination of obviousness on a principled and objective basis requires that the Court take into consideration a number of factors. These factors may vary in number and importance dependant upon the circumstances of the case...
>
> ...Of secondary importance are factors arising after the time that the alleged invention is made

since, after all, the Court is to be concerned with "inventive ingenuity" exercised at the time of making the invention.

(31) Furthermore, Sharlow J of the Federal Court of Appeal in *Janssen-Ortho Inc. v. Novopharm Limited* 2007 FCA 217; (*Janssen-Ortho*) noted at paragraph 26 that while secondary factors may be relevant, they generally bear less weight because they relate to facts that arise after the date of the invention. Additionally, commercial success may reflect things other than inventive ingenuity, such as, marketing skills, marketing power, lack of an alternative, pricing etc. Therefore, while evidence of commercial success upon the introduction of a patented product is not to be disregarded, but taken alone, it is not conclusive evidence of inventiveness: *Pfizer Canada Inc v. Apotex* 2005 FC 1421, 43 C.P.R. (4th) 81, 282 F.T.R. 8, para 121; *Diversified Products Corp. v. Tye-Sil Corp*. (1991), 35 C.P.R. (3d) 350, 125 N.R. 218 (Fed. C.A.), para 45-47.

(32) Notwithstanding the success of Etanercept7 in treating TNF-α related diseases, Etanercept7 and TNF-BP are two different proteins and thus cannot be directly compared. Etanercept7 is a fusion protein consisting of a TNF-BP and an immunoglobulin protein (IgG) that was developed and marketed as a treatment for rheumatoid arthritis, juvenile rheumatoid arthritis and psoriatic arthritis. The phenomenal and unexpected success of Etanercept7, therefore, cannot be solely attributed to the TNF-BP portion thereof, but is the result of the unique attributes of the fusion protein which include both TNF-BP and IgG components. Although *Janssen-Ortho, supra*, noted that secondary factors, including economic success, are to be given some consideration, the commercial success of Etanercept7 is not relevant to the present enquiry since the Applicant has failed to show a nexus between the claimed invention and evidence of commercial success.

Claim Categories and Inventive Concept

(33) As noted by the Applicant in the response to the Final Action, the claims of the divisional application and parent patent fall into different claim categories; in the case of the instant divisional application the Applicant "wishes to obtain protection on the use of the peptide and not the peptide itself". The Applicant makes reference to *MOPOP* Chapter 11 to define various categories of claims to conclude that claims belonging to different claim categories are not directed to the same invention.

(34) However, *MOPOP* Chapter 11, Section 11.10.02 (March 1998 version) also states that [emphasis added]:

> When a claim to a compound has been found allowable in an application, then a claim to a method of use of that compound or a claim to the use of that compound is also allowable in the same application. When a claim to a compound has been found allowable to the inventor in one application, then claims in a different application of the same inventor to a use of that compound or methods of using that compound which are obvious from the utility disclosed for the compound, and upon which utility the patentability of the compound was predicted, are not allowed.

(35) This concept was applied in *Re: Application of Norimasa Miyairi et al.*, (1976), Commissioner's Decision 332, to a similar fact situation as the present case, where the parent patent claimed a product, and the divisional claimed the intended use of it. In that Decision, the Board took the position that the claims [emphasis added]:

> ...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 antibiotic 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 "directed 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.

(36) Similarly, the Federal Court in *Merck & Co. v. Apotex Inc.*, 59 C.P.R. (3d) 133, aff=d [1995] 2 F.C. 723, 60 C.P.R. (3rd) 356, (*Merck & Co.*), in considering whether the compound Enalapril7 and its use in treating hypertension were different inventions, concluded that [emphasis added]:

> ...several or many compounds, and several compositions, and specific uses for them, [are] 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.

(37) As is evident from the decisions of *Norimasa Miyairi et al.* and *Merck & Co*, claims belonging to different claim categories are not necessarily indicative of ingenuity. To access whether ingenuity is present, the disclosure may be considered in order to ascertain the nature

of the invention claimed and its underlying utility.

(38) Although an allegation of double-patenting involves a comparison of the claims and not the specifications, under certain circumstances, reference to the description is permitted since claims are read in light of the description. For example, the law on double-patenting permits consideration of the description when evaluating a "selection" claim. In *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, 69 C.P.R. (4th) 25; see para 114, in order to assess the ingenuity of the claimed selection, the Supreme Court referred to the description to determine "the nature of the characteristic which the patentee alleges to be possessed by the selection".

(39) Just as it is necessary to refer to the description for a selection claim, in our opinion, it is necessary here to refer to the description to assess the ingenuity of the product claims. While the specification of the selection patent must define an advantage or an avoidance of a disadvantage attributed to the selection, a product claim must have utility. That utility need not be recited in the claim, as is the case here, but can be understood from the description. In the present instance, once the utility of the parental product claims is understood based on the reading of the description it is possible to assess the ingenuity of the use of that product claimed in the divisional application.

Utility of TNF-BPs

Protein Function versus Protein Use

(40) In the Final Action the Examiner asserts that the utility of the invention is the same as that upon which the patentability of the parent proteins was predicated. In response, the Applicant submits that the TNF-α inhibiting effect of the protein describes a function of the protein rather than the use of the protein. In the biological sciences it can be generally understood that knowledge of the functional characteristics of a protein does not necessarily translate into knowledge of the usefulness for said protein and *vice versa*. However, in the present case, the medical use of a TNF-BP is self-evident from its stated biological function as indicated in the divisional claims themselves as well as from the description of the parent patent.

Use of TNF-BPs for producing a drug

(41) In the response to the Final Action, the Applicant contended that claims 1 and 2 of the divisional application were directed towards the use of the proteins "for producing a drug@ for treating diseases and differed from the parent patent which claimed the proteins themselves.

(42) The language in claim 1 of the divisional application is consistent with the phrasing of >Swiss-type' claims; a format that originated in the European Patent Office to enable patent protection for a second or subsequent medical use of a known compound or composition. In Canada, >Swiss-type' claims have been construed by the courts, and have been considered to be an alternative format for claiming uses of a medicine (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).

(43) We note first that the TNF-BPs and muteins thereof of divisional claim 1 are equivalent to the TNF-BPs and muteins thereof of parent patent claims 1 and 2, as well as TNF-BP exchange or deletion muteins of the prior art (see parental Office Action dated July 4, 2001). Secondly, the utility taught for the TNF-BPs and muteins thereof in the parent patent is the inhibition of TNF-α (see description page 3, lines 23-29, examples 1 and 8), in particular, their use in treating the group of diseases listed in claim 2 of the divisional application. When claims 1 and 2 of the divisional application are interpreted in view of how >Swiss-type= claims have been construed in Canadian courts, the use of the claimed TNF-BP for treating diseases is equivalent to the intended or implied use of the proteins of the parent patent.

Formulations

(44) Even if the claims of the divisional application were interpreted as being directed towards the preparation of pharmaceutical drugs to treat TNF-α related diseases and not the use of the drugs *per se*, they would still not be considered to involve an inventive step. As was noted by the Examiner in the Final Action "[f]ormulating the parent peptide into a pharmaceutically acceptable drug and using the peptide in the manner for which it was intended do not require an inventive step for the skilled person". Furthermore, in the Applicant=s response to the Final Action, the Applicant failed to establish that inventive ingenuity was required to prepare pharmaceutically acceptable drugs. In the absence of a compelling argument the Board finds no reason to disagree with the Examiner=s conclusion that the formulations are not inventive.

(45) In *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, (1964), S.C.R. 49 (*Hoechst*), in which the divisional application claimed a

diluted substance, where its medical uses were established in the parent patent, a dilution of the new substance did not result in a further invention justifying a second patent. Beginning at paragraph 11, the *Hoechst* decision stated that [emphasis added]:

> ...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 the same invention.

(46) As noted in the *Hoechst* decision further at paragraph 14, the inventive feature resides in the medicinally active compound and not the fact that the compound is associated with a carrier. Further, in the medicinal arts, it is general practice to associate an active compound with a suitable diluting or carrying agent because, usually, such a compound cannot be used in its pure form.

(47) With respect to the present case, the parent patent clearly discloses the use of TNF-BP in treating diseases even though said uses were not claimed. Moreover, it would be understood or implied that the TNF-BPs of the parent patent would require some degree of formulation in order for them to be useful in treating diseases. The use of TNF-BPs "...for producing drugs for treating diseases", therefore, cannot be considered patentably distinct from the proteins themselves; ingenuity resides in the TNF-BPs and not in generalized methods of producing pharmaceutical drugs of the TNF-BPs. Furthermore, as previously noted, the Applicant did not refute or challenge the Examiner=s assertion that the compositions were not inventive.

Utility is a Requirement of Invention

(48) Although the use of the proteins was not claimed, *per se*, in parent patent 2,050,300, the patentability of the proteins requires that there be an associated utility. In particular, section 2 of the *Patent Act* requires that an invention have utility [emphasis added]:

> "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

(49) The Applicant=s disclosure of the usefulness of the parent peptides in treating diseases in which the concentration of TNF-α in body fluids is elevated was part of the bargin between the Applicant and the public in exchange for the grant of a monopoly to the invention as claimed in the parent patent; *viz.* the *quid pro quo*. A subsequent application which now explicitly claims (regardless of what claim language is used) the usefulness of TNF-BP, based on the same utility as that in the parent, provides the public with nothing further and therefore cannot justify a subsequent patent.

SUMMARY:

(50) Since a sole utility is taught for the TNF-BP of the parent patent and divisional application, it follows that claims 1 and 2 of the divisional application cannot be considered patentably distinct from the claims of the parent patent. The claimed proteins of the parent patent and claimed uses of the proteins of the divisional application are, therefore, regarded as different aspects of the same invention. As such, claims 1 and 2 of the divisional application are obvious in view of claims 1 to 3 of the parent patent.

RECOMMENDATION OF THE BOARD:

(51) The Board finds that neither of claims 1 and 2 in divisional application 2,245,101 define subject matter that is patentably distinct over claims 1 to 3 of the parent patent 2,050,300. It is therefore recommended that the Application be refused.

Nicole Harris	Ed MacLaurin	Mark Couture
Board member	Board member	Board member

COMMISSIONER'S DECISION

(52) 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 (6) months within which to appeal my decision to the Federal Court of Canada.

Mary Carman

Commissioner of Patents

dated at Gatineau, Quebec,

this 7th day of January , 2010