Commissioner=s Decision #1352
Décision du Commissaire #1352

TOPIC: O00; C00; B00
SUJET: O00; C00; B00

Application No. : 2,356,706

Demande n^{o} : 2,356,706

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,356,706 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] Patent application number 2,356,706 concerns multi-use pharmaceutical formulations which are useful, *inter alia*, for treating diabetes. It stands rejected for two reasons:

(1) because the invention is considered obvious in view of two prior publications; and,

(2) because the specification does not clearly state the advantages of the invention.

[2] Due to an inadvertent error on the Applicant=s part when responding to the rejection, an ambiguity issue also arose in respect of one claim.

[3] The application has therefore been referred to the Patent Appeal Board for review. Our review is based on the record to date which includes the Examiner=s Final Action, a Summary of Reasons (SoR) prepared by the Examiner, the Applicant=s reply to the Final Action, a declaration, and the Applicant=s written and oral submissions made before the Board at a hearing on the matter.

BACKGROUND

[4] The claimed invention relates to pharmaceutical compositions that contain as their physiologically active ingredient a particular peptide known as Aexendin-4@. Exendins are peptides (short strings of amino acids) that are derived from the saliva of certain venomous lizards. Exendin-4 is known to be able to reduce blood sugar levels, thus indicating its application in the treatment of diabetes. It is also able to regulate gastric motility and gastric emptying. Exendin-4 is an agonist of a human hormone known as Aglucagon-like peptide-1@ (GLP-1) and the two have similar physiological properties.

[5] The claimed invention deals with compositions of exendin-4 that have been formulated with carriers, excipients, buffering agents, preservatives and the like that are combined with the physiologically active ingredient in order to generate a form suitable for repeated administration

to patients.

CLAIM CONSTRUCTION

[6] We begin our analysis with a purposive construction of claims. During purposive construction, the elements of the claimed invention are identified as either essential or non-essential: *Free World Trust v Electro Santé Inc*, 2000 SCC 66 [*Free World Trust*]. In order for an element to be considered Anon-essential@, Ait must be shown either (i) that on a purposive construction of the words of the claim it was clearly *not* intended to be essential, or (ii) that at the date of publication of the patent, the skilled addressees would have appreciated that a particular element could be substituted without affecting the working of the invention@ (*Free World Trust* at para. 55).

The Person Skilled in the Art and the Relevant Common General Knowledge

[7] Claims are construed in an informed and purposive manner from the viewpoint of the notional Aperson skilled in the art@ in light of that person=s common general knowledge and based on the patent specification itself without resort to extrinsic evidence (*Free World Trust* at para. 66). Likewise, the four-step approach to obviousness set out by the Supreme Court in *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 [A*Sanofi*@] mandates an analysis from the same viewpoint.

[8] The SoR prepared by the Examiner follows the four-step *Sanofi* approach and identifies the skilled person as a Ateam of people including: scientists with experience in molecular biology and recombinant technology; general practitioners; clinical endocrinologists specializing in diabetes, obesity and other pancreatic deficiencies; pharmacists; and drug manufacturers.@

[9] The Applicant submits that the specification is directed to Ascientists in protein formulation, especially proteins or peptides involved in regulating plasma glucose.@

[10] In the written submissions provided to the Board the Applicant takes issue with the Examiner=s definition saying that it Aappears to be too diverse a group@. The Applicant questions why the group would include a molecular biologist, what is meant by Ageneral

practitioners@, and asserts that the term Adrug manufacturers@ is too broad because it includes technical and non-technical (e.g., pharmaceutical company executives) areas.

[11] In our view, an appropriate definition of the skilled person assimilates the definitions provided by the Examiner and the Applicant. The specification is neither concerned with the problem of manufacturing exendin peptides *per se* nor is it concerned with general medical practices. Therefore, the team need not include persons familiar with molecular biology and recombinant peptide technology methods or a general medical practitioner. Since the application is concerned with formulations of an insulinotropic peptide, the skilled person is a team of people including: clinical endocrinologists specializing in diabetes, obesity and other pancreatic deficiencies; pharmacists; and scientists in protein formulation, especially proteins or peptides involved in regulating plasma glucose.

[12] As for the relevant common general knowledge, the Examiner states in the SoR that the skilled person Awould have knowledge of both exendin-4 and GLP-1 and understand the structural differences and functional similarities between the two proteins, including the recognition that the two were not genetic homologs@ and that the skilled person Awould be knowledgeable of the various exendin and GLP-1 analogs available and utilize conventional techniques . . . to formulate pharmaceuticals of such for conventional use.@

[13] The Applicant=s characterization of the common general knowledge is in line with that of the Examiner:

> With respect to general knowledge, we agree with the examiner that the skilled person would be knowledgeable about exendin-4 and GLP-1 and the structural differences between them. The skilled person would also be aware of conventional formulation techniques utilized by those in the protein or peptide art.

The Claims

[14] In this case, we are led to the conclusion that all of the claim elements are essential.

[15] Since neither the Examiner nor the Applicant make an appreciable distinction between the various claims on file, the claims will either stand or fall together. Claim 1 is representative:

> 1. A pharmaceutical formulation which is a stable liquid dosage form suitable for multi-use administration comprising:

(a) 0.005% to 0.4% (w/v) of exendin-4,
(b) an acetate buffer,
(c) mannitol as an iso-osmolality modifier, and
(d) 0.005% to 1.0% (w/v) of a preservative which is m-cresol, said formulation having a pH between 4.0 and 5.0.

[16] The physiologically active agent, exendin-4, recited in part (a) is essential in order for the formulation to work against its target disease(s).

[17] The claim preamble includes the phrase Asuitable for multi-use administration@. A multi-use pharmaceutical formulation, as opposed a unit-dose formulation, is one designed to be used by a patient or medical practitioner on repeated occasions. Due to repeated use, the likelihood of contamination is much higher in such formulations. It is therefore necessary to include a preservative in order to maintain sterility. But the skilled person would not understand the particular preservative and other excipients claimed to be non-essential because they represent mere examples of elements that could be varied without affecting the performance of the claimed multi-use formulation; that is, each combination of known preservative, buffer, iso-osmolality modifier and exendin-4 would not be understood to work equally well. Although the skilled person would know of a variety of buffers, isomolarity agents and preservatives, that person would more importantly also understand that there must be co-operativity amongst each type of excipient in order for the claimed formulation, when considered as a whole, to operate for its intended purpose in its intended manner. For example, maintenance of exendin activity and maintenance of preservative activity are considerations and neither should be negatively affected by other ingredients in the formulation.

[18] The combination of excipients claimed is the one the Applicant has put forth as necessary in order to render the claimed formulations suitable for their intended manner of administration. As discussed above, there is no reason to conclude that these elements, when considered individually or collectively, are non-essential. There is also no dispute between the Examiner and the Applicant that any of these elements is non-essential. Further, the prosecution record establishes that the specificity in claim language has been maintained throughout prosecution, indicating that the claimed combination of elements has always been considered essential. This leads us to conclude that all the claim elements should be considered essential for the purposes of this decision.

ISSUE 1: IS THE INVENTION OBVIOUS?

[19] The statutory provision relevant to obviousness is section 28.3 of the *Patent Act* which states:

> The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to
> (a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and
> (b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

[20] Our obviousness assessment follows the four-step approach set out in *Sanofi*:

> (1) (a) Identify the notional Aperson skilled in the art@;
> (b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the Astate of the art@ and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

Analysis

Step 1: Identify the notional Aperson skilled in the art@ and the relevant common general knowledge of that person

[21] This first step is common to our claim construction and has been explained above.

Step 2: Identify the inventive concept of the claim in question or if that cannot readily be done,

construe it

[22] The Examiner states that the inventive concept is Ato provide stable liquid dosage form exendin-4 formulations suitable for multi-use administration.@ In line with this statement, the Applicant says that the Apresent application provides exendin-4 in a formulation suitable for multi-use administration.@ Of the two statements, we consider the Examiner=s more accurate because of its reference to a liquid formulation. We will adopt it for the purposes of our analysis.

[23] At a high-level the inventive concept is an accurate précis of the claimed invention. However, to give practical effect to the inventive concept the skilled person would understand that it is the essential elements, as determined through a purposive construction, that are required for proper operability of the claimed subject matter. As such, these elements cannot be left aside when considering the question of obviousness; in fact, much of the debate between the Examiner and the Applicant focusses on their nature.

Step 3: Identify what, if any, differences exist between the matter cited as forming part of the Astate of the art@ and the inventive concept of the claim or the claim as construed

[24] The Examiner has cited two Canadian patent applications whose disclosures, when taken together, are said to make the claimed invention obvious to the skilled person: application 2,277,112 by Beeley et al. [A*Beeley*@], and application 2,264,243 by Knudsen et al. [A*Knudsen*@]. Each differs in at least one respect from the inventive concept.

Beeley

[25] According to the Examiner *Beeley* discloses Apharmaceutical formulations of exendin in an isotonic buffer solution of a pH of about 3.0 to 8.0, preferably a pH of 3.5 to 5.0, which are used to treat diabetes, obesity and eating disorders. Preferred formulations comprise a sodium acetate/acetic acid buffer and iso-osmolality modifier mannitol. Further, Beeley et al. disclose the common general knowledge in the art regarding the potency of exendin-4 and exendin agonists.@

[26] Though the Applicant has submitted that *Beeley* does not disclose the pH of the claimed formulation, we note that acetate buffer is clearly indicated as a preferred buffering agent. Since the skilled person, based on their common general knowledge, would know that the suitable

buffering range of acetate lies between about 3.7 and 5.6, it would be apparent to the skilled person that the claimed pH range of 4 to 5 lies within this range. We therefore do not believe that a difference exists in this respect between *Beeley* and the inventive concept.

[27] As the Applicant points out, *Beeley* Adid not disclose a formulation comprising a preservative and did not disclose a formulation for multi-use administration.@ We agree that it is these differences which stand out.

Knudsen

[28] According to the Examiner *Knudsen* discloses Apharmaceutical formulations of the exendin agonist GLP-1 comprising an isotonic agent selected from sodium chloride, mannitol or glycerol; a buffer and a preservative selected from phenol, m-cresol, methyl p-hydroxybenzoate or benzyl alcohol which are used to treat obesity and diabetes.@

[29] The Applicant submits that *Knudsen* is concerned with GLP-1, not exendins, and focusses on derivatives with a Aprotracted profile of action.@ The Applicant further notes that AKnudsen did not disclose the pH recited in the claims. Knudsen also did not disclose a formulation for multi-use administration. Other than mannitol, the composition Knudsen used for testing their derivatives is different in every way from the claimed exendin-4 formulation.@

[30] Though the Applicant has submitted that neither *Beeley* nor *Knudsen* disclose an exendin-4 formulation for multi-use administration, we note that *Knudsen* discloses on page 34 at line 29 the use of a Apen-like@ syringe to administer GLP-1 formulations. This indicates to the skilled person a commonly known multi-use manner of administration. Therefore, no difference exists in this respect between *Knudsen* and the inventive concept. As was explained in the case of *Beeley*, we also find no difference in respect of the pH and/or buffer system to be used since *Knudsen* also prefers acetate (see page 35, line 22).

[31] In our view, the critical difference between the inventive concept and *Knudsen* is the nature of the bioactive agent: GLP-1 in *Knudsen* versus exendin-4 in the inventive concept.

Other documents cited by the Applicant

[32] In our view, the state of the art does not consist solely of the two references cited by the Examiner. The Applicant has put on record two scientific articles published by Kim and Haren (1995, Pharm. Res. 12: 1664 B A*Kim 1995*@) and Kim et al. (1994, J. Pharm. Sci. 83: 1175 B A*Kim 1994*@).

[33] The Examiner acknowledges that neither reference discloses a multi-use formulation of exendin-4 and, as such, there is no discussion of differences between their disclosures and the inventive concept. Instead their relevance is disputed. According to the SoR they are not relevant because the articles Aprovide no teachings as to the limitations, if any, of the use of a preservative in a pharmaceutical formulation of GLP-1 or the like@ (emphasis in original). We find otherwise. They are relevant because they form part of the state of the art and their disclosures would be considered by the skilled person to be informative B in general and specific terms B of the problem at hand. They are also relevant in specific terms because they deal with an insulinotropic peptide and, as the Applicant argues, because they suggest that the skilled person would be pointed away from the presently claimed subject matter.

[34] In general terms, the *Kim 1994* article starts with an introduction that makes clear the problems particular to the art of formulating peptides: AWhen they are exposed to unnatural environments, they tend to form precipitates or aggregates as a result of decreasing solubility@ and AThe physical basis for protein insolubility is still unclear.@ *Kim 1994* mentions that Phenol and cresol are widely used as preservatives to control microbial growth for multi-use pharmaceutical and cosmetic products@ (our emphasis).

[35] In specific terms, each article indicates that phenolic preservatives may cause GLP-1 to fall out of solution. *Kim 1995* indicates that cresol caused GLP-1 to precipitate out of solution. *Kim 1994* deals with studies of GLP-1 structure in a highly soluble form and an insoluble form and similarly discusses disruptions in GLP-1 structure caused by phenolic groups.

[36] Accordingly, the two articles have been considered in our obviousness analysis, as explained below, but differences between their disclosures and the inventive concept need not be formally addressed at this point as part of the third step in the *Sanofi* approach.

[37] We note also that, during prosecution, the Applicant has put on record a third publication: Meyer et al. (2007, J. Pharm. Sci. 96:3155 B A*Meyer*@). Although this article was published after the claim date of the present application, and therefore cannot formally be considered as state of the art, it does make a valid point: even three years after the claim date there still remained little

information with respect to the compatibility of preservatives and peptide biopharmaceutical products. It states at page 3163 that: APrior to 2002, few articles were published that described the problems of compatibility between biopharmaceutical products and preservatives . . .@ It is therefore relevant in assessing the expectations of the skilled person and can factor into the obviousness analysis.

Step 4: Do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[38] The combined disclosures of *Beeley* and *Knudsen* do reveal the features of the Applicant=s inventive concept. The principal question is whether the skilled person, when faced with the challenge of developing a multi-use exendin-4 formulation, would have combined the two references and been so led to the inventive concept. For the reasons that follow, we believe that the skilled person would not have done so and for that reason the claimed invention would not have been obvious to that person.

[39] Notwithstanding the fact, as argued by the Examiner, that the two disclosures are related, in that they each deal with peptides of the same class of medicament and do disclose formulations of each type of peptide, the information on record satisfactorily establishes that the skilled person would not look to disclosures concerning GLP-1 when faced with a problem concerning formulations of exendin-4. In this particular art field, the skilled person would therefore not turn to the disclosure of *Knudsen* and would not think to combine it with *Beeley*.

[40] Of record is a declaration submitted by a Mr. C. Russell Middaugh B a scientist with a Ph.D in medical sciences. His declaration was not before the Examiner during prosecution, and although not necessarily determinative on its own, it confirms the panel=s conclusions on the climate in the relevant art field. He has no past or present employment relationship with the Applicant and he describes himself as having experience in the formulation and delivery of peptides, proteins, nucleic acids and so on, including their behaviour in solution. As such he approximates a key member of the skilled person=s Ateam@: a scientist in protein formulation. He attests that he has reviewed the subject application and the prior art and opines that a person skilled in the art would not rely on the *Knudsen* reference and that preparing peptide formulations is not a matter of picking from amongst various known carriers, excipients and preservatives. His declaration includes the following statements:

> In my opinion, protein formulation scientists would not expect that they could simply pick and choose from components of known formulations to create a new formulation such as that in claim 1 of the [subject] application. This was understood at the time of the invention.
>
> . . .
>
> Before embarking on a formulation project, a protein formulation scientist would typically look for all available information about the physical and chemical characteristics of the protein being formulated, especially its potential interaction with other components in the formulation.
>
> . . .
>
> In my opinion, a protein formulation scientist would not have relied on a GLP-1 formulation such as disclosed in Knudson [*sic*] to guide him in preparing an exendin-4 formulation. As is evident, GLP-1 and exendin-4 display only 53% sequence similarity and thus for at least this reason would have been expected to behave in entirely different ways.
>
> . . .
>
> Accordingly, in my opinion, a protein formulation scientist would likely not look to use a phenolic preservative, such a m-cresol, as a first choice when preparing a formulation like that in the claims of the [subject] application.

[41] Without *Knudsen* the skilled person, looking for information particular to exendin-4, would have been left only with the guidance of *Beeley*. Although *Beeley* is clearly concerned with exendin-4, there is a notable absence of discussion of critical aspects of the inventive concept, namely its multi-use aspect and the inclusion of a preservative necessary in order to render the claimed formulations most suitable for that manner of use. The closest *Beeley* comes to disclosing a multi-use formulation are two vague passages found on page 34. There we find a reference to Adivided@ doses at line 7 and a suggestion at lines 2-24 that Athe optimal formulation and mode of administration@ of exendins depends on known factors such as the particular disease, the desired effect, and the type of patient. In our view, these are not sufficient to point the skilled person to the inventive concept of the claimed invention and its attendant features.

[42] Even if the skilled person were to look to GLP-1 formulations for guidance in making a multi-use exendin-4 formulation, the state of the GLP-1 art, when broadly considered, does not suggest the inventive concept. The Middaugh declaration confirms that, when formulating bioactive peptides or proteins, the skilled person would look to gather as much relevant information about a peptide(s) when setting out to make a formulation of that peptide. If the skilled person were to consider the GLP-1 art as relevant, the disclosures of *Kim 1995* and *Kim*

1994 would reasonably be included in the state of the art. That being the case, the skilled person would see from the *Kim* disclosures that phenolic preservatives can destabilize a GLP-1 formulation and, by extension, would approach their use in exendin-4 formulations with caution, if at all.

[43] There remains the notion that the skilled person, once presented with the problem of formulating a multi-use exendin-4 composition, would rely on their common general knowledge of preservatives, buffering systems and osmotic agents and arrive at the claimed formulations. Knowing that a multi-use formulation is obviously desirable for treating the types of disorders for which exendin-4 is indicated, it would have been obvious for the skilled person to try to make such a formulation.

[44] Along these lines, the Examiner argues in the Final Action that Athere is no indication in the prior art, by Knudsen et., Beeley et al. or others, that the inclusion of a preservative in any pharmaceutical formulation was problematic or unpredictable in nature.@ The Final Action states, invoking the Aobvious-to-try@ considerations set out in *Sanofi*, that the state of the art indicates Ait would have been more or less self-evident to a skilled person that the inclusion of a preservative in a multi-use formulation of exendin >ought to work=.@

[45] Although not an unreasonable suggestion, we do not see that the claimed invention would have been obvious-to-try. According to the Supreme Court , Aa possibility of finding the invention is not enough@ (*Sanofi* at para 85). In the present case, the problem to be solved is not simply the inclusion of a preservative; it is the making of a complete formulation containing a suitable combination of excipients. Further, the information on record supports the conclusion that success was not more or less self-evident. Contrary to the Examiner=s assertions, we see from *Meyer* and the Middaugh declaration that, as of the claim date, the art had not advanced to a high level of predictability.

[46] The prior art has never before disclosed even a single type of multi-use exendin-4 formulation. The claimed invention is therefore not a subset of a broader previous disclosure and should not be considered *prima facie* obvious. Rather, it represents a non-obvious advancement. Accordingly we find that the claimed invention complies with section 28.3 of the Act.

ISSUE 2: FAILURE TO DISCLOSE ADVANTAGES OF THE INVENTION

[47] The other reason the application was not allowed is founded on the argument that the

claims are not compliant with the Act because they are not supported through the disclosure of unexpected advantages. This is raised as a defect under subsection 27(3) of the *Patent Act,* the relevant portions of which state:

> The specification of an invention must:
> (*a*) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
>
> (*b*) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it; . . .

[48] A defect under subsection 27(3) of the Act is typically referred to in the jurisprudence as Ainsufficiency of disclosure.@ In this case however, the SoR ties this issue to the question of obviousness, explaining that the application is defective because it fails to disclose advantages that would render the invention non-obvious:

> Without demonstrating in the instant disclosure that the inclusion of a preservative in liquid multi-use dosage formulations of exendin-4 (or exendin agonist peptide analog) was advantageous (or avoided disadvantage) over prior art exendin agonist peptide analog formulations or, alternatively, providing formulations of new exendin agonist peptide analogs, a person skilled in the art was given, by way of disclosure, no more than that which was already available from the prior art. That being that each combination of preservative, buffer, iso-osmolality modifier and exendin-4 worked equally as well. An unexpected advantage (or disadvantage to be avoided), *. . .* can support an otherwise obvious invention, however, that advantage (or disadvantage to be avoided) must be clearly stated in the description. In the instant case it is not. As such, the specification cannot support a determination of

unobviousness. [emphasis in original]

[49] To briefly paraphrase, the Applicant submits that: there is no question of compliance with subsection 27(3); there is no requirement to Ademonstrate inventive ingenuity at the time of filing@; the invention is a specific exendin-4 formulation suitable for multi-use administration; and that the facts of the present case clearly indicate satisfaction of the legal test for sufficiency under subsection 27(3).

Analysis

[50] According to the Examiner, the obviousness issue brings into play a question of sufficiency of disclosure because advantages are not clearly stated in the description. Subsection 27(3) of the Act contains no general requirement to disclose advantages. That said, it can be the case, for example in the case of a selection patent, that the recognition of an unexpected advantage forms the basis of the invention and must therefore be disclosed (see *Sanofi* at para. 114; *Eli Lilly Canada Inc v Novopharm Ltd*, 2010 FCA 197 at para. 78).

[51] Sufficiency of disclosure has recently been considered by the Supreme Court in *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 [*Teva*]. The Federal Court in *Teva Canada Limited v Novartis AG*, 2013 FC 141 at para 344 followed the Supreme Court=s guidance by asking whether the disclosure satisfactorily answers the following three questions:

(a) What is your invention?

(b) How does it work?

(c) Having only the specification, can the person of ordinary skill in the art produce the invention using only the instructions contained in the disclosure?

[52] Answering these questions in the present case leads to the conclusion that the specification is

sufficient.

[53] The invention is a pharmaceutical composition containing an active compound, a buffer, an iso-osmolarity agent, and a preservative. These ingredients have been properly described in the specification as have their relative proportions. The invention, considered as a whole, works to allow an anti-diabetic agent to be administered in repeated doses. The claimed invention is also enabled because their manner of compounding is adequately set forth in the specification and we believe that it can be successfully made by the skilled person once given the direction to do so as set out in the specification.

[54] The specification is therefore compliant with subsection 27(3) of the Act.

OTHER ISSUE: AMBIGUITY IN CLAIM 7

[55] The SoR notes that dependent claim 7 includes the phrase Aan exendin agonist peptide analog@ whereas its parent claim is limited to exendin-4. This is identified as a defect under subsection 27(4) of the *Patent Act* and section 84 of the *Patent Rules*.

[56] In its submissions to the Board the Applicant apologized and characterized the inclusion of the phrase as an oversight. It was proposed that claim 7 be amended to replace the phrase Aan exendin or an exendin agonist peptide analog@ with Aexendin-4@.

[57] We agree with the Applicant=s proposal.

[58] By operation of subsection 87(3) of the *Patent Rules*, claim 7, being a dependent claim, would normally Abe understood as including all the limitations contained in the claim to which it refers.@ However, on its face, claim 7 is plainly more expansive than its parent claim. Therefore, without considering compliance with section 84 of the Rules, the claim is defective and must be amended in order to comply at least with subsection 27(4) of the Act.

RECOMMENDATION OF THE BOARD

[59] We recommend that the application not be refused for the reasons set out in the Final Action. We further recommend that the Applicant be informed that, in order to comply with subsection 27(4) of the *Patent Act*, the Applicant must submit an amendment under subsection 31(*c*) of the *Patent Rules* such that claim 7 is amended to replace the phrase Aan exendin or an exendin agonist peptide analog@ with Aexendin-4@.

Ed MacLaurin Paul Sabharwal Stephen MacNeil
Member Member Member

DECISION OF THE COMMISSIONER

[60] I concur with the findings and the recommendation of the Board. I hereby inform the Applicant that, in order to comply with subsection 27(4) of the *Patent Act*, the Applicant must submit an amendment under subsection 31(*c*) of the *Patent Rules* such that claim 7 is amended to replace the phrase Aan exendin or an exendin agonist peptide analog@ with Aexendin-4@.

[61] The amendment under subsection 31(*c*) of the *Patent Rules* must be submitted within three months of the date of this decision failing which it is my intention to refuse the application.

Sylvain Laporte

Commissioner of Patents
Dated at Gatineau, Quebec
this 23rd day of October, 2013