Commissioner’s Decision #1328
Décision du Commissaire #1328

TOPIC: A20
SUJET: A20

Application No. : 2,368,934
Demande n^{o} : 2,368,934

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,368,934 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 decision of the Commissioner are as follows:

Agent for the Applicant:

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INTRODUCTION

[1] This is a review of patent application no. 2,368,934 following its rejection by a patent examiner on the grounds of double patenting.

[2] The application was rejected in the Examiner's Final Action dated 22 September 2009, to which the Applicant provided a response. As the Examiner subsequently maintained the rejection, the application is subject to review by the Commissioner pursuant to subsection 30(6) of the *Patent Rules*. The Patent Appeal Board has conducted the review on behalf of the Commissioner.

[3] The Examiner provided the Board with a Summary of Reasons (SOR) dated 11 August 2010 detailing the reasons for maintaining the rejection. The Board forwarded the SOR to the Applicant on 6 December 2010 and offered the Applicant an opportunity to be heard pursuant to subsection 30(6) of the *Patent Rules*.

[4] In a letter dated 3 March 2011, the Applicant declined its opportunity to be heard, asking instead that the Board review the application on the basis of the written record.

[5] The Commissioner must now decide whether to allow the application, refuse the application, or requisition amendments to the application that would place it in condition for allowance. For the reasons that follow, the Board recommends that the application be refused.

BACKGROUND

[6] The present application, entitled "METERED DOSE INHALER FOR FLUTICASONE PROPIONATE" is one of a series of related applications and patents owned by SmithKline Beecham Corporation. The inventor in this case is Ignatius Loy Britto.

[7] The present application is a "divisional application," as it was divided (under section 36 of the *Patent Act*) from an original ("parent") application, now patent 2,217,948 (hereafter '948).

[8] The Applicant divided yet another application from '948, namely 2,367,013, from which the Applicant further divided out application 2,447,517 (hereafter '517), both of which issued to patent.

[9] Pursuant to subsection 36(4) of the *Patent Act*, as a divisional application, the filing date of the present application, and of both the '013 and '517 patents, is the same as the original application ('948): 10 April 1996.

[10] The invention described in the present case relates to improving so-called metered dose inhalers (MDIs) in order to provide consistent dosing with each spray. MDIs are used to administer medication in aerosol form, and generally comprise a can with a crimped cap covering the mouth of the can, and a valve situated in the cap. The aerosol comprises a medicine

in powder form that is suspended in a propellant. Each activation of the MDI discharges a dose of the aerosol formulation. Doses discharged by the MDI must be within close tolerances so as to ensure delivery of the prescribed quantity of medication.

[11] According to the Applicant, it has been discovered that the medicine can adhere to the inner surfaces of the MDI, particularly where the propellant comprises a fluorocarbon. Consequently, the patient may receive less than the prescribed amount of medication with each dose.

[12] The Applicant has found that coating the interior surfaces of the can with a fluorocarbon polymer addresses the adhesion problem, thereby ensuring consistent dosing.

ISSUES

[13] In the Final Action, the Examiner found that all claims violated the prohibition on "double patenting" (which prohibits the granting of more than one patent for an invention) drawing a comparison of the present claims with those of patent '948 and with those of patent '517.

[14] As stated in *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para. 37, "[a] patentee who can 'evergreen' a single invention through successive patents by the expedient of obvious or uninventive additions prolongs its monopoly beyond what the public has agreed to pay." This is what the prohibition on double patenting serves to prevent.

[15] The prohibition has been addressed several times by the Board in recent years. We find the following summary of the law on double patenting, from *Re Genentech Patent Application No 2,407,304* (2006), 92 CPR (4th) 241 (Patent Appeal Board and Commissioner of Patents), CD 1307, to be helpful here:

> [9] [*Whirlpool*] is considered the leading authority on double patenting. Although the prohibition against double patenting is judge made law, the Supreme Court accepted in *Whirlpool* that there is an inherent prohibition against double patenting in the *Patent Act*. According to subsection 36(1) of the *Patent Act*, an inventor or applicant is only entitled to "a" patent for one invention. In the same decision, the Court held further that there are two branches of the prohibition on double patenting.
>
> [10] The first branch is called "same invention" double patenting and the second branch is called "obviousness" double patenting. The first branch applies in situations where the claims are identical or conterminous.
>
> [11] The second branch of the prohibition against double patenting is more comprehensive and applies in situations where the claims are not "patentably distinct". The second branch is described at para. 66 of *Whirlpool*:
>
> > 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.

[16] While same invention-type double patenting considers whether two claims are identical or conterminous, in order to avoid a finding of obviousness-type double patenting a claim must exhibit ingenuity relative to the claim under comparison (see, e.g., *Bayer Schering Pharma Aktiengesellschaft v. Canada (Attorney General)*, 2010 FCA 275 at para. 30). In our view, a scintilla of ingenuity would suffice, consistent with the law on obviousness.

[17] The Examiner's reasoning in finding double patenting hinges on excluding certain elements from the comparison of the claims because they are non-essential, while adding others on the basis that they are found in the description of the application or patent.

[18] In response, the Applicant submitted that there was no basis for finding certain elements recited in the instant claims to be "non-essential" and that the Examiner's double patenting analysis must remain grounded in the claims; any reference to the description to support a finding of double patenting is improper, according to the Applicant.

[19] The Applicant also argued that, because the term of a patent (i.e., the expiry date) is determined from its filing date, and because the two cited patents share the same filing date as the present application, there would be no prolongation of monopoly if the present application were to issue to patent. Consequently, argued the Applicant, no double patenting could arise.

[20] From the Board's reading of the SOR, the Examiner maintained the rejection on the basis of the second of the two branches of double patenting, namely, "obviousness" double patenting. We take from the SOR that the Examiner was not alleging a defect under the first branch of double patenting, namely "same invention" double patenting.

[21] The Examiner elaborated in the SOR that certain features were found to be "non-essential features known in the art", adding that the claims are to be "viewed in view of the whole specification and [the reader must] not indulge in meticulous verbal analysis," citing *Free World Trust v Électro Santé Inc*, 2000 SCC 66 and *Whirlpool*.

[22] In light of the abovementioned positions, the Board sees the issues to be resolved in this review as follows:

Does the prohibition against double patenting operate when there is no prolongation of monopoly?

Are claims 1-10 of the present application in violation of the prohibition on obviousness double patenting? To address this issue, two questions must be addressed, including:

1) When may an element of a claim be found "non-essential"?
2) To what extent is it appropriate to have recourse to the description of the application or patent when assessing double patenting?

ISSUE 1. DOUBLE PATENTING WITHOUT PROLONGATION OF MONOPOLY

[23] As noted by the Applicant, if the present application were to issue to patent, it would expire the same day as the two patents cited by the Examiner. The question is: as the grant of the present application would not give rise to successive patent terms for the same invention, does the prohibition on double patenting operate in this case?

[24] The Examiner submits that *GlaxoSmithKline Inc v Apotex Inc*, 2003 FCT 687, 27 CPR (4th) 114, (*GSK*), discussed below, settled this issue, finding that double patenting still applies where two patents expire on the same date.

[25] The Applicant argues that double patenting does not apply here and that the Examiner was incorrect to rely on *GSK* to support the position to the contrary. In particular, the Applicant argues that *GSK* should be viewed narrowly and that "the findings in the [*GSK*] case are no longer relevant since the [*Patented Medicines (Notice of Compliance)*] Rules have been changed to remove the 'quirk' on which the findings in that case were based": see pg. 7 of the Applicant's response to the Final Action. The Applicant did not elaborate on the nature of the amendment to the *Patented Medicines (Notice of Compliance)* (*NOC Regulations).*

[26] In *Re Genentech* at para. 13, the Board found that double patenting applied when comparing a divisional and its parent, citing *GlaxoSmithKline Inc v Apotex Inc*, 2003 FCT 687, 27 CPR (4th) 114 at paras. 90 and 91 as follows:

> I cannot agree with GSK that "the sin of double patenting" has evaporated. GSK has overlooked the impact that a second patent can have under the Regulations. Under paragraph 7(1)(e) of the Regulations, the Minister is prohibited from issuing the requested NOC for 24 months once the owner of a patent has applied for an order under subsection 6(1). The effect of this provision is to put in place a mandatory injunction that remains in force until either the case is disposed of or the 24-month period expires. The existence of additional patents allows the patent-holder to bring additional applications, thereby obtaining multiple injunctive periods. There is no need to look further than the case at bar for an excellent example of this practice. Even though Apotex successfully invalidated the '637 patent in 2001, the filing of this application by GSK has prohibited Apotex from bringing its product to market for the past two years.
>
> Furthermore, regardless of whether "the sin of double patenting" still exists a patent holder should not be able to receive additional patents for the same invention. Support for this position can be found in the decision of Lutfy J. (as he then was) in *Bayer Inc. v. Canada (Minister of National Health and Welfare)* (1998), 154 F.T.R. 192, 82 C.P.R. (3d) 359, aff'd (2000) 6 C.P.R. (4th) 285 (F.C.A.). Bayer had two patents, filed as divisional applications, that covered the same invention. The period of patent protection ran from the date of issue and the term of the second patent ran for an additional eighty months after the expiry of the initial patent. Bayer later made a terminal disclaimer that brought the expiry date of the second patent in line with that of the first. Bayer argued that the second patent was not invalid for double patenting because the terminal disclaimer had removed the harm of double patenting. The argument was rejected by Lufty J., who held that inventive ingenuity was still needed to support the second patent. I agree. As Binnie J. noted in *Whirlpool* at paragraph 63, subsection 36(1) of the Act states that an inventor is only entitled to "a" patent for each invention. The logical extension of this is that two inventions are required to support two patents. This is confirmed by the wording of subsection 36(2).

[27] Though the *NOC Regulations* were not discussed in any detail during the prosecution, we take the "quirk" to be a reference to the 24-month injunction referred to in the *GSK* decision. This is a reference to the 24-month stay provided by paragraph 7(1)(e) of the *NOC Regulations* which prohibits the Minister of Health from issuing a Notice of Compliance to a "second person" for 24 months.

[28] While this provision still exists today, amendments were made in 2006 to restrict the use of this provision. In particular, ss. 5(4) was added making it unnecessary for a "second person" (i.e., the generic pharma company) to address any patent not yet added to a drug's patent list when applying for a notice of compliance: see Regulatory Impact Analysis Statement of SOR/2006-242, Canada Gazette, Part II, vol. 140, no. 21 — 18 October 2006.

[29] As it would be unnecessary for a generic to address any patent (divisional or otherwise) not registered with the Minister of Health at the time the generic company applies for a notice of compliance, further 24-month stays would not be possible. Thus the Board agrees with the Applicant that amendments to the *NOC Regulations* have removed the "quirk" that was discussed in the *GSK* decision.

[30] However, as is apparent from the above quote, *GSK* supports the proposition that, irrespective of any "quirk" in the *NOC Regulations*, a patent holder should not be able to receive additional patents for the same invention, and that inventive ingenuity is still required to support a second patent, citing *Bayer* (cited above in *Re Genentech*).

[31] Accordingly, the possibility of double patenting exists in the present case, notwithstanding the fact that the present application would expire on the same date as the patents cited by the Examiner.

ISSUE 2. OBVIOUSNESS DOUBLE PATENTING: CLAIMS 1-10

[32] Having found, as in *Re Genentech*, that double patenting is not avoided on account of terms coinciding, it is necessary to assess whether double patenting exists between the present claims and the claims of the two cited patents.

[33] Central to the dispute between the Examiner and the Applicant on this point were the two questions identified above at para. 22, namely: a) when can an element of a claim be found "non-essential" and b) to what extent the description of an application or patent may be considered in the context of double patenting. Both questions relate to the concept of "purposive construction."

[34] Purposive construction entails interpreting the meaning of the terms and expressions used in the claims as well as "differentiating the essential features ('the pith and marrow') from the unessential" (see *Whirlpool* at para. 48). Both tasks are conducted through the eyes of the skilled person, based on a knowledgeable reading of the whole specification (which comprises both the description and the claims). In answering the two questions identified in para. 22, we will therefore consider the principles of purposive construction.

Non-Essential Elements

[35] While a disagreement on whether or not certain elements were essential was central to the impasse in prosecution, in our view the essentiality of the particular features in dispute does not affect the outcome of the double patenting analysis in this case, as our double patenting analysis will show. Nonetheless, we feel it appropriate to comment on the matter for the sake of completeness.

[36] As noted in the SOR, the Examiner found certain elements of the present claims to be "non-essential features known in the art." We understand this statement to suggest that essential elements must be novel, since no other explanation was provided of why the elements are non-essential.

[37] Finding an element to be non-essential simply because it is known in the art does not appear to be supported by the principles articulated in *Whirlpool* or *Free World*. Granted, subsequent to the *Free World* decision, several Federal Court decisions discussed novelty as a factor in identifying essential elements (see, e.g., *Norac Systems International Inc v Prairie Systems and Equipment Ltd*, 2002 FCT 337, 19 CPR (4th) 360 at para. 16; allowed in part without consideration on this point, 2003 FCA 187, 25 CPR (4th) 1; and, *Halford v Seed Hawk*, 2004 FC 88, 31 CPR (4th) 434 at para. 83.

[38] However, the Federal Court of Appeal, in dealing directly with this issue on appeal in *Halford v Seed Hawk*, 2006 FCA 275, 54 CPR (4th) 130, rejected the notion that the essential elements are simply the ones that are novel and/or inventive, stating that this was "not the test as stated in *Free World*": see *Halford* at para. 14.

[39] In *Free World*, the Supreme Court identified two relevant factors for determining which elements are essential: a) the intent of the inventor as understood by the skilled person from a reading of the specification and b) whether an element has a material effect on the way the invention works: see *Free World* at para. 31.

[40] Therefore, if the Examiner found that certain elements are non-essential simply because they were known in the art, we do not agree. However, as we noted above, whether or not they are non-essential when the correct factors are applied in the present case is a moot point. For the purposes of the double patenting analysis that follows, we will presume all elements to be essential.

[41] Before turning to the double patenting analysis, we must address the question of whether it is appropriate to refer to the description when assessing double patenting.

Use of the Description of an Application/Patent in Double Patenting

[42] This question relates to the other aspect of purposive construction discussed above, namely, the interpretation of the meaning of the terms and expressions used in the claims.

[43] In setting out the case for double patenting, the Examiner makes frequent reference to the descriptions of both the present application and of the two patents. The Applicant argues that double patenting is to be considered only on the basis of the claims and that any reliance on the description of the present application or on the description of either patent is improper.

[44] The Board agrees with the Applicant that double patenting (whether same invention or obviousness-type) is to be based on a comparison of the claims: see *Whirlpool* at para. 63. However, that claim comparison is not to be done on a literal construction of the claims. As we noted above, claims are to be given a purposive construction, taking into account the specification as a whole, which includes the description.

[45] Since claims are to receive one and the same interpretation for all purposes (*Whirlpool* at para. 41), including double patenting, it follows that in the context of a double patenting analysis, it is appropriate to refer to the description so long as it is to construe the claim in accordance with the principles of purposive construction.

[46] In our double patenting analysis, below, we will be mindful that any reference to the description of the application and patents be consistent with the principles of purposive construction.

Double Patenting Analysis

[47] While the principles of double patenting and purposive construction discussed thus far apply equally to both branches of double patenting, as stated above, our analysis will focus on obviousness double patenting.

[48] In the Final Action, the Examiner compared all of the present claims (1-10) with certain claims of ‘948 and certain claims of ‘517, as will be discussed in the analysis below. The claims of all three documents are set out in Appendix A.

[49] In its response to the allegation of double patenting made in the Final Action, the Applicant emphasized four characteristics of claim 1 as follows:

> (a) The fluorocarbon polymer is selected from the group consisting of PTFE, PFA, FEP, and mixtures thereof;
> (b) The non-fluorocarbon polymer is selected from the group consisting of polyamideimide and polyethersulfone;
> (c) The inhaler comprises a can made of aluminium or an alloy thereof; and,
> (d) All of the internal metallic surfaces of the can are coated with the polymer blend.

[50]

As claims 2-10 of the present application ultimately depend on claim 1, these characteristics are relevant to every claim and they will be referenced in the analysis below.

[51] Having reviewed the specifications of the two patents and the present application, paying particular attention to the nature of the elements recited in various claims, we feel that the strongest case against claims 1-7 is made using patent '948, while the strongest case against claims 8-10 is made using patent '517; we will conduct our analysis accordingly. Table 1 sets out, for each claim in the present application, the claims that we will compare in our analysis below.

Present Claims	'948 Patent Claims	'517 Patent Claims
1	claim 20 (as dependent on claims 18, 17, 16, 15, and 1)	
2	claim 20 (as dependent on claims 18, 17, 16, 15, 2, and 1)	
3	claim 20 (as dependent on claims 18, 17, 16, 15, 3, 2, and 1)	
4	claim 20 (as dependent on claims 18, 17, 16, 15, 4, 3, 2, and 1)	
5	claim 20 (as dependent on claims 18, 17, 16, 15, 5, 4, 3, 2, and 1)	
6	claim 20 (as dependent on claims 18, 17, 16, 15, 13, 5, 4, 3, 2, and 1)	
7	claim 20 (as dependent on claims 18, 17, 16, 15, 14, 13, 5, 4, 3, 2, and 1)	
8		claim 19 (as dependent on claims 18, 17, 16, and 1)
9		claim 25 (as dependent on claims 19, 18, 17, 16, and 1)
10		claim 26 (as dependent on claims 25, 19, 18, 17, 16, and 1)

Table 1. Claim Comparisons in the Double Patenting Assessment

Present Claim 1 v. Claim 20 '948 (as dependent on claims 18, 17, 16, 15, and 1)

[52]
The Examiner found that claim 1 was not patentably distinct over claim 20 of '948, when dependent on claims 18, 17, 16, 15, and 1. Where a claim refers to an earlier claim, it is referred to as a "dependent claim" and is read to include the feature(s) of the claim or claims

to which it refers. In this case, claim 20 of '948 is to be read to include all of the features of claims 1, 15, 16, 17, and 18.

[53]
The Applicant argued that claim 1 of the present application is distinguished from claim 20 of '948 in that the latter is not limited to characteristic (d) (i.e., that all, not just part, of the internal metallic surfaces are coated, see para. 47) and that, unlike claim 1 of the present application, claim 15 of '948 (upon which claim 20 depends) recites a "crimped cap covering the mouth of the can, and a drug metering valve situated in the cap."

[54]
Regarding characteristic (d), the Applicant argued that it is a required element in claim 1 of the present application whereas it is only optional in claim 20 of '948. The Examiner argued that the limitation in the present claims did not take it outside of claim 15 of '948 as the latter requires that the can be made of metal and that part or all of the internal surfaces be coated.

[55]
Insofar as obviousness double patenting is concerned, we do not see that this feature patentably distinguishes these claims. Where the choice of coating part or all of the surfaces is given, we see no ingenuity in choosing to coat all of the surfaces.

[56]
As for the "crimped cap covering the mouth of the can, and drug metering valve situated in the cap," defined in claim 20 of '948, through its dependence on claim 15, the Examiner found this feature to be non-essential, seemingly because it was known in the art. Consequently, the Examiner held that this feature could not be taken to patentably distinguish the claims.

[57]
The Applicant responded that the feature is essential as it is a required element of the claim, and stated that this feature distinguishes over claim 1 of the present application as the latter does not require the cap and valve.

[58]
Based on the following, we find that this feature fails to patentably distinguish the claims even if the crimped cap and valve are assumed to be essential elements of the above noted claims of the '948 patent.

[59]
In the description of the present application, the Applicant provided a definition of the term "metered dose inhaler," as follows: "a unit comprising a can, a crimped cap covering the mouth of the can, and a drug metering valve situated in the cap."

[60] Where, in a case such as this, the description includes a definition of a term, that meaning is to be used in interpreting the claims: *Lundbeck Canada Inc v Ratiopharm Inc*, 2009 FC 1102 at para. 46.

[61] As claim 1 recites an MDI, taking into account its definition in the description, this claim is necessarily limited to the cap and valve disposed in the same manner as recited in claim 15 of '948.

[62] It follows that, even if the cap and valve are assumed to be essential elements of claim 20 of '948 (through its dependency upon claim 15), these features would not patentably distinguish claim 1 of the present application over claim 20 of '948 as they are also included in present claim 1 when purposively construed.

[63]
We conclude that claim 1 of the present application fails to exhibit ingenuity over claim 20 of patent '948 (when taken as dependent on claims 18, 17, 16, 15, and 1).

Present Claims 2-7 v. Claim 20 '948

[64] The Applicant argued that claims 2 to 7 of the present application are distinct as they include all of the features of claim 1. No argument was put forward regarding the further elements recited in these claims; these claims are found word-for-word in '948 as claims 2-5, 13, and 14, respectively. Accordingly, they fail to demonstrate the required ingenuity over the claims of the '948 patent.

Present Claim 8 v. Claim 19 (as dependent on claims 18, 17, 16, and 1) of '517

[65]
Claim 8 of the present application recites that the inhaler comprises "a substantially ellipsoidal base." That is, the base of the MDI can has this shape.

[66] While the Examiner and Applicant disagreed as to whether the substantially ellipsoidal base is essential, we need not make a finding on the construction of this element. Even presuming the element to be essential, claim 8 would be defective for double patenting.

[67] That said, if we were to make a finding on the essentiality of this shape, the substantially ellipsoidal base appears to provide a material effect on the way the invention works, given that it is said to facilitate the coating process and to strengthen the can, particularly when exposed to the high temperatures employed in the coating process: see present description at pg. 7.

[68] As this element is not found in any claim of the '948 patent but is explicitly recited in the claims of the '517 patent, we will use '517 as the basis of comparison for claim 8 of the present application to address whether this claim is patentably distinct.

[69]
The Examiner found that claim 19 (as dependent on claims 18, 17, 16, and 1) of '517 and claim 8 of the present application are not patentably distinct.

[70]
In addition to reciting a substantially ellipsoidal base, claim 1 of '517, upon which claim 19 depends, recites that part or all of the internal surfaces are coated and that the can is made of "strengthened aluminium." It is not, however, limited to the same two non-fluorocarbon polymers recited in claim 1 of the present application.

[71] The Applicant replied that claim 19:

> does not include, to refer again to the list of characteristics above at para. 47, characteristic (d), requiring all of the internal metallic surfaces to be coated;
> does not include characteristic (b), but rather recites a broader group of non-fluorocarbon polymers; and,
> is more specific in that it recites strengthened aluminium, stating that "[th]e fact that 'aluminium' encompasses 'strengthened aluminium' is... not relevant" as the claims must be considered in their totality with all the features recited.

[72]
As for the Applicant's point regarding characteristic (d), claim 19 of '517, through its dependency on claim 16, recites that part or all of the internal metallic surfaces of the can are coated. Our findings regarding characteristic (d) in relation to claim 1 of the present application apply equally to claim 8 (see paras. 51-53).

[73]
In its second point, the Applicant submits that the two non-fluorocarbon polymers recited in claim 1 of the present application, namely polyamideimide and polyethersulfone, are selected from a broader group of non-fluorocarbon polymers.

[74]
The identification of a subset of compounds from a wider, previously known genus is considered a selection. To justify the grant of a patent on a selection, among other requirements, "[t]here must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members": see *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at para. 10. When considering a selection claim in the context of double patenting, the description may be taken into account: see *Sanofi* at 114.

[75] If polyamideimide and polyethersulfone are shown to provide a substantial advantage over the wider group of non-fluorocarbon polymers recited in claim 19 of '517, claim 8 of the present application might be found patentably distinct.

[76] The description of the present application shows that, although polyamideimide is used in certain examples, there is no evidence of a substantial advantage or avoidance of a substantial disadvantage arising from its use, only a general statement that the coated MDIs, with or without the non-fluorocarbon polymers, provide an advantage over uncoated cans (see page 17). This advantage is not specific to the selection of the two recited polymers.

[77]
As we find no evidence of a substantial advantage or the avoidance of a substantial disadvantage, restricting claim 1 of the present application to polyamideimide and polyethersulfone does not represent a patentably distinct selection over the broader group of non-fluorocarbon polymers recited in claim 19 of '517.

[78]
The Applicant's final point was that present claim 8 (through its dependency on claim 1) recites that the can comprises "aluminium or aluminium alloy," whereas claim 19 of '517 (through its dependency on claim 1) recites "strengthened aluminium."

[79] In our view, there is no ingenuity in claiming aluminium broadly in comparison to strengthened aluminium, even when taken in combination with all elements recited in the claims, as addressed above. And since aluminium and aluminum alloy are recited in the claim as alternatives, there is no ingenuity in claiming aluminium alloy as opposed to strengthened aluminium.

Present Claims 9 and 10

[80] As with claims 2-7, the Applicant argued that claims 9 and 10 are distinct through their dependency on earlier claims, making no argument in support of the additional elements recited in claims 9 and 10. We note that claim 9 substantially correlates to claim 25 of '517, while claim 10 substantially correlates to claim 26 of '517. We find that claims 9 and 10 are not patentably distinct from those claims.

CONCLUSION

[81]
In light of the above reasons, the Board finds that the claims of the present application are not patentably distinct over the claims of patents cited by the Examiner, as outlined above.

RECOMMENDATION OF THE BOARD

[82] The Board finds that none of the claims in application 2,368,934 define subject matter that is patentably distinct over the claims of patents 2,217,948 and 2,447,517. It is therefore recommended that the application be refused.

Mark Couture Member	Paul Fitzner Member	Stephen MacNeil Member

DECISION OF THE COMMISSIONER

[83]
I concur with the Patent Appeal Board's findings and their recommendation that I uphold the rejection of the application on the basis of obviousness double patenting in view of patents number 2,217,948 and 2,447,517.

[84]
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.

Sylvain Laporte
Commissioner of Patents

Dated at Gatineau, Quebec,
this 12th day of July, 2012

Appendix A, CD 1328

Claims Considered in Double Patenting Analysis

A) Present Application

1. A metered dose inhaler characterised in that part or all of its internal surfaces are coated with a polymer blend comprising one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation which comprises fluticasone propionate or a physiologically acceptable solvate thereof, optionally in combination with one or more other pharmacologically active agents; and a fluorocarbon propellant; wherein (a) the fluorocarbon polymer is selected from the group consisting of PTFE, PFA, FEP and mixtures thereof, (b) the non-fluorocarbon polymer is selected from the group consisting of polyamideimide and polyethersulfone, c) the inhaler comprises a can made of aluminium or an alloy thereof, and (d) all of the internal metallic surfaces of the can are coated with the polymer blend.

[claims 2-7 omitted]

8. An inhaler according to any one of claims 1 to 7 comprising a substantially ellipsoidal base.

[claims 9 and 10 omitted]

B) Patent 2,217,948

1. A metered dose inhaler having part or all of its internal surfaces coated with a polymer blend comprising one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation comprising fluticasone propionate or a physiologically acceptable solvate thereof and a fluorocarbon propellant, optionally in combination with one or more other pharmacologically active agents or one or more excipients.

[Claims 2-15 omitted]

15. An inhaler according to any one of Claims 1 to 14, comprising a can, a crimped cap covering the mouth of the can, and a drug metering valve situated in the cap characterised in that the can is made of metal and part or all of the internal surfaces are coated.

16. An inhaler according to Claim 15, wherein the metal is aluminium or an alloy thereof.

17. An inhaler according to any one of Claims 1 to 16, wherein said fluorocarbon polymer is a perfluorocarbon polymer.

18. An inhaler according to Claim 17, wherein said fluorocarbon polymer is selected from polytetrafluoroethylene (PTFE), perfluoroalkoxyalkane (PFA), fluorinated ethylene propylene (FEP) and mixtures thereof.

[claim 19 omitted]

20. An inhaler according to any one of Claims 1 to 19, wherein said fluorocarbon polymer is in combination with a non-fluorocarbon polymer selected from polyamideimide and polyethersulphone.

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1. A metered dose inhaler comprising a can said metered dose inhaler having part or all of its internal surfaces coated with a polymer blend comprising one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers, and wherein said can is made of strengthened aluminium and comprises a substantially ellipsoidal base, for dispensing an inhalation drug formulation comprising fluticasone propionate or a physiologically acceptable solvate thereof and a fluorocarbon propellant.

[claims 2-15 omitted]

16. An inhaler according to any one of claims 1 to 15 wherein part or all of the can's internal metallic surfaces are coated.

17. An inhaler according to any one of claims 1 to 16 wherein the one or more fluorocarbon polymers is/are a perfluorocarbon polymer(s).

18. An inhaler according to Claim 17 wherein the one or more fluorocarbon polymers is/are selected from PTFE, PFA, FEP and mixtures thereof.

19. An inhaler according to any one of Claims 1 to 18, wherein the one or more non-fluorocarbon polymers is/are selected from polyamide, polyimide, polyamideimide, polyethersulfone, polyphenylene sulfide and amine-formaldehyde thermosetting resins.

[Claims 20-26 omitted]