

Commissioner's Decision # 1267

Décision du commissaire # 1267

TOPIC: D02

SUJET: D02

Application No.: 2,303,601 (Class A61K-9/12)

Demande No.: 2,303,601 (Classe A61K-9/12)

COMMISSIONER'S DECISION SUMMARY

C.D. 1267 App'n 2,303,601

Divisional status

The examiner refused to grant this application divisional status because the claims claimed an invention which was not disclosed in the parent application. The Board agreed with the examiner.

The application was returned to the examiner for further prosecution as a regular application.

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,303,601 having been rejected under Subsection 30(4) of the Patent Rules, the Applicant asked that the Final Action of the Examiner be reviewed. The rejection has been considered by the Patent Appeal Board and by the Commissioner of Patents. The findings of the Board and the decision of the Commissioner are as follows:

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This decision deals with a request that the Commissioner of Patents review the Examiner's Final Action on patent application number 2,303,601 which was filed on 14 April 2000 and is entitled "MEDICINAL AEROSOL FORMULATIONS ". The Applicant is Riker Laboratories, Inc., assignee of inventors Tarlochan S. Purewal and David J. Greenleaf. Application number 2,303,601 is a divisional of Canadian patent application number 2,004,598 which was filed on 5 December 1989 and which issued to patent on 7 November 2000.

On 5 January 2001, the Examiner in charge issued a Final Action in which divisional status was rejected. The Final Action states that the abstract, description and claims contain subject matter not disclosed in the specification of the parent application (now patent number 2,004,598).

The Applicant responded to the Final Action on 4 July, 2001 by arguing that the application is a proper divisional and that the Final Action should be withdrawn. When contacted by the Patent Appeal Board with respect to an oral hearing, the Applicant's agent requested that the Board review the file and that the Commissioner render a decision without the benefit of a hearing.

Parent application (now patent) 2,004,598 describes and claims a 4-component aerosol formulation substantially free of chlorofluorocarbons and containing a medicament, 1,1,1,2-tetrafluoroethane, a surface active agent and at least one compound with a higher polarity than 1,1,1,2-tetrafluoroethane and miscible with 1,1,1,2-tetrafluoroethane. Application number 2,303,601 (the divisional application) describes and claims an aerosol canister equipped with a metering valve and containing a 3-component aerosol formulation free of chlorofluorocarbons and containing a medicament, 1,1,1,2-tetrafluoroethane and a compound with a higher polarity than 1,1,1,2-tetrafluoroethane. The formulation claimed in the divisional application lacks the surface active agent found in the formulation of the parent application.

The Final Action states in part:

The subject matter of the instant divisional application in the abstract, page 2a of the description and claims 1 to 4 contain new subject matter not disclosed in the original specification of the parent application 2,004,598.

The new subject matter of the instant divisional was the subject of a Final Action in the parent 2,004,598. The subject matter was refused in the Final Action under Subsection 27(4) of the Patent Act as being incomplete and failing to recite sufficient elements for proper operation of the alleged invention, for being broader in scope than the teaching of the description under Subsection 138(2) of the Patent Rules and for adding new subject matter under Section 38.2 of the Patent Act. The abstract, page 2a and claims 1 to 4 contain new subject matter not disclosed in the original parent application 2,004,598 and therefore the divisional status is refused.

.....

When reading the disclosure in complete, together with the examples and what was considered conventional, the conclusion is a 4-component system including a conventional surfactant. The specification does not contemplate the absence of the conventional surfactant to make a stable suspension of drug particles.

In its response to the Final Action, the Applicant stated in part:

It is well established in Law that there must some support of the original specification of a patent application for anything that the Applicant wants to claim. However, there is no requirement that the original specification must necessarily disclose as such and exemplify what is being claimed. Rather, it is well established in Law that the Applicant “*needs not restrict his claims to what has been specifically disclosed in the specification but within the breath of his invention, may claim it as broadly as it would normally be construed by a person skilled in the art on reading the whole specification*” (Riddell - v - Patrick Harrison & Co. Ltd. (1957) 28 C.P.R. 85 at 125).

The response to the Final Action also refers to specific passages in the description of the parent application (2,004,598) where in the Applicant’s view, support is found for a 3-component aerosol formulation:

... one may refer to page 3, lines 1 to 7 and 14 to 17 of the original description. In this part of the original description, no reference is made to the use of a surfactant. Rather, the invention is disclosed as being based on the discovery that propellant 134 may be employed in an aerosol formulation suitable for inhalation therapy, when used in combination with an adjuvant. Thereafter, on page 4 and subsequent, it is explained that “*the use of propellant 134a and drug as a binary mixture or in combination with a conventional surfactant ... does not provide formulation having suitable properties for use with pressurized inhaler*”. Then, it “*has been established that ... by a suitable selection of a compound having a plurality higher than that of propellant 134, stable aerosol formulations using propellant 134a may be prepared*” (see page 4, lines 5 to 15 of the original description).

As may be noticed, this part of the original description does not disclose that a surfactant must necessarily be used. Rather, the conjunction “or” underlined hereinabove is a proof that such is just an alternative (even though such was actually recited in the original set of claims submitted when the parent application 2,004,598 was filed).

The Applicant also states:

Page 4, lines 5-9, when read closely, is quite specific in that its language merely refers to binary mixtures of 134a and drug or with a “conventional” surfactant as having unsuitable properties for use with pressurized “inhalers”. This is not tantamount to a statement that the “invention” *per se* requires 134a, drug, polar adjuvant and surfactant. To the contrary, it would be clear to those skilled in the art that, for example, unconventional surfactants may be used, and also that 3-component formulations like the one recited in claim 1 (viz. 134a, drug and polar adjuvant) are not excluded

and further that,

any one skilled in the art, upon reading the whole specification, would understand that the presence of a surfactant in the aerosol formulation is very interesting but not actually essential, since the invention does not lie in the use of such a surfactant which is quite standard but rather in the use of the adjuvant whose characteristic is specifically disclosed.

The question for the Board is whether there is support in the specification of parent application (now patent) number 2,004,598 for a 3-component aerosol formulation. If there is no support, then application number 2,303,601 is not entitled to divisional status.

The Applicant has referred to passages from pages 3 and 4 of the 2,004,598 specification as

support for formulations which do not contain a surfactant. The Applicant has stated that on page 3 at lines 1 to 7 and 14 to 17, “no reference is made to the use of a surfactant”. However, this passage is not directed to a formulation *per se* but rather to the discovery that Propellant 134a may be used in formulations suitable for inhalation therapy when used in combination with an adjuvant having a higher polarity. The combination can then be used in formulations with other components as indicated on page 3, lines 14 to 19:

The combination of one or more such adjuvants with Propellant 134a provides a propellant system which has comparable properties to those of propellant systems based on CFC’s, allowing use of known surfactants and additives in the pharmaceutical formulations and conventional valve components. (emphasis added)

There is no disclosure of a 3-component formulation comprising a medicament, Propellant 134a and an adjuvant with a higher polarity than that of Propellant 134a.

The text referred to on page 4 of the specification (lines 5 to 15) does not disclose inventive formulations but rather formulations which are not suitable for use with pressurized inhalers. Thus, using Propellant 134a and a drug as a binary mixture, with or without a surfactant, does not provide a formulation that is suitable for use with pressurized inhalers. Again, there is no disclosure of 3-component formulations which do not contain a surfactant as an embodiment of the invention.

On page 2 of the 2,004,598 specification the invention is described as follows:

It has now been found that 1,1,1,2-tetrafluoroethane has particularly suitable properties for use as a propellant for medicinal aerosol formulations when used in combination with a surface active agent and an adjuvant having a higher polarity than 1,1,1,2-tetrafluoroethane.

According to the present invention there is provided an aerosol formulation comprising a medicament, 1,1,1,2-tetrafluoroethane, a surface active agent and at least one compound having a higher polarity than 1,1,1,2-tetrafluoroethane.

The formulation contains 4 components, including a surfactant. There is no suggestion that the surfactant is optional. On pages 2a and 2b, other embodiments of the invention are disclosed. All of these define a 4-component aerosol formulation including a surface active agent.

On page 4, at lines 16 to 24, a benefit of using a compound having a higher polarity than 1,1,1,2-tetrafluoroethane (also known as Propellant 134a) is described:

The addition of a compound of higher polarity than Propellant 134a to Propellant 134a provides a mixture in which increased amounts of surfactant may be dissolved compared to their solubility in Propellant 134a alone. The presence of increased amounts of solubilised surfactant allows the preparation of stable, homogenous suspensions of drug particles. The presence of large amounts of solubilised surfactant may also assist in obtaining stable solution formulations of certain drugs.

There is no suggestion in this passage that formulations not containing a surfactant are contemplated. Indeed, in the Board’s opinion, quite the opposite, as the presence of a compound with a higher polarity than Propellant 134a permits “increased amounts of surfactant” in the

formulation. This passage also suggests that the surfactant can stabilize the formulation. On page 8, at lines 6 to 8, the Applicant says as much:

The aerosol formulations comprise a surface active agent to stabilise the formulation and lubricate the valve components.

As the examiner has pointed out in the Final Action, all of the examples (24 in total) describe a 4-component formulation comprising a surfactant. There are no examples of any formulations which do not comprise a surfactant.

The Board is not satisfied that the 2,004,598 specification discloses inventive formulations which do not contain a surfactant. Rather, the specification is directed to 4-component formulations including a surfactant. The Board therefore recommends that application number 2,303,601 be refused divisional status.

M. Gillen
Chairman

M. Wilson
Member

I concur with the findings and recommendation of the Patent Appeal Board. Accordingly, I refuse to accept the divisional status of application number 2,303,601. Under Section 42 of the Patent Act, the Applicant has six (6) months within which to appeal my decision to the Federal Court of Canada.

David Tobin
Commissioner of Patents

Dated at Gatineau, Quebec,
this 17th day of August , 2006