## COMMISSIONER'S DECISION

SECTION 2 - Reducing The Desire For Smoking

A method of administering a substance to a patient falls under Section 2 of the Patent Act. The Applicant's amended claims are not directed to a medical treatment.

Rejection Affirmed - Amended claims accepted.

Patent application 261,672 (Cl. 167-247) was filed on September 21, 1976 for an invention entitled METHOD FOR ELIMINATING OR REDUCING THE DESIRE FOR SMOKING. 'The inventor is Emanuel Revici. The Examiner in charge of the application took a Final Action on December 11, 1979 refusing to allow it to proceed to patent.

The application is directed to a method of preventing or reducing the desire for smoking tobacco in humans by administering a sulfurized polyunsaturated oil.

In refusing the method claims under Section 2 (the composition claims were found allowable) the Examiner had this to say (in part):

The applicant in his letter argues that the process claimed in this application is not a medical treatment because the composition of the invention is not a medicine. He also argued in his letter in response to the Office action dated September 27, 1978 that the method was not for effecting the prevention or cure of an ailment in humans. These arguments however do not overcome the objection because the examiner is convinced that the composition comes under the definition of medicine. The applicant's attention is directed to the definition of drug provided by Parliament for the purpose of the Food and Drug Act (1970) R.S.C. modifying organic function in man or animal. According to this definition, the composition of this application is clearly a drug and the process of administering it to a human is therefore a method of medical treatment. As to the second argument, the examiner is convinced that a method for reducing or eliminating the desire for tobacco in a human is a method of preventing ailment. For example it is well-known that heavy smoking causes lung cancer. The method of this application therefore falls well-within the definition of non-patentable subject matter, namely a method of preventing ailment using drug.

Claims 1 to 19 and 38 to 40 must be removed since they are outside of the scope of patentable invention as set forth in Section 2 of the Patent Act.

In response to the Final Action the Applicant stated (in part):

The proper approach for considering whether or not the composition employed in the method of the invention, is a "medicine" would therefore seem to be that one should consider if in the ordinary and popular sense, rather than the scientific sense, it would be considered a medicine. In other words if the laymen or ordinary person would consider the composition a medicine. It is respectfully submitted that the ordinary person would not consider a composition employed to reduce the desire for smoking to be a "medicine". It is known, for example, to chew gum and suck peppermints or boiled sweets to alleviate the craving for tobacco, however, such use would hardly be considered a medical treatment by the ordinary person, and chewing gum, peppermints and boiled sweets would hardly be considered "medicine". It is also known to employ materials that will produce an unpleasant taste during smoking, whereby smoking is discouraged, it is not thought that this would be considered a medical treatment by the ordinary person in the ordinary and popular sense as opposed to the scientific sense.

Even materials apt to be used in medicine or during surgery have been considered as not being medicines. For example, in Burton Parsons Chemicals Inc. et al v. Hewlett-Packard (Canada) Ltd. et al, reported in 17 CPR (2d) 97, the Supreme Court found that an electrocardiograph cream was not a medicine or even "intended for medicine". In the Decision of the Court it was commented -

"It is clear that such (that is the use) is primarily and mainly for the taking of electrocardiograms in routine examinations, not necessarily or mainly in connection with the treatment of diseases. It is obviously a matter of some difficulty to draw the line between what is a medicine and what is only a product apt to be used in connection with medical treatments." The composition of the present invention is neither a medicine nor a product apt to be used in connection with medical treatments. It is respectfully submitted that the approach taken in the

Official Action, by reference to the definition of drug in the Food and Drug Act, is not the proper approach, and is not the approach that has been sanctioned by the Courts, and that the rejection on this ground therefore fails.

The issue before the Patent Appeal Board is whether or not method claims fall under the provisions of Section 2 of the Patent Act. Method claim 1 reads: 1. A method for eliminating or reducing the desire for tobacco in a human which comprises, internally administering thereto a liquid composition produced by the process comprising oxidizing a liquid containing allylic unsaturation of the type -CH=CH=CH=CH=CHand/or -CH=CH=CH=CH=CH\_2selected from fatty acids and fatty esters for a period of time sufficient to produce a peroxide titer substantially greater than that of the untreated compound, in an amount sufficient to eliminate or reduce the craving for tobacco.

On a complete review of the prosecution of the application we find nothing to change our stand on whether or not a method of administering a substance to a patient falls under Section 2 of the Patent Act. Our stand is that any substance for use in modifying organic functions in man or animal is a medicine in the broad sense and any method directed to a medical treatment falls under Section 2 of the Patent Act. There is no doubt but that the presently claimed substance "a sulfurized polyunsaturated oil" modifies the organic functions of the body as a consequence of use.

With this in mind, we contacted the Agent Mr. K. Murphy and discussed our view with him. After due consideration, Mr. Murphy, on September 24, 1981 cancelled or amended all of the method claims and renumbered the composition claims accordingly.

No further discussion is therefore deemed necessary and we recommend that the composition claims be accepted.

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Assistant Chairman Patent Appeal Board, Canada

I have reviewed the prosecution of this application and concur with the easoning and findings of the Patent Appeal Board. Accordingly, I direct that prosecution should resume on the basis of the amended claims.

J.H.A. Gariépy Commissioner of Patents

Dated at Hull, Quebec this 29th. day of October, 1981

Agent for Applicant

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