## DECISION OF THE COMMISSIONER

STATUTORY - S.2(d): Vaccine for Immunization of Animals.

NO AGGREGATION: Mixture of Vaccine Viruses Unobvious.

Processes and products in the microbiological field are not excluded under Section 2(d), vide GD, 125. The specified mixture of virus incredients produce a new result which was the result of inventive experimentation.

FINAL ACTION: Reversed.

## XXXXXXXXXXXXX

This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated October 28, 1971 on application 879,884. This application was filed in the name of Kurt Drager et al and refers to "Polyvalent Canine Vaccine Preparation".

In the prosecution terminated by the Final Action the examiner refused the claims as being directed to an aggregation, and that the claims refer to modified living matter which do not represent a patentable invention according to Section 2(d) of the Patent Act.

At the outset it is made clear that the examiner was following office policy with respect to living matter at the time the Final Action was written. However, this rejection is withdrawn in view of a change in policy as set out in a recent Commissioner's Decision which held that processes and the products thereof in the microbiological field are not excluded from patentability under Section 2(d) of the Patent Act provided the prerequisites of novelty, unobviousness and, more particularly, utility are satisfied.

With respect to the first rejection "... the claims are directed to an aggregation", the applicant stated in part: (action of February 5, 1971)

The Examiner has also rejected the claims 1 and 2 directed to vaccines because he regards them as being directed to an unpatentable aggregation. Applicants consider that the kxaminer is completely incorrect in alleging that "It is expected skill to produce a vaccine that has the effect in a single treatment of what previously required several treatments". Hence applicants are in a position to show that the vaccines prepared according to this invention do

not show a simple additive effect of their components and are even superior to other combined vaccines of the same type which were known prior to the convention date of this application. Applicants are enclosing a copy of an affidavit which was filed in the corresponding United States Application in which it is shown that the use of a live apathogenic tissue culture distemper virus component" in a divalent vaccine according to the present invention results in a significantly higher hepatitis antibody count than that produced by a vaccine prepared according to what was known before the date of this invention. There can be no question that this is a surprising and unexpected result which could not be foreseen by any one skilled in the art prior to the making of the present invention. It is believed therefore that the Examiner's allegations that the vaccine claims 1 and 2 present in this application directed to an unpatentable aggregation are completely untenable.

This application refers to a Polyvalent Canine Vaccine and the process for manufacture. Claim 1 reads as follows:

A vaccine for the simultaneous immunization of dogs and foxes against distemper, hepatitis contagiosa canis and leptospirosis (Stuttgart disease and Weil's disease) consisting of a lyophilized mixture of inactivated hepatitis contagiosa canis viruses, modified distemper viruses and destroyed leptospira canicola cultures and destroyed leptospira icterohaemorrhagiae cultures.

Having considered the subject matter of the application the Board is satisfied that claims 1 and 2 are not directed to a mere mixture of four viruses for each virus is present in a particular <u>form</u>, and agrees that the applicant is not claiming any haphazard mixture of four known viruses. Among a variety of possible mixtures he selected a particular one containing an inactivated hepatitis virus, a modified (attenuated) distemper virus and two destroyed leptospira cultures. This mixture is further subjected to lyophilization to improve its stability and storability (see page 1, lines 18 to 22). The selected mixture could not have been inferred from the known properties of the four single viruses. It appears obvious that this selection is the result of an extensive experimentation which finally narrowed down the

content of the composition to the specific mixture presently claimed. It is sufficient to read the experimental data given on pages 2 to 9 to realise the complexity of the problem solved by the applicant.

As noted in the above mentioned affidavit, the vaccine, according to the present invention, gives significantly better results than any vaccine prepared according to what was known before the date of this invention, therefore, any vaccine which gives a new and better result cannot be considered as an aggregation.

Also, in a recent decision, <u>Burton Parsons v. Hewlett-Packard (1972) T-390-7</u>, the Federal Court held that a mixture of prior art ingredients is patentable if it produces a new result. Based on the evidence before it, the Board is satisfied that a new result is produced by the mixture under consideration, and that there was sufficient ingenuity in so doing to satisfy the Commissioner that the application should proceed to grant.

Consequently, the Board recommends the Final Action be withdrawn.

R.E. Thomas, Chairman, Patent Appeal Board.

I concur with the finding of the Patent Appeal Board and withdraw the Final Action and return the application to the examiner for resumption of prosecution.

Decision accordingly,

A. M. Laidlaw, Commissioner of Patents.

Dated at Ottawa, Ontario, this 14th day of October, 1972.