COMMISSIONER'S DECISION

UTILITY OF KNOWN COMPOUND: STERILIZATION PROCESS

Applicant claims a known composition (B.C.G.) for use in sterilization of mammalian species. The rejected claims failto define the relationship of any limited form of BCG in terms of its make-up or constitution together with the other necessary components that formulate a composition.

Final Action: Affirmed

This decision deals with Applicant's request for review by the Commissioner of Patents of the Final Action of application 322,706 (Class 167-135), entitled "Sterilization Process for Mammals." The inventor is G.P. Talwar. The Examiner wrote a Final Action on July 8, 1982 refusing claims 1 to 4 of the application to proceed to patent.

The invention relates to a method of sterilization of mammalian species.

Bacillus of Calmette and Guerin (hereinafter referred to as BCG) is a known vaccine for protection against tuberculosis. Applicant has discovered a new, unexpected use for BCG having regard to its known utility and properties. He discloses that sterilization in mammalian species occurs when BCG is intra-testicularly injected at a dose of at least 1.5 x 107 organisms.

In the Final Action the Examiner said in rejecting claims 1 to 4 (in part):

Claims 1 to 4 are directed to known products in terms of a novel utility. BCG per se is old and known as acknowledged in the disclosure on page 1 and remains old and known no matter what purpose it is used for. Only novel adaptations thereof are patentable. The BCG per se defined in terms of utility as in claims 1 to 4 does not define patentable subject matter.

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

It is submitted that the definition of the novel form of BCG in claims 1 to 4 is as equally allowable as the definition of the novel form of BCG in claims 5 and 6. Claims 1 to 4 define a novel composition of matter in the same way that claims 5 and 6 define a novel composition of matter. Both groups of claims define novel adaptations of BCG.

It is submitted that there is nothing in The Patent Act which prevents the patenting of claims 1 to 4. While limiting a product claim by reciting the use to which it is to be put may be an unusual form of limitation, nevertheless, it is submitted that such recitation is a limitation. It is noted that the Examiner has chosen to cite no case law or other authority which would support his position.

claims 1 to 4 are infringed only if BCG is used in the manner recited therein, and, therefore, these claims extend only to such use. The claims are not directed to BCG per se, but rather to the restricted form of BCG recited therein.

The utility is novel and unobvious and worthy of patent protection. The applicants, in claims 1 to 4, have chosen to define the invention in terms of a composition of amtter limited to use in the novel and unobvious manner. It is submitted that such limitation results in a claim which is novel and unobvious and hence patentable.

. . .

On page 4 of the response it is argued (in part):

Claims 1 to 4 do <u>not</u> claim BCG per se. BCG is a known substance and hence cannot be claimed. What is claimed is that compound <u>limited</u> by the end use to which it is put. It is submitted that the recitation of the use in the claims is a proper limitation and one which distinguishes the claims from the prior art.

. . .

The issue before the Board is whether or not claims 1 to 4 define patentable subject matter. Claims 1 to 4 read as follows:

- The <u>Bacillus</u> of <u>Calmette and Guerin</u> when used in the sterilization of <u>mammalian</u> species.
- The invention of claim 1, wherein the mammalian species is selected from the group consisting of rams, non-human primates, rats, guinea pigs or rabbits.
- The invention of claim 1, wherein the mammalian species is dogs.
- 4. The <u>Bacillus</u> or <u>Calmette and Guerin</u> when used for intratesticular injection in an amount of at least 1.5 x 10⁷ organisms per testicle.

We see from the prosecution both the Applicant and the Examiner agree that BCG is known and old. Applicant argues that claims 1 to 4 represent a limited form of BCG in terms of a composition of matter. He points to the term "when used" in claims 1 and 4 to illustrate that these claims are directed to a composition, but we are not persuaded that these words impart any patentably limiting chemical or physical feature to BCG. They merely indicate an intention without including a material diference over the known BCG. Also in claim 4 we note an amount is given. In our opinion, merely referring to BCG in terms of an amount, does not lend to claim 4 any

characteristics or properties which may be said to be properly definitive of a new composition. We note further that claim 4 is not directed to a composition. We are persuaded claim 4 recites no more than the same BCG used in treating tuberculosis. In summary, we find claims 1 to 4 fail to define the relationship of any limited form of BCG in terms of its make-up or constitution together with the other necessary components that formulate a composition. We are satisfied therefore that claims 1 to 4 do not define patentable subject matter.

We recommend that the rejection of claims 1 to 4 be maintained.

under the provisions of Section 44 of the Patent Act.

A. McDonough

Chairman Patent Appeal Board

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M.G. Brown Assistant Chairman

S.D. Kot

I concur with the findings and recommendation of the Patent Appeal Board.

Accordingly, I refuse to grant a patent containing claims 1 to 4 of the application. The Applicant has 6 months within which to appeal my decision

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J.H.A. Gariépy Commissioner of Patents

Dated at Hull, Québec

this 9th. day of August, 1984

Agent for Applicant

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