IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 527,445, having been rejected under Rule 47(2) of the Patent Regulations, the Applicant asked that the Final Action of the Examiner be reviewed. The rejection has consequently been considered by the Patent Appeal Board and by the Commissioner of Patents. The findings of the Board and the ruling of the Commissioner are as follows:

Representative for the Applicant

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This decision deals with the Applicant's request that the Commissioner of Patents review the Examiner's Final Action on patent application number 527,445 (Class 326-4) filed on January 15, 1987 in the name of Liber J. Montone and entitled METHOD AND APPARATUS FOR TREATING MALIGNANT CELLS. The Examiner in charge of the application issued a Final Action on November 8, 1991 refusing all of the claims of the application and stating essentially that, since the rejection could not be overcome by amendment, the application itself was refused.

The application in the words of the abstract relates to a method and apparatus for destroying or retarding the growth of malignant cells and tumours using one or more coils of wire, externally applied to the body, for chosen periods, which are connected to an alternating current source to produce a low frequency sinusoidal magnetic field of desired intensity at the irradiated malignant region to be treated.

Figures 1 and 2 shown below indicate the general form of applicant's apparatus as it would be applied to a test animal having implanted in its body human cancer cells, whilst further drawings 5 to 8 show how Applicant's apparatus would be employed in a human patient.

Figure 1

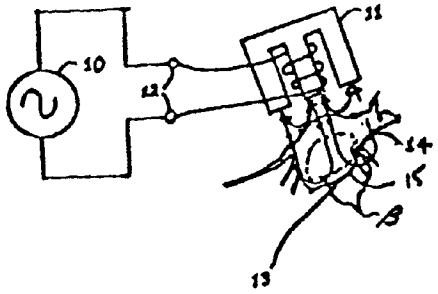
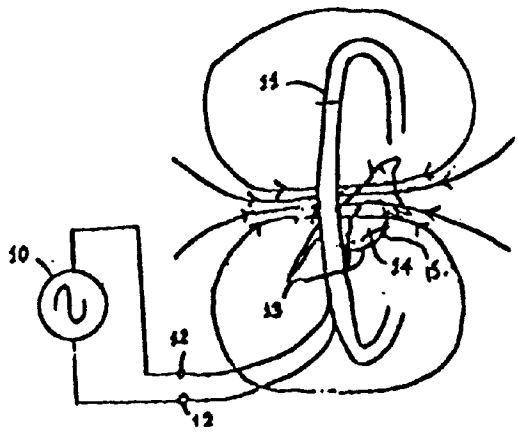


Figure 2



Thus Figure 1 is a representation of ferrite core demagnetizing field coil 11 positioned over lump 15 to treat small mammary carcinoma tumour 14 in female breast 13. Coil 11 receives alternating current power through terminal 12 from adjustable A.C. power source 10. "B" represents the resulting alternating magnetic field.

Figure 2 is a representation of air core circular wound demagnetizing field coil 11 positioned so as to treat large mammary carcinoma tumour 14 in female breast 13. Coil 11 receives alternating current power through terminal 12 from adjustable A.C. power source 10.

At the time of the Final Action the application contained 16 claims, being claims 1 to 12 directed to a method of treating malignant cells in living tissue, claims 13 to 15 directed to an apparatus for treating malignant cells in accordance with the method of claims 1 to 12 and claim 16 directed to a method of operating apparatus as defined in claims 13 or 14. Independent claims 1, 13 and 16 were as follows:

1. A method for treating malignant cells in living tissue comprising:
externally applying a sinusoidal magnetic field having a field strength of between 50 and 550 gauss throughout the malignant cells to inhibit mitosis of said malignant cells.

13. Apparatus for treating malignant cells in living tissue comprising means for producing a sinusoidal magnetic field, and means for causing restriction of field strength of said field to between 50 and 550 gauss at a location throughout said malignant cells.

16. A method of operating apparatus as defined in claim 13 or 14 comprising bringing said apparatus near said malignant cells for substantially at least 5 minutes per day for a plurality of days and producing said field while said apparatus is adjacent said malignant cells.

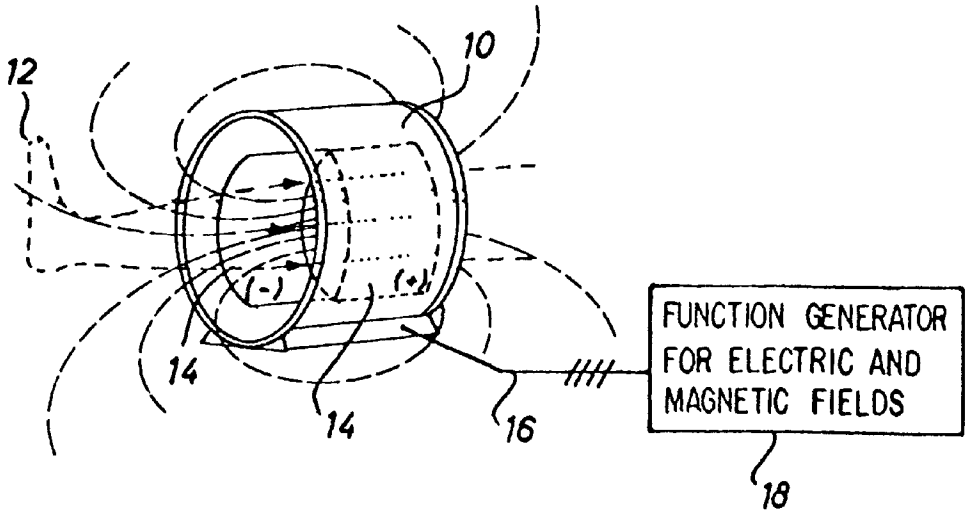
In his Final Action the Examiner refused claims 1 to 12 as not falling within the ambit of Section 2 of the Patent Act essentially because they were held to be directed to methods of medical treatment. Claims 13 to 16 were rejected for two main reasons, firstly because the claims were held to be merely disguised process claims and secondly because the apparatus disclosed was held to be anticipated by that disclosed in prior United States patent number 3,915,151 to Kraus. In his Final Action the Examiner stated his objections to claims 13 to 16 in the following terms:

> Turning now to newly introduced claims 13-16, these are merely process claims rewritten in the guise of an apparatus. As such, the wording is seen to be misleading; thus while a coil is undoubtedly a "means for producing a sinusoidal magnetic field" the "means for causing restriction of field strength ..." in claim 13 turns out to be merely a spacer or distance piece (see page 11 lines 1-9) which does not, properly speaking, restrict the field strength at all.
>
> Furthermore, the apparatus of claims 13-16, when strictly read for the structure claimed is anticipated by that disclosed by Kraus, United States Patent 3,915,151 issued October 28, 1975. There is a coil, 10, (see Figure 1) which can be supplied with symmetrical AC at 50 Hz or 60 Hz (see column 2, lines 42 to 56) and some means to restrict the field strength to 200 gauss (column 3 line 21). Phrases such as "for treating malignant cells" are thus seen to be merely an intention in the mind of the writer while the Kraus apparatus, of itself, would fall within the scope of claims 13-15. This consideration is by no means new grounds for the rejection of the application as the Kraus patent was cited in the previous action of December 31, 1991.
>
> Incidentally, claim 16 is additionally objectionable for at least two more reasons. A method of operating cannot define an apparatus (formally, claim 16 does not add an additional characteristic to claims 13 or 14 as required by Rule 24) and the claim is indefinite contrary to Section 34(2) of the Patent Act.

The Kraus patent discloses an apparatus for creating a magnetic field for promoting healing processes. The apparatus comprises a coil adapted to be applied to the affected body part. The coil is connected to a source for a varying AC current with a low frequency for causing the coil to produce a corresponding magnetic field which pervades the part of the body to be treated. The frequency of the AC of the coil current is adjustable and lies in the range of 1 to 100 Hz. The amplitudes of the AC current are adjustable to vary the energy content of the magnetic field. The magnetic field strength in body tissue lies between 20 and 200 Gauss. For the treatment of deeper regions or parts of

the body substantially higher field strength may be applied. Figure 1, shown below, is a diagrammatic representation of an apparatus in accordance with a first embodiment of the invention, which it is stated is especially suitable for treating extremities of the human body.

Figure 1



The figure shows cylindrical coil 10 which can be slid over the extremity, for example leg 12, to be treated. On the inner wall of coil 10, on opposite sides, two electrodes 14 are arranged. Coil 10 and electrodes 14 are connected respectively with wires 16 leading to electrical function generator 18 which supplies a current for coil 10 and a voltage for electrodes 14.

In his response dated March 4, 1992 to the Final Action the Applicant requested that claims 1 to 16 be replaced by claims 1 to 6, essentially deleting method of medical treatment claims 1 to 12 and method of operating an apparatus claim 16 and amending apparatus claims 13 to 15. In his response the Applicant recognized that method of medical treatment claims are unpatentable in Canada in view of his statement that:

> ".....the Claims in their present US format method form, are not only non-statutory (as the Examiner states), but also specifically prohibited by Canadian Statute Law just as they were under UK law which similarly prohibits patents for medical treatment methods."

Subsequent to his first response to the Final Action the Applicant also made several further submissions, each time requesting, among other things, that the claims of the application be changed. Thus in his brief to the Board attached to the letter dated May 5, 1992 the Applicant requested that claims 1 to 4 be entered into the application, in his letter dated August 30, 1992 that claims 1 to 6 be entered and in his letter dated February 22, 1993 that different claims 1 to 6 be entered. A supplement to Applicant's brief to the Board dated April 29, 1993 provided details of the Applicant's issued U.K. patent 2,217,990 with a copy of the allowed claims and the Board notes, as mentioned in Applicant's letter of February 22, 1993, that the latest set of claims are identical to those claims allowed in the U.K.

The question before the Board is therefore whether or not the claims, with the exception of claim 6 which is in a form considered unpatentable in Canada, submitted with the letter of February 22, 1993 are patentable over the Krause prior art. The claims in question are as follows:

> 1. Apparatus for treating malignant cells in living tissue, comprising; a toroidal shaped air core demagnetizing coil connected to a low frequency sinusoidal energizing source to generate substantially spheroid shaped alternating magnetic field patterns, positioned to encompass and irradiate a malignant cell volume with a said field flux density of between 50 to 550 RMS (average) gauss.
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> 2. Apparatus as in claim 1; with a said field flux range of 150 to 250 said gauss throughout the said malignancy cell volume area.
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> 3. Apparatus as claimed in claim 1; wherein a plurality of said toroidal shaped coils are adjacently oriented, substantially parallel to each other to function with electromagnetic equivalence to a continuous-space occupying cylindrical walled coil, with said toroidal shaped coils operating as parts of said cylindrical walled coil to produce readily changeable magnetic field patterns to accommodate large, deep, multiple and/or elongated malignant cell volumes.
>
> 4. Apparatus as in claim 3 wherein; said coils of said plurality have individual power input terminals, which results in multi-point power inputs.
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> 5. Apparatus for treating malignant cells in living tissue comprising; a demagnetizing magnetic field coil, connected to a continuous duty sinusoidal energizing source, with said field coil containing a ferro-magnetic core to concentrate, compress and selectively direct the magnetic field to encompass and irradiate a malignant cell volume within its shallow effective range with a field flux density of between 50 and 550 RMS (average) gauss.
>
> 6. Apparatus for treating malignant cells substantially as described herein with reference to Figures 1 to 8 of the accompanying drawing.

In his submission dated August 30, 1992 the Applicant after pointing out the dominant features of closely similar claims stated that:

> In summary form covering 3 Kraus prior art patents, it should be stated that all Kraus embodiments generate long longitudinal fields, with the field axis always positioned parallel to the blood vessels. He derives novelty by use of conventional solenoid coils in combination with metal sheets to generate electric fields. This then severely limits his continuous duty magnetic field strengths because these metal sheets would act as short-circuited turns in the secondary winding of a transformer and the power dissipation and eddy current effect would cause a thermal runaway and companion self destruct state, thus he is limited to low repetition rate, pulse type waveforms. Therefore these embodiments cannot meet my apparatus continuous duty field power requirements. His other embodiments use "odd-ball" wiring and "turn configurations" such as serpentine flat windings from end to end on a cylindrical wall structure. Always, there is a tangible, space occupying, cylinder solid wall structure.
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> In claim 1, the toroidal shaped air core demagnetizing coil (partially defined in paragraph 2) [of Applicant's amendment] having substantially a "point" axis, will therefore when properly energized, generate a spheroid shaped magnetic pattern. Kraus has no such coils or patterns.

> Claim 3 can readily be appreciated by looking first at Figures 7, then at 8. Note that the individual coils 11 and 11A operate electromagnetically as "halves" of an assimilated continuous cylindrical coil which generates a very uniform elongated magnetic field in the imaginary cylindrical volume between the peripheries of the coils and since the assimilated cylinder wall is not space-occupying because it does not physically exist, we can, therefore, pass the very uniform field, right through the human body, spine and all reaching even bone marrow, with virtually no obstacle insertion loss. Note also, the independent power input terminals 12 and 12A so it does not matter whether the body is fat or thin, just vary the power accordingly. Kraus has nothing capable of this type of application.....
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> ...
>
> The alleged "anticipation" is based on the Examiner's combining "out of context" phrases (wherein Kraus was talking about very low power continuous operation with a sentence in another column (where he was talking about peak power of short duration, at low pulse repetition, human body rates, thus distorting the factual content.....

In examining the Kraus patent the Board agrees with the Applicant's position as stated above that the patent fails to teach apparatus as defined in the amended claims. Since the Board is unable to find Applicant's toroidal coils disclosed in the Kraus patent it is the Board's opinion that claims 1 to 5 are patentable over the cited prior art. Accordingly, the Board recommends both the withdrawal of the Examiner's refusal of the application in view of the citation and the entry of claims 1 to 5 submitted with the letter of February 22, 1993.

In his various submissions subsequent to the Final Action the Applicant has requested that several amendments to the disclosure of the application be made; thus in the letter of March 4, 1992 the following amendments are requested:

Page 1,	Line 1,	delete "METHOD AND"
	Line 6,	delete "a method and"
	Lines 7 & 8,	delete "a method and"
Page 3,	Line 31,	delete "method and"
	Line 35,	delete "method and"
Page 22,	Line 20	delete "spirit and"

In the letter dated August 30, 1992 the following amendments are requested:

Page 11,	Line 13,	after "Such circular coils" and before "provide", please insert, --,each coil essentially being a gathering of concentric insulated wire turns with a few equal and most with slightly varying radii, which become self-supporting when the gathering is held together in a wrapper made of an overlapping spiral of tape, --
	Line 36,	delete "or three" and "as a" after "wired", please insert, --In series, field additive--
Page 12,	Line 1,	delete "cylindrical coil"

Finally in the letter dated February 22, 1993 the following amendment is requested:

Page 4,	Line 14,	at end of paragraph, please insert --The essential features of the apparatus which is provided by the invention are defined in the accompanying claims.--

The Board has considered these amendments and, being satisfied that they introduce no significant new matter to the application, recommends that the requested changes to the disclosure be entered.

The Applicant also requested in his letter dated February 22, 1993 that the drawings presently in the application be replaced by new drawings. Since the Board agrees with the Applicant that the new drawings are much neater and more exact in detail with nothing added or omitted from the original drawings, the Board recommends that the new drawings be entered.

In summary the Board recommends that the Examiner's refusal of the application be reversed, that claims 1 to 5 submitted with the letter dated February 22, 1993 be entered, that the amendments to the disclosure detailed above be entered and that the new drawings submitted with the letter dated February also be entered.

P.J. Davies	E. Maher	M. Howarth
Acting Chairman	Member	Member
Patent Appeal Board	Patent Appeal Board	Patent Appeal Board

I concur with the findings and the recommendations of the Patent Appeal Board. Accordingly I agree that the Examiner's refusal of the application be reversed, that claims 1 to 5 submitted with the letter dated February 22, 1993 be entered, that the amendments to the disclosure detailed above be entered, that the drawings submitted with the letter dated February 22, 1993 also be entered and that the application be returned to the Examiner for further prosecution consistent with these recommendations.

M. Leesti
Commissioner of Patents

Dated at Hull, Quebec
this 23 day of December 1993