Commissioner's Decision

Section 2 Method to accelerate natural cell renewal

The method for improving the capacity of the human body to increase the renewal of skin cells is found to be a method for treating living portions of the body. Rejection affirmed.

This decision deals with Applicant's request for review by the Commissioner of Patents of the Final Action on application 374,547 (Class 167-310) filed April 2, 1981. It is assigned to Lilly (Eli) and Company and is entitled "SKIN CELL RENEWAL REGIME". The inventors are J.A. Cella, M.G. Flom, A.M. Herrold, J.O. Martin, O. Vargas. The Examiner in charge issued a Final Action on February 17, 1983 refusing to allow the application. A Hearing was held on June 17, 1987, at which Applicant was represented by his Patent Agents, Mr. G.E Fisk and Mr. F. Pole.

The application relates to a method to accelerate natural cell renewal by applying to the skin four components: a cleanser, a cream, a lotion, and a tonic.

The Examiner bases his rejection on Section 2 of the Patent Act, and says, in part, as follows:

. . .

> The refusal of all claims is maintained because they are directed to a method of medical treatment which is outside the definition of invention as given in Section 2 of the Patent Act and judicially declared unpatentable by Tennessee Eastman v. Commissioner of Patents (1974) S.C.R. 111.
>
> Applicant's argument is a rejection of the pertinence of the Tennessee Eastman decision on the ground that the instant method claimed is a cosmetic method. See amendment letter of December 8, 1982 on pages 7, 36 and 37.
>
> Applicant's argument is rejected because the instant method claimed has for its objective an increase of skin cell turnover (see preamble of claim 1). As such this method modifies the physical condition of the human body and affects its metabolism. It treats an integral part of the human body, the skin, and is equivalent to a method of medical treatment which may be applied by persons not in the field of medicine.

In the Court decision of Tennessee Eastman Co. v. The Commissioner of Patents (62 C.P.R.) at page 154, the judge gave his reasons for holding methods of treatment unpatentable when he said:

> "In my view the method here does not lay in the field of the manual or productive arts nor, when applied to the human body, does it produce a result in relation to trade, commerce or industry, or a result that is essentially (sic) economic. The adhesive itself may enter into commerce, and the patent for the process, if granted, may also be sold and its use licensed for financial considerations, but it does not follow that the method and its result are related to commerce or are essentially economic in the sense that those expressions have been used in patent case judgments. The method lies essentially in the professional field of surgery and medical treatment of the human body, even although it may be applied by persons not in that field. Consequently, it is my conclusion that in the present state of the patent law of Canada and the scope of subject matter for patent, as indicated by authoritative judgements that I have cited, the method is not an art or process or the improvement of an art or process within the meaning of s. 2(d) of the Patent Act."

. . .

Following the initial response to the Final Action, the Applicant submitted several submissions discussing numerous Canadian Court decisions, as well as foreign jurisprudence dealing with the patentability of medical and non-medical methods of treatment. Amongst several Canadian cases felt by the Applicant to be supportive of the acceptability of the claimed method are Tennessee Eastman Co. v. The Commissioner of Patents (1973) 8 C.P.R. (2d) 202, hereinafter Tennessee Eastman, Burton Parsons Chemical Co. v. Hewlett Packard (Canada) Ltd. 17 C.P.R. (2d) (1975) 97, 7 C.P.R. (2d) (1973) 198 hereinafter Burton Parsons, Imperial Chemical Industries Limited v. The Commissioner of Patents 1 Ex. C.R. (1967) 57, 51 C.P.R. (1967) 102, hereinafter ICI 1967, and Imperial Chemical Industries Limited v. The Commissioner of Patents (1986) 9 C.P.R. (3d) 289, hereinafter ICI.

Included with the submissions are an affidavit by Warren E. Epinette, a doctor of medicine from Stanford Medical School and for many years a part-time dermatology consultant with Elizabeth Arden Inc., and an affidavit by Marguerite Russell-Pavier, a Training Director for facial treatments in the employ of the Red Door Salons of Elizabeth Arden, Inc..

In the Applicant's written submissions, the following statements are made concerning the above Canadian cases:

re Tennessee Eastman -

> ...(the) decision of the Supreme Court of Canada, upon which the Examiner has heavily relied as support for his position, is not considered as especially detrimental to applicants' position, because the Court in the Tennessee Eastman decision was concerned only with patentability of methods of medical or surgical treatment in the strict sense of the term; and there is nothing from that decision which would indicate that the Court intended its ruling to apply to all methods or processes whatsoever in which the human or animal body is, or might be, in some way involved. The present invention is directed to patentable subject matter.
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> ...
>
> ...In applicants' method there is nothing comparable involved: there is no surgical procedure; no professional skills are required; and no deformity, malfunction, or defect of the human body is being corrected thereby,...

re Burton Parsons -

> Thus it will be seen that a compound which is used in a medical context, to carry out a test for the information of physicians, and which is applied to the skin, was not held to be "intended for medicine", because it was not necessarily or mainly used in connection with the treatment of diseases. The present method is not used in connection with the treatment of disease at all, so it is considered that the Burton Parsons case clearly supports applicant's position that it (applicant's method) is patentable.

re ICI 1967 -

> ...In each and every definition, it is inherent and specifically stated that the medicine must have a curative or preventative action, or must in its widest meaning, be part of a therapeutic regimen. None of the definitions give any interpretation of the word "medicine" as broad as that given by the Patent Appeal Board in some of its recent decisions. It is manifestly clear therefore, that Mr. Justice Gibson in deciding that Halothane was a medicine did not broaden the definition of "medicine" in the manner suggested by the Patent Appeal Board, but broadened it only to include any substance which forms part of the therapeutic regimen. Thus, it is submitted that Mr. Justice Gibson in referring to biological agents and to hormones as "medicine" clearly envisages such compounds as taking part in the therapeutic regimen, such as surgical bonding agents as were considered in the Tennessee-Eastman decision.

re ICI -

> ...there was evidence that one main function of the I.C.I. method which was the subject of appeal was the treatment of periodontal disease by removal of dental

> plaque and/or the prevention of caries, both of which could (at least in a broad sense) be considered as the treatment of a disease condition in a part of the human body, viz., the teeth. In contrast, in the present case, there is no evidence that applicants' method has any medical function; in fact the evidence points the other way - that the present method is solely cosmetic in effect. Moreover the Federal Court in the above-discussed I.C.I. Ltd. v. Commissioner decision (at least impliedly) made a clear distinction between a cosmetic function or purpose and a medical function or purpose. It is submitted, then, that the above-discussed Federal Court of Appeal decision in I.C.I. Ltd. v. The Commissioner of Patents is not controlling with respect to the present appeal.

The issue before the Patent Appeal Board is whether or not Applicant's claims for applying various formulations to the skin are directed to a method that is acceptable under Section 2 of the Patent Act.

Section 2 specifies:

> "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;

Claim 1 reads:

> A cosmetic method, whereby the rate of skin cell turnover is increased without causing skin irritation, which method comprises applying to the skin in a regime;
>
> a) a cleanser formulation which comprises, in percent by weight:

Ingredients	Percent
deionized water	39.73
propylene glycol	6.00
magnesium aluminum silicate	1.10
sodium carboxymethyl cellulose	0.10
methyl p-hydroxybenzoate	0.20
imidazolidinyl urea	0.30
ethylenediaminetetraacetic acid	0.02
sodium N-lauryl-β-iminodipropionate	4.00
titanium dioxide	0.75
sodium isostearoyl-2-lactylate	2.00
soya sterols	1.00
polyoxyethylene (10) soya sterols	2.50
polyoxyethylene (3) myristyl ether myristate	8.00
polyoxypropylene (15) stearyl ether	8.00
heavy mineral oil	8.00
propylene glycol dicaprylate/dicarprate (80/20 to 50/50)	7.00
cetyl alcohol (1-hexadecanol)	4.00
stearyl alcohol (1-octadecanol)	2.00
propyl p-hydroxybenzoate	0.10
glyceryl monostearate and polyethylene glycol (100) monostearate	2.00
triple pressed stearic acid	2.50
lactic acid	0.10
fragrance	0.60

b) a cream formulation which comprises, in percent by weight:

Ingredients	Percent
light mineral oil	4.45
polyethylene homopolymer (1500 MW, density 0.91 g/cc)	2.50
undecanoic triglyceride	2.00
squalane	5.00
distilled lanolin alcohol	0.55
white beeswax	1.00
polydimethyl cyclosiloxane	9.00
triglyceryl diisostearate	4.00
isopropyl myristate	5.00
propyl p-hydroxybenzoate	0.10
quaternary bentonite	0.40
deionized water	59.00
methyl p-hydroxybenzoate	0.20
70% sorbitol solution	5.00
imidazolidinyl urea	0.30
urea	0.50
glyoxyldiureide	0.20
DL-pantothenyl alcohol	0.50
cis-1-(3-chloroallyl)-3,5,7-triaza-1 azoniaadamantane chloride	0.10
fragrance	0.20

c) a lotion formulation which comprises, in percent by weight:

Ingredients	Percent
deionized water	69.35
xanthan gum	0.15
propylene glycol	5.00
polyoxyethylene (30) stearate	1.70
methyl p-hydroxybenzoate	0.20
imidazolidinyl urea	0.30
polyphenylmethylsiloxane	3.00
polyethylene homopolymer (1500 MW, density 0.91 g/cc)	1.00
glyceryl monostearate, neutral non-emulsifying	2.00
propyl p-hydroxybenzoate	0.20
sorbitan monostearate	2.00
ethylene glycol monostearate	1.00
lanolin oil	2.50
isopropyl myristate	3.00
squalane	8.50
fragrance	0.10

and

d) a tonic formulation which comprises, in percent by weight:

Ingredients	Percent
deionized water	80.12
polyethylene and polypropylene glycol	2.00
glyoxyldiureide	0.20
polyethylene glycol (300)	9.00
imidazolidinyl urea	0.40
denatured alcohol	7.00
methyl p-hydroxybenzoate	0.10
propyl p-hydroxybenzoate	0.05
polyoxyethylene (60) sorbitan fatty acid ester	0.30
polyoxyethylene (10) oleyl ether	0.50
menthol	0.03
fragrance	0.30

Mr. Fisk argues that nowhere in the application is there any description of a medical treatment. He draws attention to pages 1 and 14 thereof, saying the Applicant's invention is a skin cell renewal cosmetic regime to increase the rate of skin cell turnover without skin irritation.

Mr. Fisk points to Dr. Epinette's affidavit in which it says the method is not to treat any disease. Mr. Fisk notes that Ms. Russell-Pavier's affidavit identifies the method is practiced as the Elizabeth Arden Millenium Method Face Treatment by beauty specialists for a fee. It relates the commercial success of the treatment by Elizabeth Arden, and Mr. Fisk reasons the Applicant's method is a commercial method.

Of concern to the Board is the meaning of the term "rate of skin cell turnover without causing skin irritation" as used in the application in order to have new cells in the outer skin layer. Mr. Fisk comments that dead cells are continually being released from the skin during the natural renewal cycle. He suspects that by removing the outer layer of dead cells more quickly the body reacts and encourages the growth of new skin tissue. In this way, he suggests the body works harder to replace the dead cells.

In our view, the application does not provide a description of the reaction that occurs. For example, there is no information given that describes how the components provide the cell renewal process and prevent skin irritation. We recall, however, from pages 1 and 14 of the application, that the invention is aimed at acceleration of natural cell renewal in order to speed up the replacement of new cells to increase the rate of cell turnover. On neither of these pages, nor elsewhere, do we find a disclosure of what occurs when the components are applied to the skin. The purpose of applying the various products set out in the Applicant's method is to increase or accelerate natural cell renewal. This indicates to us that the Applicant intends that the method actually does accelerate new skin cell growth. Indeed, the Applicant submits a table of tests made and relies on the results shown therein as proof that the rate of new cell growth has, in fact, been accelerated. Such proof, in our opinion, points not to a cosmetic method, but to a treatment of living portions of the human body.

We refer to Tennessee Eastman page 204, and to the passage by Kerr J. which the ICI case considered was reproduced with approval, as follows:

> In my view the method here does not lay in the field of manual or productive arts nor, when applied to the human body, does it produce a result in relation to trade, commerce or industry or a result that is essentially economic. The adhesive itself may enter into commerce, and the patent for the process, if granted, may also be sold and its use licensed for financial considerations, but it does not follow that the method and its result are related to commerce or are essentially economic in the sense that those expressions have been used in patent case judgments. The method lies essentially in the professional field of surgery and medical treatment of the human body, even although it may be applied at times by persons not in that field. Consequently, it is my conclusion that in the present state of the patent law of Canada and the scope of subject-matter for patent, as indicated by authoritative judgments that I have cited, the method is not an art or process or an improvement of an art or process within the meaning of s. 2(d) of the Patent Act.

In Tennessee Eastman the subject matter related to the use of a substance to adhere living tissue together during a surgical treatment. Here, the Applicant teaches the use of several substances for application to the skin to accelerate the rate of natural cell renewal.

We look now to the Australian Case discussed at the Hearing, Joos v. The Commissioner of Patents (1973) R.P.C. No. 3, p. 65. In Joos, the subject matter involves the treatment of keratinous material, such as hair and nails, of a human, such material being inanimate matter, not living matter, as the Court observed on page 63:

> Those who apply chemical preparations to the skin to prevent sunburn in climates which enjoy sunshine and moderate air temperatures can scarcely be regarded either as, in a relevant sense, treating their bodies or as undergoing treatment. On the other hand, the application to the skin of an ointment designed and effective to remove keratoses from the skin would be an instance of medical treatment. To be treatment, in the relevant sense, it seems to me that the purpose of the application to the body whether a substance or a process must be the arrest or cure of a disease or diseased condition or the correction of some malfunction or the amelioration of some incapacity or disability.
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> and on page 66:

> In my opinion, if it be accepted that process claims for medical treatment of human disease, malfunction, disability or incapacity of the human body or of any part of it cannot satisfy the requirements of an invention under the Act, the class of such claims should be narrowly defined. I can find no warrant in public policy or in the decided cases for including in that class processes and methods for improving, or at any rate for changing, the appearance of the human body or of parts of it. Such cosmetic processes and methods are, in my opinion, not of a like kind with medical prophylactic or therapeutic processes or methods.
>
> There may, of course, be many borderline instances of processes for use upon the human body or parts of it in respect of which a decision as to whether the process constitutes medical treatment or not may prove difficult. But I do not have here such a borderline case. The process with which I am presently concerned with is clearly not a method of treatment of a disease, malfunction, disability or incapacity of the human body or of any part of it. In fact, it does not purport to deal with living tissue of the body; the hair to which the solution is to be applied being dead, though its attachment to the body is by or through the follicles which may be regarded as part of the living tissue. The process here is clearly cosmetic, in high contradistinction to a prophylactic or therapeutic medical process. In my opinion, it does not fall within the class of medical treatment which, for the purposes of this case, may be taken to be an inappropriate subject to the grant of letters patent. As I have mentioned earlier, I am not concerned in this case to discover and express a basis for excepting such a class of process claims. If I had to do so, as at present advised, I would place the exception, if it is to be maintained, on public policy as being, in the language of the Statute of Monopolies, "generally inconvenient", not limiting what may fall within those words to things of a like kind to those described by the preceding words. Thus, after due consideration, I have reached the conclusion that it cannot properly be said that the appellant's application cannot be granted simply because its claims are for a process for application to the human body. They are not, in my opinion, claims for a manner or method of medical treatment of the human body within the narrow exception to patentability to which I have referred.

We note that keratinous material may contain keratin, a principal constituent of epidermis, hair, and nails.

In Joos, the treatment of dead parts of the body, namely the hair, was held to be a cosmetic treatment, after considering whether it resided in the category of a method of treatment of disease, malfunction, disability or incapacity of the human body. Here, we feel that an objection made on the ground that the process is to be applied to the human body, is not supportable solely for that reason. In this case, however, we are instructed by

the application and the submissions both written and oral that the desired result is to accelerate the rate of new cell renewal. This invention is different from that in Joos where the invention was to improve the appearance of inanimate portions of the body, for example the hair. The Applicant here proposes to accelerate the new growth of cells. It is explained that the old cells will be displaced more quickly when there is an accelerated rate of growth of new cells. Nowhere do we find, however, that the Applicant has described any treatment to be performed on the dead cells that may be compared in any way to treating the human hair to obtain a difference in its texture. Applicant's method is to increase the rate of natural cell renewal without irritating the skin or causing damage thereto.

We are persuaded that the Applicant's method is for improving the capacity of the body to renew skin cells at an increased rate so that they may surface sooner. We are informed by the information in the application that all the new products identified therein are intended to improve the rate of renewal of new cells. In our opinion, the Applicant's method purports to deal with living tissue and is designed to improve the capacity of the body by treating it to produce new cells at an improved rate. We believe the method is directed to more than performing a cosmetic treatment such as waving hair. We find nowhere that the dead cells are massaged or acted on to change their appearance. They are merely pushed off.

We are unable to find any patentable invention in view of Section 2 of the Act. We obtain direction from Mr. Justice Kerr's passage above in Tennessee-Eastman which we believe was not discredited by the Supreme Court. In our opinion, this passage indicates that a method of treatment that may be likened to a medical treatment of living tissues, as we so find the Applicant's method, may be applied at times by persons that may or may not be in the medical field. We consider the Applicant's method is not merely an application of a substance to the human body, such as was determined in the case of applying a dye to a tooth solely for identification purposes. We regard the Applicant's method to be in the same category of subject matter as that in the ICI case, in that there is an intent for the method to improve the function or health of a particular

living part of the body, not merely to add cosmetic improvement even though that condition may be present. From the ICI case therefore, we learn that if a medical treatment and a cosmetic treatment occur together as a result of the substance used, no patent may issue for either treatment.

Subsequent to the Hearing the Applicant submitted an affidavit from Patricia Warrick, accompanied by Exhibits A, C and D. Ms. Warrick was responsible for testing to determine the mechanism by which the skin cell renewal regime acts to increase epidermal cell turnover. She states " ... it was determined that the mechanism by which the regime operates is to enhance epidermal cell turnover by removal of the outer layer of the stratum corneum ... by detaching dead cells from the outer surface of the skin and removing them. The body then functions in its normal way to rebuild the stratum corneum by generating more cells which die and form a layer of the stratum corneum." In support of her conclusions, Ms. Warrick's affidavit refers to Exhibit A in which John A. Cella, Vice President of Elizabeth Arden Inc. describes skin cell renewal. Mr. Cella states that

> "The above studies demonstrate that Millenium causes the skin's cell renewal rate to accelerate and, in so doing, causes it to function younger since the renewal rate of younger skin is faster."

Further, he states that "this study clearly demonstrates that the skin cells produced during the use of the millenium regime are of better quality and appearance".

We note that, Exhibit A, by stating that the skin cell renewal is accelerated, does not support Ms. Warrick's views' that the method relates to separation of dead tissue from the body. We are unable therefore to attribute any weight to the Warrick affidavit, since Mr. Cella's statements describe cell renewal rate which in our view deals with living tissue function.

In summary, we find that the Applicant's claims, although phrased in terms of a cosmetic method, are directed to a method for treating living portions of the human body to obtain skin cell renewal.

We recommend that the refusal of the claims be affirmed for being directed to unpatentable subject matter.

M.G. Brown
Acting Chairman
Patent Appeal Board

S.D. Kot
Member

I concur with the findings and recommendation of the Patent Appeal Board. I am satisfied this application is not directed to statutory subject matter. Accordingly, I refuse to grant a patent under Section 42 of the Act. The Applicant has six months within which to appeal my decision, under Section 44 of the Act.

J.H.A. Gariépy
Commissioner of Patents

dated at Hull, Quebec
this 20 day of April 1988

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