BEFORE THE CONTROLLER OF PATENTS
THE PATENT OFFICE, DELHI

THE PATENTS ACT 1970
(Section 15)

In the matter of patent application No. 1565/DELNP/2004 dated 4th June, 2004

Hearing Date : 12/01/2012
Present: For Applicant : Ms. Arpita Kulshrestha of Anand and Anand, registered Patent Agent

D E C I S I O N

An application for a patent bearing number 1565/DELNP/2004 was filed in Patent Office; Delhi on 04/06/2004 entitled " METHOD FOR HAIR REMOVAL". A request for examination under Section 11-B was filed on 04/10/2006 and was assigned a Request No. 8044/RQ-DEL/2006. As per the provision under Section 11-A of Patents Act, the said application was published on 17/08/2007.

The said application was examined under Section 12 and 13 of Patents Act and First Examination Report (henceforth referred to as FER) containing a statement of objections was forwarded on 15/09/2009 and the applicant's agent filed response to FER on 23/08/2010 vide their letter with reference no. 12909(P-1)

As per the provisions under Section 13 (3) of Patents Act, the said amended case after reply to FER, was again examined and investigated in like manner as the original specification and the applicant was offered a hearing on 12/01/2012 vide official letter dated 08/12/2011 by the then Controller and hearing held on the scheduled date. The statement of objections which were to be discussed during hearing and be complied consequently are as follows:

1. **Claims 5-17 define a plurality of Distinct inventions.**

2. **Claims 11-17 relate to an invention Distinct from the rest.**

3. **Claims 1-17 fall within the scope of such clause of section 3(i) of the Patent Act, 1970, as the subject matter of the said claims relate to method of treatment of human beings/animals and are not allowable.**

4. **Claims 5-17 are inconsistent and beyond the scope of claim 1.**

5. **1. Claim 1 is not supported by complete specification in view of the term non-therapeutic.**

   2. Claim 1 defines the use of Composition, whereas only one compound is mentioned in claim 1, the other ingredient is not given in claim1

6. **Title of invention in application form-1 and complete specification should be consistent with principal claim and opening para of description**

7. **Details regarding application for Patents which may be filed outside India from time to time for the same or substantially the same invention should be furnished within Six months from the date of filing of the said application under clause(b) of sub section(1) of secton 8 and rule 12(1) of Indian Patent Act.**

8. **Details regarding the search and/or examination report including claims of the application allowed, as referred to in Rule 12(3) of the Patent Rule, 2003, in respect of same or substantially the same invention filed in all the major Patent offices such as USPTO,EPO and JPO etc., along with appropriate translation where applicable, should be submitted within a period of Six months from the date of receipt of this communication as provided under section 8(2) of the Indian Patents Act.**

The applicant submitted the following on 12/01/2012 with respect to the said hearing-

We thank you for your hearing notice dated 8th December 2011 in respect of the Afore mentioned patent application. ·
Our humble submissions to the objections raised by the Learned Controller are as follows:

Paras 1 and 2
With regard to the Learned Controller's objection, we humbly submit that claim 5 is an optional feature involving administration of an agent reducing the PpIX level in the epidermis of the mammal and hence not distinct. Claims 6 to 17 being dependent on claim are consequently also not distinct.

Para 3
Claims 1-17 do not fall within the scope of Section 3(i) of the Patents Act. Section 3(i) prohibits

the grant of patent to *"any process for the medicinal, curative, prophylactic [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products'*

In ***Joos v. Commissioner of Patent*** **(1973) RPC 59,** it was held that "Treatment" in relevant senses means that the purpose of application of a process or substance to the body must be to arrest or cure of a disease or diseased condition or correcting some malfunction or amelioration of some incapacity or disability.

The method of hair removal does not amount to being a "TREATMENT" as the same does not result in curing a disease.

Thus, the present invention nowhere falls within the ambit of section 3(i) as the same does not qualify as being a method of treatment but rather is a more directed to a mere method for removal of hair not involving any kind of medical treatment.

In light of the aforesaid submissions we request the Learned Controller to kindly waive the objection raised.

The applicant further submitted the following on 24/01/2012 specifically with respect to PARA 3 of section 3(i) objection with respect to the said hearing-

Para 3

With regard to the Learned Controller's objection that claims 1-17 fall within the scope of section 3(i) our humble submissions are as follows:

Advantages of the present invention over prior art

In the prior art there are innumerable methods for hair removal. However, all such methods suffer from the following drawbacks:

a. inadequate and must be used on a regular basis;
b. Provoke adverse skin reactions by damaging tissues surrounding hair follicles

The method of the present invention has the following advantages:

a. Not time consuming;
b. Results in long lasting and more permanent hair removal
c. Removes hair selectively without damaging nearby skin tissues and produces no side effects

<u>Technology</u>

The present invention provides a non-therapeutic method of removing hair from an area of skin of a mammal. Said method includes the following steps

Administering topically a composition to a skin area comprising a compound of formula I

being an ester derivative of 5-amino-4-oxo-pentanoic acid:

R_2R_3N- CH_2COCH_2- CH_2COOR
I

Wherein R is Rn-R_1, wherein Rn represents a polyalkylene glycol chain of formula II

$-[-Rpi - O-]_n-$
II

Wherein pi represents n integers and n is an integer from 1 to 50, Rpi is an alkyl of pi carbon atoms, and wherein R1, R_2, R_3 each separately represent H, or an unsubstituted alkyl
or a substituted alkyl, wherein substituents are selected from aryl, acyl, halo, hydroxyl, amino, amonoalkyl, alkoxy, acylamino, thioamino, acyloxy, aryloxy, aryloxyalkyl, mercapto, thio, azo, oxo or fluoroalkyl groups, saturated and non-saturated cyclohydrocarbons and heterocyles, or
Represent an alkyl chain interrupted by oxygen, nitrogen, sulfur, or phosphor atoms, or an alkoxycarbonyloxy, alkoxycarbonylalkyl or methane group, and
Irradiating said skin area thereafter with a light irradiation, within a time interval of between 5 minutes and 10 hours, after beginning of said administration

The present invention provides a method of hair removal which is quite selective in that it simultaneously

a. Minimizes the PpiX level in the epidermis
b. Obtaining an efficient level of PpiX in the pilo-sebaceous apparatus,
both simultaneously a the moment of light irradiation

Section 3(i)

Section 3(i) of the Patents Act prohibits the grant of patent to *"any process for the medicinal surgical curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products'*

In order to fall within the ambit of section 3(i) the invention must satisfy the following conditions

1. It should be a process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings, or
2. process for a similar treatment of animals to render them free of disease or
3. to increase their economic value or that of their products

Not a medical teatment

It is submitted that the present invention is not a method of treatment in view of the following case laws:

In ***Joos v. Commissioner of Patent*** **(1973) RPC 59,** wherein the patent application was directed to a process for improving strength and elasticity of keratinous material, it was held

that "Treatment" in relevant senses means that the purpose of application of a process or substance to the body must be to arrest or cure a disease or diseased condition or correcting some malfunction or amelioration of some incapacity or disability.

The method of the present invention being a method of hair removal does not result in the curation of a disease or diseased condition or correcting some malfunction or amelioration of some incapacity or disability.

In ***General Hospital Corp/Hair removal method T 383/03 (2005) OJEOPO 159,*** it was held that methods which were neither clearly suitable nor potentially suitable for maintaining or restoring the health, the physical integrity or the physical well being of human beings or animals fell outside the exclusion in Article 53(c) EPC 2000.

Article 53(c) of the EPC states as follows:

"European patents shall not be granted in respect of ..... methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body, this provision shall not apply to products_, in particular substances or compositions, for use in any of these methods. "

In the *General Hospital* decision, the Technical Board of Appeal held that surgical treatment is that which aims at curing. On this basis, it was held that methods which were 'neither clearly suitable nor potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well being of human beings or animals' fell outside the exclusion in Article 53(c) EPC 2000. The TBA held that patent protection should be available for surgical methods that do not relate to or are not suitable for the well being of human beings or animals. Consequently, the TBA accepted that "a claimed method is patentable only if it is clearly not potentially suitable for maintaining or restoring the health, the physical integrity and the physical well being of a human being or an animal."

The claimed method in the above decision was hair removal by optical radiation. The TBA noted that while excess hair may be a disease, the 'excess hair is itself not harmful and its removal does not treat the underlying causes of the unwanted hair.' It further noted that it was not relevant to the physical health of the treated person, the treatment merely results in an aesthetic improvement in the appearance of the person'. The claim was therefore, a quintessential cosmetic method which was aimed primarily at improving the aesthetic appearance of the individual treated rather than cure the underlying malady. It also noted that the 'underlying medical condition of itself is not a sufficient ground for classifying the method as a method of medical treatment. In any event, the TBA concluded that although the claimed method involved a non-insignificant intentional physical intervention which was to be regarded as a surgical operation, it was 'clearly neither suitable nor potentially suitable for maintaining or restoring the health, physical integrity or physical well being of the individual'. Such a method 'is not to be considered as falling under the exclusion of protection foreseen in Article 52(4) The claimed method in the instant decision was hair removal by optical radiation. The Technical Board of Appeal in the above case noted that the method was not relevant to the physical health of the treated person and hence was not excluded from patent protection.

The method of hair removal of the instant application therefore does not amount to being a "TREATMENT" as the same does not result in curing a disease. Further, said method is not relevant to the physical health of the subject. Accordingly, the method of the present invention does not qualify to be a method of treatment as defined by section 3(i).

No enhancement of economic value

As stated above, the conventional methods for hair removal are known in the past. All of said methods resulted in removal of hair. The method of the present invention is a cosmetic method resulting in improvement of the appearance of the skin. However, said method does not result in enhancement of economic value of the subject as compared to the conventional methods.

In light of the above submissions it is humbly submitted that the method of claims 1-17 does not fall within the ambit of section 3(i) as the same does not qualify as being a method of treatment but rather is directed to a mere method for removal of hair not involving any kind of medical treatment. Accordingly, we request the Learned Controller to kindly waive the objection raised.

Para 4
We have complied with this requirement.

Para 5
We are enclosing herewith a copy of petition under rule 137 (filed on 11th January 2012) for correction of irregularity in submitting details of corresponding foreign patent applications vide Form 3 dated 22nd March 2010.
In light of our above submission we request the Learned Controller to kindly allow the application to proceed in order for grant.

With respect to the amendments done therein and submissions made therein and after duly verifying the said documents as referred therein the Controller is satisfied that the instant application comply with the requirements of the Act as per the objections raised with respect to the hearing notice, and hence I hereby proceed with the instant application for grant along with 17 claims.

Dated :17/03/2017

(Dr. Sunita Rani)
Assistant Controller of Patents & Designs.

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