

TRANSLATION

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 05/109-21	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/RU2006/000385	International filing date (<i>day/month/year</i>) 19.07.2006	Priority date (<i>day/month/year</i>) 20.07.2005
International Patent Classification (IPC) or national classification and IPC A61H39/00, A61H39/04, A61H39/08		
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1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of _____ sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. (*sent to the applicant and to the International Bureau*) a total of _____ sheets, as follows:

sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/RU	Authorized officer
Facsimile No.	Telephone No.

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Box No. I	Basis of the report
1.	<p>With regard to the language, this report is based on:</p> <p><input checked="" type="checkbox"/> the international application in the language in which it was filed</p> <p><input type="checkbox"/> the translation of the international application into _____, which is the language of a translation furnished for the purposes of:</p> <p><input type="checkbox"/> international search (Rule 12.3(a) and 23.1(b))</p> <p><input type="checkbox"/> publication of the international application (Rule 12.4(a))</p> <p><input type="checkbox"/> international preliminary examination (Rule 55.2(a) and/or 55.3(a))</p> <p>2. With regard to the elements of the international application, this report is based on (<i>replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report</i>):</p> <p><input checked="" type="checkbox"/> the international application as originally filed/furnished</p> <p><input type="checkbox"/> the description:</p> <p>pages _____ as originally filed/furnished</p> <p>pages* _____ received by this Authority on _____</p> <p>pages* _____ received by this Authority on _____</p> <p><input type="checkbox"/> the claims:</p> <p>nos. _____ as originally filed/furnished</p> <p>nos.* _____ as amended (together with any statement) under Article 19</p> <p>nos.* _____ received by this Authority on _____</p> <p>nos.* _____ received by this Authority on _____</p> <p><input type="checkbox"/> the drawings:</p> <p>sheets _____ as originally filed/furnished</p> <p>sheets* _____ received by this Authority on _____</p> <p>sheets* _____ received by this Authority on _____</p> <p><input type="checkbox"/> a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.</p> <p>3. <input type="checkbox"/> The amendments have resulted in the cancellation of:</p> <p><input type="checkbox"/> the description, pages _____</p> <p><input type="checkbox"/> the claims, nos. _____</p> <p><input type="checkbox"/> the drawings, sheets/figs _____</p> <p><input type="checkbox"/> the sequence listing (<i>specify</i>): _____</p> <p><input type="checkbox"/> any table(s) related to sequence listing (<i>specify</i>): _____</p> <p>4. <input type="checkbox"/> This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).</p> <p><input type="checkbox"/> the description, pages _____</p> <p><input type="checkbox"/> the claims, nos. _____</p> <p><input type="checkbox"/> the drawings, sheets/figs _____</p> <p><input type="checkbox"/> the sequence listing (<i>specify</i>): _____</p> <p><input type="checkbox"/> any table(s) related to sequence listing (<i>specify</i>): _____</p>
<p>* If item 4 applies, some or all of those sheets may be marked "superseded."</p>	

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1.	Statement		
	Novelty (N)	Claim <u>2, 6, 13-75</u>	YES
		Claim <u>1, 3-5, 7-12</u>	NO
	Inventive step (IS)	Claim <u>21-29</u>	YES
		Claim <u>2, 6, 13-20, 30-75</u>	NO
	Industrial applicability (IA)	Claim <u>1-75</u>	YES
		Claim _____	NO
2.	Citations and explanations (Rule 70.7)		
	<p>The preliminary report was drafted taking into consideration the following documents:</p> <p>D1: RU 2233149, C1 (MUHINA M.M.), 27.07.2003.</p> <p>D2: RU 2176496, C1 (POKATILOV I.O.), 10.12.2001</p> <p>D3: RU 2003107817, A (MUHINA M.M.), 10.12.2004</p> <p>D4: RU 22120060, (GOU VPO SANKT-PETERBURGSKAYA GOSUDARSTVENNAYA PEDIATRITCHESKAYA MEDITSINSKAYA AKADEMIA), 10.09.2001</p> <p>D5: SU 1680177, A1 (KRUGLIAK Л.И.), 30.09.1991</p> <p>D6: SU 1264942, A1 (SHARONIN V.G. et al.), 23.10.1986</p> <p>D7: RU 92000824, A (KUZNETSOV I.I.), 27.07.1996</p> <p>D8: RU 93052109, A (KORSAK A.N.), 20.09.1996</p> <p>D9: RU 2195917, C2 (LIAPKO N.G.), 10.01.2003</p> <p>D10: RU 26402 U1, 10.12.2002</p> <p>D11: Ukrashenia dlia pirsinga, 2004 [Found on the Internet 07.12.2005 on the site http://www.mixtura.ru]</p> <p>D12: SU 1296164 A1, 15.03.1987</p> <p>D13: US 4195492 A, 01.04.1980</p> <p>D14: Spravochnik. Statia «Shtanga», 03.05.2005. [Found in internet 07.12.2005 on a site</p>		

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<http://www.piercing.ru>

D15: SU 1335286 A1, 07.09.1987

D16: RU 2018300 C1, 30.08.1994

D17: SU 952252 A, 23.08.1982

D18: RU 2145834 C1, 27.02.2000

D19: EP 0271775 A2, 22.06.1988

D20: SU 1804764 A1, 30.03.1993

D21: SOONG Y. S. «The treatment of exogenous obesity employing auricular acupuncture», Am J Chin Med (Gard Cit N Y). 1975 Jul; 3(3):285-7.

D1 discloses a method which is used for prolonging an action on acupuncture points and for reducing excessive body weight and consists in introducing a needle, one end of which is rounded, into one of the acupuncture points AP17 or AP18, in passing said needle under the skin, in extracting the free end thereof from the other point and, afterwards, in securing the needle by means of a clip. The method makes it possible to simultaneously act on two points with one needle. The securing of the needle with a clip produces a prolonged action resulting from the weight of the rounded end of the needle and the weight of the clip. The massaging of said points, including the use of pressure techniques, enhances the effect consisting of the local effect obtained by the action performed on said points and of a general action due to the link thereof with the central sections of the nervous system, and allows a patient to become accustomed to the action of the microneedles. The securing of the micro-needles at the above-mentioned points for a long period of time provides the required rate for reducing excessive body weight with the aid of the weight of the clip and by modifying the surface of

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the contact thereof with the points during the massage. The method provides the required rate for reducing excessive body weight by means of a progradient correlation of the intensity of the action produced on said points when using said a pressure massage technique. The application of micro-needles with no adhesive tape makes it possible, without complications, to increase the time of action of auricular acupuncture, and the linking of two auricular points by means of one needle makes it possible to enhance the blocking of a hunger centre and to normalise (conditioning) the food reflex, taking into consideration the personality traits of a patient.

Since D1 discloses a method in which all the features contained in independent claim of the claimed invention are intrinsic, including the feature of use, claim 1 does not meet the requirement of novelty.

Some features of claim 2, namely the fact that the progradient correlation of the intensity of the action, which is performed on auricular points for correcting excessive body weight, is carried out by means of finger pressure, are known from D1. With regard to the remaining features of dependent claim 2, namely relating to the action performed on auricular points by means of an electropulse and/or sound and/or photo and/or micro- or short-wave stimulation, it should be stated that the method for producing an action on acupuncture points for correcting excessive body weight is very well known to a person skilled in the art.

In line with the above, claim 2 does not meet the requirement of inventive step.

The features of dependent claims 3-5 and 7-12 are known from D1 (application, description, pp. 6 and 7).

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Consequently, said claims 3-5 and 7-12 do not meet the requirement of novelty.

D2 (application) specifies that the enhancement of the action produced on the points for reducing excessive body weight without removing needles from the ear cavity is obtained out by introducing another needle into the other ear cavity, i.e. it repeats the features of dependent claim 6.

Thus, claim 6 does not meet the requirement of inventive step.

D10 is the prior art closest to the claimed device for acupuncture reflexotherapy according to claims 13-20, 21-29, 30-43, 44-49, 60-67 and 68-75.

The device disclosed in D10 comprises an acupuncture element which is made of gold and is embodied in the form of a smooth stem provided with a ring-shaped handle (head), the free end of which is connectable to a three-dimensional detachable clamp (clip) having a height of 1.5 mm (claim 1, fig. 1).

The claimed devices according to independent claims 13, 21 and 30 differ from the device disclosed in D10 in that they comprise the three-dimensional or plate head of the stem and a flat clip.

Consequently, the claimed devices according to claims 13-29 and 30-43 meet the requirement of novelty.

However, D11 discloses devices provided with a plate-like and/or three-dimensional head and with a plate-like or ring-shaped clip, thereby making it possible to obtain the same technical result expressed in the extended range of the claimed devices.

Thus, the combination of documents D10 and D11 destroys inventive step of the device according to claim

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13.

With regard to dependent claims 14-20, they also do not meet the requirement of inventive step, since the features of claims 14-17 are known from D11 (pp. 1 and 2), the features of claim 18 are known from D13 (application, fig. 1), the features of claim 19 are known from D14 (p. 1) and the features of claim 20 are known from D15 (application).

The device claimed in independent claim 21, apart from the characterising features known from D11, differs from the closest prior art (D10) in that the detachable clip is ring-shaped and at least one pendent provided with a weight is removably fastened to the stem head and/or to a cap piece.

In spite of the fact that D13 discloses a piercing device which comprises a pendent provided with a weight which makes it possible to perform a pendulum swing and affects only the aesthetic look of the piercing device, the claimed technical result, which consists in producing an additional action on acupuncture points, thereby enhancing the obtained treatment effect by weighting the article, is not known and not obvious from the prior art. Consequently, the claimed device according to claims 21-29 meets the requirement of inventive step.

Apart from the characterising features known from D11, the device claimed in claim 30 differs from the closest prior art (D10) in that the stem length is equal to or greater than 5 mm, the stem diameter is equal to or greater than 0.08 mm, the height of the clip is at least 0.15 mm and the needle mass is equal to or greater than 0.01 g.

D10 discloses a stem the length of which is 10 mm

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and the diameter of which is 0.6 mm, that is at least 5 mm and at least 0.08 mm, respectively, and the height of the clamp (clip) is 1.5 mm, that is equal to or greater than 0.15 mm. Thus, the intervals of the parameters, which lie within the range of the claimed parameters, are known from D10. The remaining values of the claimed parameters, the fact that they are experimentally obtained and are optimal for enhancing the effectiveness of the reduction of excessive body weight, and that the mass of a needle is selected according to and depends on the selected type (size) of the head, on the clip and the stem and also on the material of the device, which are important for reducing excessive body weight, are obvious for a person skilled in the art.

Therefore, independent claim 30 does not meet the requirement of inventive step.

Dependent claims 31-35 and 38-41 also do not meet the requirement of inventive step, since the features of claims 31-33 are known from D11 (pp. 1 and 2), the features of claims 35 and 39 are known from D12 (application, figs. 3 and 4), the features of claim 34 are known from D13 (application, fig. 1), the features of claim 40 are known from D14 (p. 1), the features of claim 41 are known from D15 (application), the features of claim 38 are known from D16 (application, figs. 1-3) and the features of claim 43 are known from D10 (application).

With respect to the features of claims 36 and 37, the expert notes that, since the application does not disclose how to introduce needles, the stem of which is provided with ring-shaped projections or consists of polyhedrons, and does not show how the unexpected result

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is obtained in comparison to the known embodiments of a stem, claims 36 and 37 also do not meet the requirement of inventive step.

Relating to dependent claim 42, the expert notes that the application does not disclose the feature which is referred to by the applicant as "the head is connected to the detachable clip by means of a link", wherein, for example said link can be embodied in the form of the stem known from D10. In line with the above, claim 42 also do not meet the requirement of inventive step.

The features of dependent claims 36 and 37 are not found in the prior art and are not obvious and, therefore they meet the requirement of inventive step.

The device claimed in independent claim 44 differs from the device disclosed in D10 in that it comprises an acupressure element embodied in the form of a plate or a three-dimensional body which, directly or through a joining element, are secured to one end of a stem or detachably connected to the other end thereof.

However, D17 discloses a device for ear acupuncture which comprises a needle, two spring branches and a support ring embodied therebetween (application, fig.1). Such an embodiment of the device makes it possible to increase the reliability of the device attachment to the patient's body. D18 discloses an acupressure element which is embodied in the form of a plate (application) and makes it possible to enhance the treatment effect by means of a close contact with points exposed to the action.

Thus, claim 44 does not meet the requirement of inventive step.

The features of dependent claims 45-49 also do not

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meet the requirement of inventive step, since the features of claims 45 and 46 are known from D18 (application), the features of claim 47 are known from D12 (application, figs. 3 and 4), the features of claim 48 are known from D20 (application, figs 1-2) and the features of claim 49 are known from D17.

D3 is the prior art closest to the claimed method according to claim 50 and discloses a method for carrying out a prolonged action produced on acupuncture points, consisting in topographically defining acupuncture points, one of which is defined as a needle-inserting point and the other is defined as an extraction point, and in puncturing said points by stringing them on the same needle. The needle is made of a material which is biologically neutral with respect to the patient, is secured by a clip and remains at the point during the time required for therapy.

Claim 50 differs from D3 in that one or two end segments of the needle are bent in such a way that a clip or pins are formed therefrom.

However, the securing of a needle which, being inserted, forms a clip with the end thereof is known from D4.

Consequently, the claimed invention according to claim 50 does not meet the requirement of inventive step.

The selection of points AP 17 or AP 18 in the form of acupuncture points in the ear cavity, i.e. the features of dependent claim 51, is known from D1.

The formation of a clip by winding a needle end about the free segment thereof, i.e. the features of dependent claim 52, wherein the needle end is wound in such a way that at least one coil is obtained, i.e. the

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features of dependent claim 53, is known from D5 (application, column 3).

The features of claim 54 are known from D3 (abstract), the features of claims 55 and 57 are known from D6 (application), the features of claims 56 and 57 are known from D7 (abstract) and the features of claims 57-59 are known from D8 (abstract).

The technical result is obtainable by the known properties resulting from the use of needles provided with clips for the prolonging action.

In line with the above, claims 51-59 do not meet the requirement of inventive step.

The device claimed in claims 60 and 68 differs from the device known from D10 in that the entire stem or the free end/(end segments) thereof are made of a material exhibiting mouldable properties which make it possible to form a clip/clips from a bent end /(end segments).

However, D4 does not disclose the embodiment of a clip by bending the free ends/(end segments) of a needle for providing a stable securement (description, p. 12). The features "the embodiment of the entire stem or the free end/(end segments) thereof of a material exhibiting mouldable properties" are known from D10, wherein gold and silver are selected as materials exhibiting said mouldable properties.

It is worthwhile to note that the increase of the number of clips and the end sectors, respectively, enhances only the technical result which consists in increasing the reliability of the device attachment.

Therefore, the combination of D10 and D4 destroys the inventive step of independent claims 60 and 68.

Since the features of dependent claims 63, 65, 71

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and 73 are known from D9 (application, claim 1), the features of claims 64 and 72 are known from D19 (application, claim 1), the features of claims 67 and 75 are known from D8 (abstract), claims 63-65, 67, 71-73 and 75 do not meet the requirement of inventive step.

With respect to dependent claims 61, 62, 69 and 70, for a person skilled in the art it is obvious that the embodiment of the clip/clips in the form of a bent end thereof wound about a stem or in the form of a coil also enhances the technical result, namely increases the reliability of a device holding. Consequently, claims 61, 62, 69 and 70 do not meet the requirement of inventive step.

The features included by the applicant in dependent claims 61, 62, 66, 69, 70 and 74 are not found in the prior art and therefore, said claims meet the requirement of inventive step.

Claims 1-75 are industrially applicable.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

There are some observations relating to the clarity of the application, description and drawings or to whether the invention is fully based on the description.

The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and claims shall be fully supported by the description (the PCT Regulations, Articles 5 and 6). The claimed application has been drafted without taking said requirements into consideration. For example, none of the uses claimed in claims 1-73 are supported in the description, i.e. there is no information or examples proving that a use has been implemented. The text of the application repeated in the description does not prove that the invention can be implemented.