IN OR OUT

METHOD OF TREATMENT

A Patent Perspective

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Medical diagnosis and treatment is an extremely challenging and interesting field, attracting people since inception of human civilization. As of now, millions of medical tools have been developed to diagnose and treat diseases, but simultaneous evolution of humans and virulent life and non-life forms have repeatedly pushed our intellectual acumen and focuses towards finding novel and improved method of treatment.

Since method of treatment directly involves interference with human/animal life, the lawmaker has taken special precaution to prevent exclusivity over the commercial use of these inventions. Except USA, Australia and New Zealand, the method of treatment is excluded from patent protection. Section 3(i) of the Indian Patent Act, 1970 contains the exclusion of method of treatment from patent protection. Section 3(i) of the Indian Patent Act, 1970 reads as:

However, the Indian Patent Act, 1970 does not preventthe products involved in treatment from getting patented, be they pharmaceuticals or medical devices such as scalpels, staplers, surgical sutures, stents, reagents, and diagnostic kits.

"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."

The Section 3(i) of the Patent Act, 1970 represents an exclusion clause and applies on "method for treatment of the human or animal body by surgery or therapy or medicinally and diagnostic and therapeutic method practiced on the human or animal body to render them free of disease or to increase their economic value or that of their products".

1. METHOD FOR TREATMENT BY SURGERY MEANS:

a) Methods for surgical treatment (such as incision, excision, centesis, injection and implant);
b) Methods of using, inserting, maneuvering, maintaining, operating and extracting a medical device (viz. Catheter, endoscope etc.) inside the human body (excluding inside all natural body orifices);
c) Preparatory treatment for surgery (viz. anesthetic administration for surgery and method of disinfecting skin before injection/incision);
d) Cosmetic methods involving surgical procedures which are not therapeutic or diagnostic are also considered as "methods for treatment of the human body by surgery practiced on the human body."

2. METHOD FOR TREATMENT BY THERAPY MEANS:

a) Methods of administrating medicine or providing physical treatment to a patient for cure or control of disease;
b) Methods of implanting a medical device or organ transplant such as artificial internal organs or artificial limbs;
c) Methods of preventing a disease (viz. methods of preventing tooth decay or influenza);
d) Methods of treatment for the maintenance of physical health (viz. methods of massage or Yoga or Pranayaam) are also considered to be methods of preventing a disease;
e) Preparatory treatment for therapy (viz. method for arranging electrodes for the electrical therapy), supplemental methods for improving treatment effects (viz. rehabilitation methods), or methods for nursing associated with the treatment (viz. methods to prevent bedsores).

3. METHOD FOR TREATMENT BY CURATIVE AND PROPHYLACTIC MEANS:

Therapy relates to the treatment of a disease in general or to a curative treatment as well as the alleviation of the symptoms of pain and suffering. It is established in a case law that a prophylactic treatment, aimed at maintaining health by preventing ill effects that would otherwise arise, amounts to a method for treatment by therapy.

Both prophylactic and curative methods of treating disease are covered by the word "therapy," since both are directed to the maintenance or restoration of health.

4. METHOD FOR TREATMENT BY MEDICINAL MEANS:

a) Methods of administration of different forms [viz. film, tablet, capsule, syrup, injection) of drugs for the treatment of a patient;
b) Methods of dosing drugs at definite time interval for curing or restraining a disease;
c) Methods of mixing two or more forms of drug for the treatment of a patient;
d) Doses form of a drug;

5. DIAGNOSTIC METHOD MEANS:

a) Methods of determination (excluding determination by a device) for the medical purpose of the physical condition of a human body such as diseases and physical health, the mental condition of a human body, or prescription or treatment/ surgery plans based on these conditions.

b) Methods of determination whether the patient has had any complication by observing the test result or imaging.

WHAT IS OUT [NON PATENTABLE]

1. A method for treating an affected part during operation is considered as "method for treatment."
2. A method for sampling body fluid is considered as "method for treatment."
3. A method of imaging of the internal body part using an endoscope is considered as "method for treatment".
4. A method for gene therapy is considered as "method for treatment".
5. A method for the treatment of cancer or diabetes is considered as "method for treatment".
6. A method for regenerating blood cells is considered as "method for treatment".
7. A method for giving electrical stimulus by a pacemaker.
8. A method for retinal stimulation using an artificial eye system.
9. A method for X-ray irradiation.
10. A method for blood purification.
11. A method for measuring hematocrit values of blood.
12. Treatment of sheep for increasing wool.
13. A method for cultivation of algae or farming mushroom.

INTERPRETATION ON PATENTABILITY

The Section 3(i) of the Patent Act, 1970 does not include any product for the medical, surgical, curative, prophylactic, diagnostic, and therapeutic use for the treatment of human or animal body. Therefore, patent law includes medico-physical devices for use in therapy and surgery, as well as to pharmaceuticals and diagnostic kits. When such devices are novel, their patentability is generally not affected by the prohibition on patenting method of treatment. The device and pharmaceuticals can normally be claimed as such, using a standard product claim format.

WHAT IS IN [PATENTABLE]

1. A medical device or a medicinal substance is a product, and is not considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human or animal body".
2. A method for controlling the operation of a medical device is not considered to be classified as "methods for treatment".
3. Measuring structures and functions of the various organs of the human body, is not considered to be diagnostic methods practiced on the human body.
4. Methods of extracting samples and data from the human body, or methods of analyzing. e.g., comparing such samples and data with standards.
5. Preparatory treatment for measuring structures or functions of various organs of the human body.
6. Diagnostic kits or ELISA kits for sampling and identifying disease.
7. Methods for treating samples that have been extracted from the human body.
8. A method for manufacturing a medicinal product (e.g., blood preparation, vaccine, genetically modified preparation) by utilizing raw material collected from a human being.
9. A method for manufacturing a medical material (e.g., an artificial substitute or alternative for a part of the human body, such as an artificial bone, a cultured skin sheet, etc.) by utilizing raw material collected from a human being.
10. A method of manufacturing an intermediate product for a medicinal product or a medical material (e.g. methods for differentiation and induction of the cells, methods for separation and purification of the cells) by utilizing raw material collected from a human being.
11. A method of analyzing a medicinal product or a medical material, or intermediate product thereof which is manufactured by utilizing raw material collected from a human being.

IN AND OUT [LANGUAGE OF CLAIMS]

Many a times the construction of claims decides the fate of IN andOUT for patent protection. The claim part is the heart of a patent. Therefore, every word counts and decides the patentability of disclosed invention. This will be more clarified with the help of few examples:

EXAMPLE: 1

A method for the treatment of cancer in a patient comprising administering to said patient an effective amount of siramesine or a pharmaceutically acceptable salt thereof, wherein the cancer is selected from the group consisting of fibrosarcoma, breast cancer, neuroblastoma, prostate cancer and cervical cancer.

(An invention considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body")

The method is to administration of an effective amount of an anticancer agent in cancer patient for treatment and falls under "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body."

A pharmaceutical composition comprising siramesine or a pharmaceutically acceptable salt thereof for the treatment of cancer in a patient, wherein the cancer is selected from the group consisting of fibrosarcoma, breast cancer, neuroblastoma, prostate cancer and cervical cancer.

(An invention not considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body")

The claimed treatment of cancer is an invention of a pharmaceutical composition comprising siramesine or a pharmaceutically acceptable salt thereof; hence it is a product invention. Therefore, it is not considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body."

EXAMPLE: 2

A method of detecting the presence of a regeneration initiation cell in a sample comprising: a) isolating low density mononuclear cells from the sample; b) transplanting the low density mononuclear cells into a recipient animal with tissue or organ damage; and c) determining whether or not the transplanted cells engraft the damage tissue or organ, wherein engraftment of the damaged tissue or organ indicates the presence ofregeneration initiation cells in the sample.

(An invention considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body")

The claimed invention is a method for detecting the presence of a regeneration initiation cell into a recipient animal with tissue or organ damage and thus a method for treatment of the human body by therapy. Also the claimed invention is a method to transplant transplanting the low density mononuclear cells into the body and thus a method for treatment of the human body by surgery. Therefore, the claimed invention is a "method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body."

A pharmaceutical composition for treating or preventing pancreatic damage comprising regeneration initiating cells in admixture with a pharmaceutically acceptable diluent, excipient or carrier, wherein the regeneration initiating cells are present in an effective amount to treat or prevent pancreatic damage.

(An invention not considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body")

As the regeneration initiating cells for treatment of damage pancreatic cells described in the claim itself is a product, it does not fall under "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body."

Disclaimer: The exclusion from 'diagnostic, therapeutic and surgical methods for the treatment cannot be avoided merely by drafting claims that omit one or more of the steps of such method. Those steps are in fact essential essence for properly carrying out the invention and must be disclosed in the specification.

IN AND OUT [JURISDICTIONS]

Patent is a territorial in nature. Therefore, same or substantially same invention must be filed in different jurisdictions to secure the patent right. However, it is seldom strategized during the construction of claims according to the different jurisdictions and different laws. It should be noted that the Method of treatment clause is not ubiquitous in nature. Therefore, construction of claims can be modified/amended/included while entering into a particular jurisdiction. The status of method of treatment clause is listed below:

JURISDICTION	CLAUSE	STATUS
INDIA	SECTION 3(I)	NOT ALLOWED
EUROPIAN UNION	ARTICLE 53(C)& 52(4)	NOT ALLOWED
USA	CLASS 128, 239, 897 & 899	ALLOWED
JAPAN	ARTICLE 29(1)	NOT ALLOWED
CHINA	ARTICLE 25.1(3)	NOT ALLOWED
EGYPT	ARTICLE 2	NOT ALLOWED
KOREA	ARTICLE 32	NOT ALLOWED
NEW ZEALAND	SECTION 2(1)	ALLOWED FOR NON HUMAN
PAKISTAN	SECTION 7(4)(C)	NOT ALLOWED
SOUTH AFRICA	SECTION 25(A)	NOT ALLOWED
THAILAND	SECTION 9(4)	NOT ALLOWED
AUSTRLIA	SECTION 18(1)(A)	ALLOWED
CANADA	SECTION 2	NOT ALLOWED
SINGAPORE	SECTION 16(2)(2)	NOT ALLOWED

Article 27(3)(a) of the TRIPS Agreement permits members to exclude 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' from patentability. By virtue of this, almost every member country except US, Australia and New Zealand has excluded the methods for treatment from patentability scope.

IN AND OUT [PATENT OFFICE DECISION]

Article 53(c) EPC and the Manual of Indian Patent Practice and Procedure specify a number of exceptions to patentability in the field of 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'.An independent claim must include all the essential features needed to define the invention. If the application as originally filed makes it clear that a method is the essential essence of the invention, the same cannot be accepted by the patent office merely by amending the claims that omit one or more steps of such method claim.

In decision 3044/CHENP/2006, the claims as originally filed were directed to treatingwarts with tellurium compounds. The Applicant amended the claims to include pharmaceutical composition during the examination phase. However, the essence of invention did not describe that any tellurium-containing compound [product claimed] is able to treat the huge variety of diseases claimed. The Patent office did not allow this invention on the basis of 2(1)(j), 3(e) and 3(i).

In decision 7831/DELNP/2006, the claims filed were directed a combination composition containing Ibuprofen and Paracetamol (known drug). The controller noted that the fixing of doses for treatment of patient are treated as a method of treatment under section 3(i) of the Act and it is part of medical practitioner prerogative since it is his assessment of the patient's age, state of condition ,health etc. by which practitioner decides quantum and frequency of doses. Therefore, dosage claims here falls under the method claim which is not allowed under section 3(i) of the Act.

In Decision T74/93 the Board had to decide whether a claim directed to the use of a contraceptive composition for applying to the cervix of a female mammal capable of conception is excluded from patentability by Article 52(4) EPC. The Board noted that methods of contraception are not excluded per se from patentability as stipulated in Article 52(4), first sentence, EPC, since pregnancy is not an illness and therefore its prevention is not a general therapy according to Article 52(4) EPC.

Some diagnostic methods incorporate procedures that involve an invasive interaction with the human body, for example taking a blood sample or administration by injection. The Enlarged Board indicated in their decision G1/07 that invasive method steps representing a substantial physical intervention on the body which require professional medical expertise to be carried out and which entail a health risk, even when carried out using such expertise, will be excluded from patentability under Article 53(c) EPC as being surgical steps.

In decision T 383/03 the board indicated that if a method involving a physical intervention on the human or animal body (treatment by surgery) is clearly neither suitable nor potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well-being of the person or animal, then the method does not fall under the exclusion from patentability provided for in Article 52(4) EPC.

IN AND OUT [UNDER SECTION 3(i)]

In 2013, the Indian Patent Office has decided, a total of 1695 patent cases. Out of these 62% were granted, and 34% were refused. Under section 3(i), 42 patent applications have been scrutinized. Out of these 31 were granted and 11 were rejected.

GRANTED

IN/PCT/2002/00573/MUM	1901/MUMNP/2009	3336/CHENP/2006	893/CAL/1998
228/MUMNP/2010	5934/DELNP/2005	5707/DELNP/2006	290/DELNP/2006
558/MUMNP/2007	696/KOL/2007	2520/CHENP/2004	5289/DELNP/2006
1393/MUMNP/2009	7765/DELNP/2007	72/CHE/2007	3411/DELNP/2006
2053/MUMNP/2008	5536/DELNP/2006	4608/CHENP/2006	3341/DELNP/2006
3102/DELNP/2007	670/DEL/2004	2246/DELNP/2007	4678/CHENP/2006
6774/DELNP/2006	1011/MUM/2008	1906/MUMNP/2007	4401/CHENP/2006
488/CHE/2007	1504/CHE/2005	7641/DELNP/2006	

REFUSED

3824/DELNP/2004	2582/DELNP/2006	314/KOL/2006	2335/DEL/2005
1521/MUMNP/2006	1193/DELNP/2003	7831/DELNP/2006	1729/KOLNP/2005
1537/KOLNP/2006	3371/KOLNP/2007	3044/CHENP/2006	

Since patent is a territorial right, the decision of refusal or grant is purely based on the territorial law and their practices. However, territorial patent practices within the purview of specific clause play a major role while deciding the refusal or grant of a patent. In this scenario, it is possible that same patent [family patent] may not be refused or granted in other jurisdiction having the similar clauses.

IN AND OUT [FAMILY PATENT]

APPLICATION NO.	REFUSED	GRANTED
314/KOL/2006	India	China
2335/DEL/2005	India	EPO, UK
2582/DELNP/2006	India	Australia, Europe, New Zealand, Korea, Mexico
1193/DELNP/2003	India, Russia	EPO, Korea`
7831/DELNP/2006	India	EPO, UK, Korea, Canada, Australia
1537/KOLNP/2006	India	EPO, Korea, Australia, Canada
3371/KOLNP/2007	India	EPO, US, Australia, Canada, Mexico

Many a times, refusal and grant depends on the interpretation of language of claims by the Patent Examiners or Agents. To avoid this situation, if a claimed process does constitute a method claim, it is always advisable to draft a use-limited product claim directed to a known substance or composition for use in the specified diagnostic method. It is further noticeable fact that maximum percentage of refused patent applications filed in India or EPO claiming priority from US applications. Therefore, it gives an indication that proper opinion has not been given by the Attorneys to the Client regarding non patentability subject matter of the invention.

There is a large number of further case law concerning the patentability of inventions in the medical field. The discussed cases reflect the author's personal opinions of highly relevant case law which should be taken into account when drafting a patent application in the medical field. As the discussion shows, although methods of treatment of the living animal and human body are excluded from patent protection, there is a fairly large repertoire of options for getting useful patent protection in this important field.

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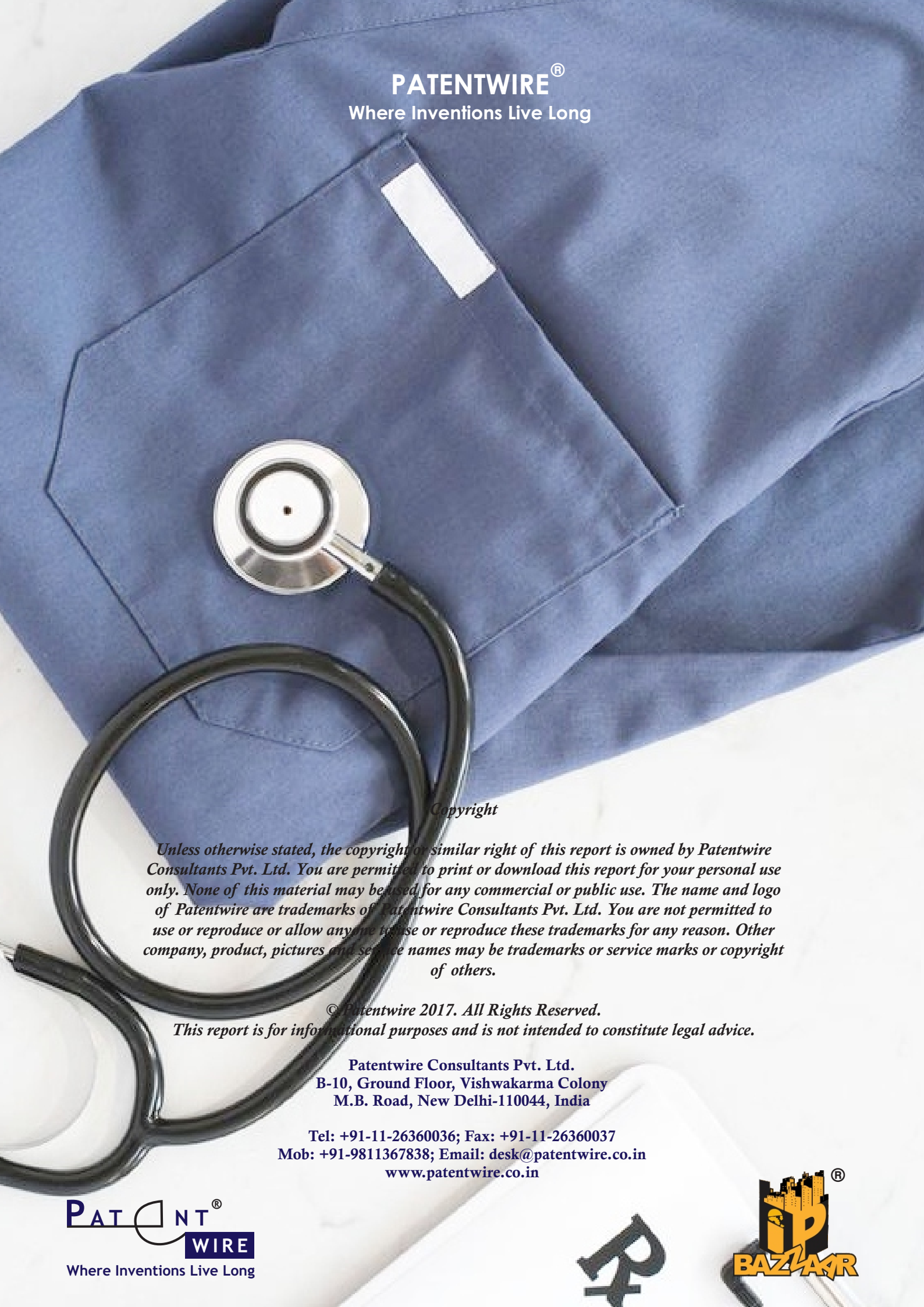

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