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PATENT AS INTELLECTUAL PROPERTY RIGHTS

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INTRODUCTION:

Intellectual property primarily entails the products and services of mental creations, as well as some time-limited rights to control how those works are used.

The primary difference between intellectual property and other types of property is that intellectual property is intangible. It can't be defined or identified by its own physical parameters, hence it needs to be protected in some way.

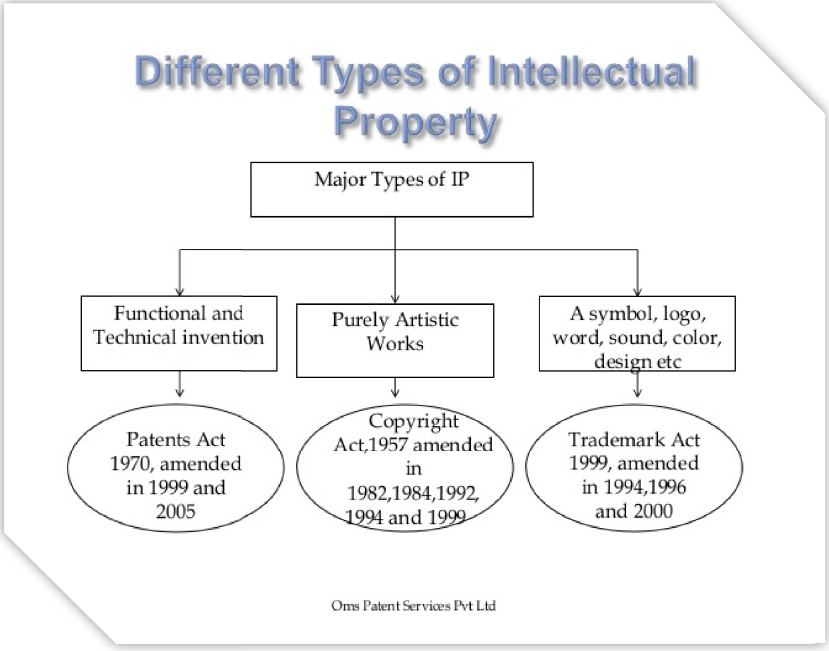
Intellectual property refers to property that is generated with the use of one's intellect, as well as the legal rights that are granted to such property. [IPRs]. The state grants IPR to encourage innovation, invention, and investment. IPR laws strive to protect intellectual property innovators and producers by granting them time-limited rights. IPR is separated into two categories.

1. Industrial property
2. Copyrights

- INDUSTRIAL PROPERTY: direct relation to the industry
  - INVENTON [PATENT]
  - TRADEMARKS [GOODS & SERVICES]
  - INDUSTRIAL DESIGN

- COPYRIGHTS:
  - Although these rights have no direct connection to the direct industry, this does not restrict copyrights from being employed in industries. several Printing, film, and software are examples.

TYPES OF INTELLECTUAL PROPERTY RIGHTS:



ACTS GOVERNING BY VARIOUS IPRs

1. Patents
The patent act 1970Amended by various Act units the patent (amended) Act 2005.
2. Trademark / or service mark
Trade & merchandise act 1958 the trademark act, 1999.
3. Copy right including computer program right the copy right act, 1957Amendment in 1999 with effect from 15.01.2000.
4. Geographical indication Geographical indication of good (registration & protection) act 1999.
5. Industrial designs the industrial designs act, 2000.
6. Semiconductor and layout design &Semiconductor integral circuit's layout designs.
7. Plant varieties right: The protection of plant varieties and farmer right act 2001.
8. Biological Diversity Act, 2002.

- Ranitidine is sold by Glaxo in India at Rs. 7.20. The same product is sold by the same company in Pakistan at Rs. 65 and in the U.S.A. at Rs. 545.
- Similarly, the anti-viral drug Acyclovir costs Rs. 33.75 in India while the same drug is sold in Pakistan at Rs. 363.

PATENTS

A patent is an exclusive right granted by the government to the applicant for a fixed time of inventions (20 years). A patent is an exclusive right granted to the owner of an invention to use, manufacture, and market the invention as long as the innovation meets specific legal requirements.It is a written document that provides the government with limited protection for a patent or inventor's creation. As a result, the issuance of a patent confers on it the power to exclude others.

During the duration of a patent, others are prohibited from making, selling, using, offering to sell, or importing his or her invention within the United States. A patent is a piece of intellectual property that can be licenced or sold like any other. When a patent expires, the innovation becomes public domain, which means that anybody can use it or modify it without the permission of the original inventor.

Patent information is very beneficial to small and medium-sized businesses. For a variety of reasons, patent information is beneficial to SMEs. The most crucial of these is that patents are the only source of technical information that SMEs may use to plan their businesses. When a patent is released, most inventions are revealed to the public for the first time. As a result, patents allow people to learn about current technology, research, and innovations long before new products hit the market. Patent documents provide technical information that can provide SME with valuable insights that can be used to improve their business:

- To save money by not spending money on research that is already known.
- Identify and evaluate technology for licensing and technology transfer
- Identify alternative technologies
- Know the latest technologies in desired field of expertise
- Find ready solutions to technical problems
- Get ideas for further innovation

From the point of view of the commercial strategy of the enterprise, patent information would help to:

- Locate business partners
- Locate suppliers and materials
- Monitor activities of real and potential competitors
- Identify new markets

Finally, the information contained in patent documents could also be used by SMEs to:

- Avoid possible infringement problems
- Assess patentability of your own inventions
- Oppose grant of patents wherever they conflict with your own patent

Patents that have expired are a good source of information. Because after a patent has expired or lapsed, anyone can use the invention.

It is past time for people to recognise the value of patent information. This information can help small and medium-sized businesses with product development, research, and development.

Why one should go for getting a patent?

- ✓ In all market economies, patents are extremely important because they provide required legal protection for newly invented products and processes. The underlying purpose of a patent is to ensure that the inventor receives an economic return for the time and money spent developing a new product. Assume that if someone puts his or her innovation on the market without obtaining a patent, anyone can replicate it and profit from it.A patentee must obtain a patent in order to prevent others from commercially exploiting the idea. In the case of medicines, it takes around 4000 crores of rupees and 12 to 14 years of persistent effort to design a new molecule from start. The stakes are also extremely high.
- ✓ The pharmaceutical sector relies heavily on research. Humans can't live without their hearts, and the pharmaceutical industry can't live without research either. Patent protection is the only weapon that will encourage businesses to invest in research and development of novel chemicals and goods.

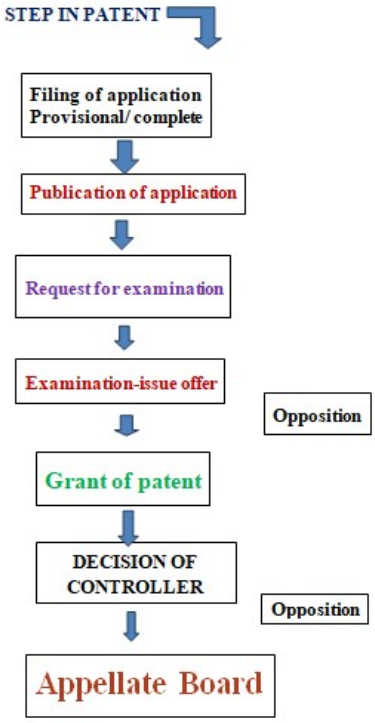
- ✓ Pharmaceutical company files patent for new drug at the time of submitting IND (Investigational New Drug) application. It means after successful completion of pre-clinical tests patent application is filed. Patent life which is now 20 years starts from the date of filing. Pharmaceutical companies spend over 8 to 10 years in performing clinical studies and to prove efficacy of the new drug by generating huge clinical studies database which is submitted to regulatory authorities in form of NDA (New Drug Application). NDAis an application filed by Innovator Company requesting regulatory authorities to grant permission to commercialize the new drug. Regulatory authorities take 2 to 3-year time for NDA clearance and granting permission to launch new drug in the market. By the time new drug enters the market, it already consumes a patent life of average 12 years. Hence the effective time available with the clinical investigations. The life of a patent, which is presently 20 years, begins on the day of filing.to recover the investments on new drug discovery and development research and to make profits is only eight years. Patent protection gives assurance of return on investment and hope for making good profits to some extent to the innovator company. If there is no effective patent protection law in place, then no pharmaceutical company will get engage in discovering and developing new drugs.

An invention is patentable only when it fulfills the criteria of
1) Novelty
2) Non-obviousness and
3) Usefulness Types of Patent:
Normally, there is a difference established between product-related inventions and process-related inventions. For example, a 'product invention' comprises of a new drug, whereas a 'process invention' consists of a new method or procedure for creating an unknown or new medicament. The matching patents are commonly referred to as a 'product patent' and a 'process patent.'.

Patents can be classified as:

- ✓ UTILITY PATENT
- ✓ DESIGN PATENT
- ✓ PLANT PATENT

- ✓ **Utility Patent** - This is the most significant form of patent, as it pertains to the invention's functionality. This type of patent is highly sought after and necessitates a high level of ability in both drafting and prosecuting the application before a Patent Office. The invention's functional utility is safeguarded.
- ✓ 2. **Design Patent** - This sort of patent is given to the invention's decorative or exterior look. It is not possible to register a design for a Design Patent if it is functionally necessary. The aerodynamic shape of a plane, for example, cannot be registered as a design patent because the shape is critical to the smooth operation of the innovation.
- ✓ 3. **Plant Patent** - Plant variations created through asexual reproduction of plant varieties are granted this sort of patent.



A PATENT CONTAINS FOLLOWING THINGS:

✓ (A) Title of the invention this is the description of the invention by the inventor himself.

✓ (B) Cross-reference to related applications, if there are any invention which are found to be closely related to the subject matter under application for grant of Patent.

✓ (C) Background of the invention, this is very important part of an invention as it helps the patent examiner to ascertain what was the prevailing problem in the particular state of the art, which led to the invention.

✓ (D) Specification it includes abstract, description, drawings and claims.

✓ (E) Abstract this is brief description of the invention and should not exceed more than 150 words according to Patent Rules, 2003.

✓ (F) Claim(s) this is a techno-legal part of the Patent and hence most important part, as claims define the scope of invention. It is a unilateral statement made by inventor in his own words to set boundaries for his patent.

✓ (G) Drawings are integral part that gives a visual description of the invention and often required by the Comptroller.

✓ (H) Description of the invention sought to be protected is an important perquisite of grant of Patent. There is no hard and fast rule as to what a description should contain but it should contain as much information as would require a person skilled in prior art to make that invention as directed.

FOLLOWING ARE NOT PATENTED ACCORDING TO PATENT ACT 1970

The following are not Inventions within the meaning of this Act,

1. An invention which is frivolous or which claims anything obviously contrary to well established natural laws;
2. An invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;
3. The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;
4. The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

- *Explanation.* —For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

5. A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
6. The mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;
7. (Omitted)
8. A method of agriculture or horticulture;
9. 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.
10. Plants and animals in whole or any part thereof other than micro organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;
11. A mathematical or business method or a computer programmer or algorithms;
12. A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;
13. A mere scheme or rule or method of performing mental act or method of playing game;
14. A presentation of information;
15. Topography of integrated circuits;
16. An invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

✓ Inventions relating to atomic energy not patentable. —No patent shall be granted in respect of an invention relating to atomic energy falling within sub section (1) of section 20 of the Atomic Energy Act, 1962 (33 of 1962).

✓ Inventions where only methods or processes of manufacture patentable: [Omitted by the Patents (Amendment) Act, 2005.

APPLICATIONS FOR PATENTS

FORM OF APPLICATION—

- Every application for a patent shall be for one invention only and shall be made in the prescribed form and filed in the patent office.
- Every international application under the Patent Cooperation Treaty for a patent, as may be filed designating India shall be deemed to be an application under this Act, if a corresponding application has also been filed before the Controller in India.
- The filing date of an application referred to in sub-section and its complete specification processed by the patent office as designated office or elected office shall be the international filing date accorded under the Patent Cooperation Treaty.
- Where the application is made by virtue of an assignment of the right to apply for a patent for the invention, there shall be furnished with the application, or within such period as may be prescribed after the filing of the application, proof of the right to make the application.
- Every application under this section shall state that the applicant is in possession of the invention and shall name the person claiming to be the true and first inventor; and where the person so claiming is not the applicant or one of the applicants, the application shall contain a declaration that the applicant believes the person so named to be the true and first inventor.
- Every such application (not being a convention application or an application filed under the Patent Cooperation Treaty designating India) shall be accompanied by a provisional or a complete specification.

INFORMATION & UNDERTAKING REGARDING FOREIGN APPLICATION.—

Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application or subsequently within the prescribed period as the Controller may allow— (a) a statement setting out detailed particulars of such application; and (b) an undertaking that, up to the date of grant of patent in India, he would keep the Controller informed in writing, from time to time, of detailed particulars as required under clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time. (2) At any time after an application for patent is filed in India and till the grant of a patent or refusal to grant of a patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed.

PROVISIONAL & COMPLETE SPECIFICATION.—

Where an application for a patent (not being a convention application or an application filed under the Patent Cooperation Treaty designating India) is accompanied by a provisional specification, a complete specification shall be filed within twelve months from the date of filing of the application, and if the complete specification is not so filed, the application shall be deemed to be abandoned. (2) Where two or more applications in the name of the same applicant are accompanied by provisional specifications in respect of inventions which are cognate or of which one is a modification of another and the Controller is of opinion that the whole of such inventions are such as to constitute a single invention and may properly be included in one patent, he may allow one complete specification to be filed in respect of all such provisional specifications. Provided that the period of time specified under sub-section (1) shall be reckoned from the date of filing of the earliest provisional specification. (3) Where an application for a patent (not being a convention application or an application filed under the Patent Cooperation Treaty designating India) in. accompanied by a specification purporting to be a complete specification, the Controller may, if the applicant be requests at any time within twelve months from the date of filing of the application, direct that such specification shall be treated, for the purposes of this Act, as a provisional specification and proceed with the application accordingly. (4) Where a complete specification has been filed in pursuance of an application for a patent accompanied by a provisional specification or by a specification treated by virtue of a direction under sub-section (3) as a provisional specification, the Controller may, if the applicant so requests at any time before grant of patent, cancel the provisional specification and post-date the application to the date of filing of the complete specification.

CONTENTS OF SPECIFICATION—

Every specification, whether provisional of complete, shall describe the invention and shall begin with a title sufficiently indicating the subject-matter to which the invention relates. (2) Subject to any rules that may be made in this behalf under this Act, drawings may, and shall, if the Controller so requires, be supplied for the purposes of any specification, whether complete or provisional; and any drawings so supplied shall, unless the Controller otherwise directs be deemed to form part of the specification, and references in this Act to a specification shall be construed accordingly. (3) If, in any particular case, the Controller considers that an application should be further supplemented by a model or sample of anything illustrating the invention or alleged to constitute an invention, such model or sample as he may require shall be furnished before the application is found in order for grant of a patent, but such model or sample shall not be deemed to form part of the specification. (4) Every complete specification shall— (a) fully and particularly describe the invention and its operation or use and the method

PRIORITYDATES OF CLAIM &COMPLETE SPECIFICATION—

There shall be a priority date for each claim of a complete specification. Where a complete specification is filed in pursuance of a single application accompanied by— a provisional specification; or a specification which is treated by virtue of a direction under subsection of section 9 as a provisional specification, and the claim is fairly based on the matter disclosed in the specification referred to in clause or clause the priority date of that claim shall be the date of the filing of the relevant specification. Where the complete specification is filed or proceeded with in pursuance of two or more applications accompanied by such specifications as are mentioned in sub-section and the claim is fairly based on the matter disclosed— in one of those specifications, the priority date of that claim shall be the date of the filing of the application accompanied by that specification; partly in one and partly in another, the priority date of that claim shall be the date of the filing of the application accompanied by the specification of the later date. Where a complete specification based on a previously filed application in India has been filed within twelve months from the date of that application and the claim is fairly based on the matter disclosed in the previously filed application, the priority date of that claim shall be the date of the previously filed application in which the matter was first disclosed.

Where the complete specification has been filed in pursuance of a further application made by virtue of sub-section of section 16 and the claim is fairly based on the matter disclosed in any of the earlier specifications, provisional or complete, as the case may be, the priority date of that claim shall be the date of the filing of that specification in which the Matter was first disclosed. Where, under the foregoing provisions of this section, any claim of a complete specification would, but for the provisions of this sub-section, have two or more priority dates, the priority date of that claim shall be the earlier or earliest of those dates. In any case to which sub-sections (and do not apply, the priority date of a claim shall, subject to the provisions of section 137, be the date of filing of the complete specification. (7)The reference to the date of the filing of the application or of the complete specification in this section shall, in cases where there has been a post-dating under section 9 or section 17 or, as the case may be, an ante-dating under section 16, be a reference to the date as so post-dated or ante-dated. claim in a complete specification of a patent shall not be invalid by reason only of— the publication or use of the invention so far as claimed in that claim on or after the priority date of such claim; or the grant of another patent which claims the invention, so far as claimed in the first mentioned claim, in a claim of the same or a later priority dateMatter was first disclosed. Where, under the foregoing provisions of this section, any claim of a complete specification would, but for the provisions of this sub-section, have two or more priority dates, the priority date of that claim shall be the earlier or earliest of those dates. In any case to which sub-sections does not apply, the priority date of a claim shall, subject to the provisions of section 137, be the date of filing of the complete specification. The reference to the date of the filing of the application or of the complete specification in this section shall, in cases where there has been a post-dating under section 9 or section 17 or, as the case may be, an ante-dating under section 16, be a reference to the date as so post-dated or ante-dated. claim in a complete specification of a patent shall not be invalid by reason only of— the publication or use of the invention so far as claimed in that claim on or after the priority date of such claim; or the grant of another patent which claims the invention, so far as claimed in the first mentioned claim, in a claim of the same or a later priority.

FORM OF PATENT

"FORM 1 THE PATENTS ACT 1970 (39 of 1970) and THE PATENTS RULES, 2003 **APPLICATION FOR GRANT OF PATENT** (See section 7, 54 and 135 and sub-rule (1) of rule 20)	(FOR OFFICE USE ONLY)
Application No.	
Filing date:	
Amount of Fee paid:	
CBR No:	
Signature:	

1. APPLICANT'S REFERENCE / IDENTIFICATION NO. (AS ALLOTTED BY OFFICE)

2. TYPE OF APPLICATION [Please tick (✓) at the appropriate category]

Ordinary ( )		Convention ( )		PCT-NP ( )	
Divisional ( )	Patent of Addition ( )	Divisional ( )	Patent of Addition ( )	Divisional ( )	Patent of Addition ( )

3A. APPLICANT(S)

Name in Full	Nationality	Country of Residence	Address of the

	Applicant
House No.	
Street	
City	
State	
Country	
Pin code	

3B. CATEGORY OF APPLICANT [Please tick (✓) at the appropriate category]		
Natural Person ( )	Other than Natural Person	
Small Entity ( )	Startup ( )	Others ( )

4. INVENTOR(S) [Please tick (✓) at the appropriate category]		
Are all the inventor(s)	Yes ( )	No ( )

PUBLICATION AND EXAMINATION OF APPLICATIONS

(1) Save as otherwise provided, no application for patent shall ordinarily be open to the public for such period as may be prescribed.
(2) The applicant may, in the prescribed manner, request the Controller to publish his application at any time before the expiry of the period prescribed under subsection (1) and subject to the provisions of sub-section (3), the Controller shall publish such application as soon as possible.
(3) Every application for a patent shall, on the expiry of the period specified under sub-section (1), be published, except in cases where the application—
(a) In which secrecy direction is imposed under section 35; or
(b) Has been abandoned under sub-section (1) of section 9; or
(c) Has been withdrawn three months prior to the period specified under sub-section (1).
(4) In case a secrecy direction has been given in respect of an application under section 35, then it shall be published after the expiry of the period prescribed under sub-section (1) or when the secrecy direction has ceased to operate, whichever is later.
(5) The publication, of every application under this section shall include the particulars of the date of application, number of application, name and address of the applicant identifying the application and an abstract.
(6) Upon publication of an application for a patent under this section—
(a) The depository institution shall make the biological material mentioned in the specification available to the public;
(b) The patent office may, on payment of such fee as may be prescribed, make the specification and drawings, if any, of such application available to the public.

REQUEST FOR EXAMINATION.—

(1) No application for a patent shall be examined unless the applicant or any other interested person makes a request in the prescribed manner for such examination within the prescribed period.
(2) Omitted by the *Patents (Amendment) Act,* 2005
(3) In case of an application in respect of a claim for a patent filed under sub-section (2) of section 5 before the 1st day of January, 2005 a request for its examination shall be made in the prescribed manner and within the prescribed period by the applicant or any other interested person.
(4) In case the applicant or any other interested person does not make a request for examination of the application for a patent within the period as specified under subsection (1) or sub-section (3), the application shall be treated as withdrawn by the applicant: Provided that— (i) the applicant may, at any time after filing the application but before the grant of a patent, withdraw the application by making a request in the prescribed manner; and (ii) in a case where secrecy direction has been issued under section 35, the request for examination may be made within the prescribed period from the date of revocation of the secrecy direction.

EXAMINATION OF APPLICATION.—

(1) When a request for examination has been made in respect of an application for a patent in the prescribed manner under sub-section (1) or sub section (3) of section 11B, the application and specification and other documents related thereto shall be referred at the earliest by the Controller to an examiner for making a report to him in respect of the following matters, namely:— (a) whether the application and the specification and other documents relating thereto are in accordance with the requirements of this Act and of any rules made thereunder; (b) whether there is any lawful ground of objection to the grant of the patent under this Act in pursuance of the application; (c) the result of investigations made under section 13; and (d) any other matter which may be prescribed. (2) The examiner to whom the application and the specification and other documents relating thereto are referred under sub-section (1) shall ordinarily make the report to the Controller within such period as may be prescribed.

Search for anticipation by previous publication and by prior claim.—

(1) The examiner to whom an application for a patent is referred under section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification— (a) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India and dated on or after the 1st day of January, 1912; (b) is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date. (2) The examiner shall, in addition, make such investigation for the purpose of ascertaining whether the invention, so far as claimed in any claim of the complete specification, has been anticipated by publication in India or elsewhere in any document other than those mentioned in sub-section (1) before the date of filing of the applicant's complete specification.

OPPOSITION PROCEEDINGS TO GRANT OF PATENTS

Opposition to the patent.—

(1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground— (a) that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims; (b) that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim— (i) in any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912; or (ii) in India or elsewhere, in any other document: Provided that the ground specified in sub-clause (ii) shall not be available where such publication does not constitute an anticipation of the invention by virtue of sub-section (2) or subsection (3) of section 29; (c) that the invention so far as claimed in any claim of the complete specification is claimed in a claim of a complete specification published on or after priority date of the applicant's claim and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the applicant's claim; (d) that the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim. ***Explanation.***—For the purposes of this clause, an invention relating to a process for which a patent is claimed shall be deemed to have been publicly known or publicly used in India before the priority date of the claim if a product made by that process had already been imported into India before that date except where such importation has been for the purpose of reasonable trial or experiment only; (e) that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim; (f) that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act; (g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed; (h) that the applicant has failed to disclose to the Controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge; (i) that in the case of a convention application, the application was not made within twelve months from the date of the first application for protection for the invention made in a convention country by the applicant or a person from whom he derives title; (j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention; (k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere, but on no other ground, and the Controller shall, if requested by such person for being heard, hear him and dispose of such representation in such manner and within

such period as may be prescribed. (2) At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner on any of the following grounds, namely:— (a) that the patentee or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims; (b) that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim— (i) in any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912; or (ii) in India or elsewhere, in any other document: Provided that the ground specified in sub-clause (ii) shall not be available where such publication does not constitute an anticipation of the invention by virtue of sub-section (2) or sub-section (3) of section 29;

GRANT OF PATENTS AND RIGHTS CONFERRED THEREBY

Grant of patents.—

(1) Where an application for a patent has been found to be in order for grant of the patent and either— (a) the application has not been refused by the Controller by virtue of any power vested in him by this Act; or (b) the application has not been found to be in contravention of any of the provisions of this Act, the patent shall be granted as expeditiously as possible to the applicant or, in the case of a joint application, to the applicants jointly, with the seal of the patent office and the date on which the patent is granted shall be entered in the register. (2) On the grant of patent, the Controller shall publish the fact that the patent has been granted and thereupon the application, specification and other documents related thereto shall be open for public inspection.

Amendment of patent granted to deceased applicant.—

Where, at any time after a patent has been granted in pursuance of an application under this Act, the Controller is satisfied that the person to whom the patent was granted had died, or, in the case of a body corporate, had ceased to exist, before the patent was granted, the Controller may amend the patent by substituting for the name of that person the name of the person to whom the patent ought to have been granted, and the patent shall have effect, and shall be deemed always to have had effect, accordingly.

Date of patent.—

(1) Subject to the other provisions contained in this Act, every patent shall be dated as of the date on which the application for patent was filed (2) The date of every patent shall be entered in the register. (3) Notwithstanding anything contained in this section, no suit or other proceeding shall be commenced or prosecuted in respect of an infringement committed before the date of publication of the application.

Form, extent and effect of patent.—

(1) Every patent shall be in the prescribed form and shall have effect throughout India. (2) A patent shall be granted for one invention only: Provided that it shall not be competent for any person in a suit or other proceeding to take any objection to a patent on the ground that it has been granted for more than one invention.

Grant of patents to be subject to certain conditions.—

The grant of a patent under this Act shall be subject to the condition that— (1) any machine, apparatus or other article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made by or on behalf of the Government for the purpose merely of its own use; (2) any process in respect of which the patent is granted may be used by or on behalf of the Government for the purpose merely of its own use; (3) any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils; and (4) in the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette.

Rights of patentees.—

Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee— (a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India; (b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India:

NEW DRUG APPLICATION

The New Drug Application has been used to regulate and oversee new pharmaceuticals in the countries for decades (NDA). Every new medicine has been subject to an approved NDA prior to commercialization in the United States since 1938. The NDA application is used by drug

companies to request that the FDA approve a novel medicine for sale and marketing in the United States. The data collected during an Investigational New Drug (INDanimal)'s research and human clinical trials becomes part of the NDA**.**

The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.

An NDA's documentation is supposed to tell the entire story of the medication, including what happened during clinical trials, what the medicine's ingredients are, the results of animal studies, how the drug acts in the body, and how it is manufactured, processed, and packed. Summary summary of NDA content, structure, and categorization, as well as the NDA review procedure, can be found in the following resources:

Resources for NDA Submission:-

The resources below have been compiled to offer you with information on the legal requirements of a new drug application, as well as CDER assistance in meeting those requirements and internal NDA review principles, policies, and procedures.

Guidance Documents for NDA'S :-

The Agency's current thinking on a given subject is reflected in guidance materials. These publications are designed to give guidance to FDA review staff and applicants/sponsors for the processing, content, and evaluation/approval of applications, as well as the design, production, manufacturing, and testing of regulated products. They also set policies to ensure that the Agency's regulatory approach is consistent, as well as inspection and enforcement methods.Guidances are not enforceable through administrative actions or the courts because they are not rules or laws. If an alternative strategy satisfies the requirements of the applicable statute, rules, or both, it may be used. Please contact the source office for more information on a specific advice document.

Guidance documents to help prepare NDA's :-

- Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs and General Considerations
- Changes to an Approved NDA or ANDA
- Changes to an Approved NDA or ANDA: Questions and Answers
- Container Closure Systems for Packaging Human Drugs and Biologics
- Format and Content of the Microbiology Section of an Application,
- Format and Content of the Clinical and Statistical Sections of an Application
- Summary for New Drug and Antibiotic Applications--Format and Content of the Summary for New Drug and Antibiotic Applications
- Formatting, Assembling and Submitting New Drug and Antibiotic Applications,
- Guideline for submitting supporting documentation in drug applications for the manufacture of drug products
- NDAs: Impurities in Drug Substances
- Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application
- Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application
- Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products
- Drug Master Files: Guidelines
- FDA IND, NDA, ANDA, or Drug Master File Binders
- PET Drug Applications - Content and Format for NDAs and ANDAs — 2011

When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the sponsor submits to FDA a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics.

NDA Application Form :-

Next Page | Export Data | Import Data | Reset Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: March 31, 2020
See PRA Statement on page 3.

1. Date of Submission *(mm/dd/yyyy)*

APPLICANT INFORMATION

2. Name of Applicant

3. Telephone Number *(Include country code if applicable and area code)*

4. Facsimile (FAX) Number *(Include country code if applicable and area code)*

5. Applicant Address

Address 1 *(Street address, P.O. box, company name c/o)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City | State/Province/Region

Country | ZIP or Postal Code

Email Address

Applicant DUNS

U.S. License Number if previously issued

6. Authorized U.S. Agent *(Required for non-U.S. applicants)*

Authorized U.S. Agent Name

Address 1 *(Street address, P.O. box, company name c/o)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City | State

ZIP Code

Telephone Number *(Include area code)*

FAX Number *(Include area code)*

Email Address

U.S. Agent DUNS

PRODUCT DESCRIPTION

7. NDA, ANDA, or BLA Application Number

8. Supplement Number *(If applicable)*

9. Established Name *(e.g., proper name, USP/USAN name)*

10. Proprietary Name *(Trade Name) (If any)*

11. Chemical/Biochemical/Blood Product Name *(If any)*

12. Dosage Form | 13. Strengths | 14. Route of Administration

15A. Proposed Indication for Use

Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☐ No

Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☐ No

If yes, provide the Orphan Designation number for this indication: ☐

Continuation Page for #15

15B. SNOMED CT Indication Disease Term *(Use continuation page for each additional indication and respective coded disease term)*

APPLICATION INFORMATION

16. Application Type *(Select one)* ☐ New Drug Application (NDA) ☐ Biologics License Application (BLA) ☐ Abbreviated New Drug Application (ANDA)

17. If an NDA, identify the type ☐ 505(b)(1) ☐ 505(b)(2)

18. If a BLA, identify the type ☐ 351(a) ☐ 351(k)

19. If a 351(k), identify the biological reference product that is the basis for the submission.
Name of Biologic: _____ Holder of Licensed Application: _____

20. If an ANDA, or 505(b)(2), identify the listed drug product that is/are the basis for the submission.
Name of Drug: _____ Application Number of Relied Upon Product: _____
Indicate Patent Certification: ☐ P1 ☐ P2 ☐ P3 ☐ P4 ☐ Section viii - MOU ☐ Statement of no relevant patents

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21. Submission *(See instructions)* ☐ Original ☐ Labeling Supplement ☐ CMC Supplement ☐ Efficacy Supplement ☐ Annual Report
☐ Product Correspondence ☐ REMS Supplement ☐ Postmarketing Requirements or Commitments ☐ Periodic Safety Report
☐ Request for Proprietary Name Review ☐ Other *(Specify)*: _____

22. Submission Sub-Type ☐ Presubmission ☐ Amendment ☐ Initial Submission ☐ Resubmission

23. If a supplement, identify the appropriate category. ☐ CBE ☐ Prior Approval (PA) ☐ CBE-30

24. For Originals and all Supplements, is the product a combination product (21 CFR 3.2(e))? ☐ Yes ☐ No | Combination Product Type *(See instructions)* | Request for Designation (RFD) Number

25. Does the submission contain: *Only* Pediatric data? ☐ Yes ☐ No | Human factors information? ☐ Yes ☐ No

26. Proposed Marketing Status *(Select one)* ☐ Prescription Product (Rx) ☐ Over-The-Counter Product (OTC)

27. Reasons for Submission

28. Establishment Information *(Full establishment information should be provided in the body of the application.)*

Establishment Name	
Address 1 *(Street address, P.O. box, company name c/o)*	Registration (FEI) Number
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	MF Number
City / State/Province/Region	Establishment DUNS Number
Country / ZIP or Postal Code	

Is the establishment new to the application? ☐ Yes ☐ No

What is the status of the establishment? ☐ Pending ☐ Active ☐ Inactive ☐ Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment	Telephone Number *(Include area code)*
Address 1 *(Street address, P.O. box, company name c/o)*	
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	FAX Number *(Include area code)*
City / State/Province/Region	Email Address
Country / ZIP or Postal Code	

Manufacturing Steps and/or Type of Testing

Is the site ready for inspection? ☐ Yes ☐ No ☐ N/A
If No, when will site be ready? *(mm/dd/yyyy)* _____

Continuation Page for #28

29. Cross References (List related BLAs, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, MAFs, and DMFs referenced in the current application.)

Contin. Page for #29

30. This application contains the following items *(Select all that apply)*

☐ 1. Index ☐ 2. Labeling *(Select one)*: ☐ Draft Labeling ☐ Final Printed Labeling ☐ 3. Summary *(21 CFR 314.50 (c))*

☐ 4. Chemistry Section
☐ A. Chemistry, manufacturing, and controls information *(e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)*
☐ B. Samples *(21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)*
☐ C. Methods validation package *(e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)*

☐ 5. Nonclinical pharmacology and toxicology section *(e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)*

☐ 6. Human pharmacokinetics and bioavailability section *(e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)*

☐ 7. Clinical microbiology section *(e.g., 21 CFR 314.50(d)(4))*

☐ 8. Clinical data section *(e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)*

Item 30 continued on page 3

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30. This application contains the following items *(Continued; select all that apply)*

☐ 9. Safety update report *(e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)*	☐ 10. Statistical section *(e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)*
☐ 11. Case report tabulations *(e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)*	☐ 12. Case report forms *(e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)*
☐ 13. Patent information on any patent that claims the drug/ biologic *(21 U.S.C. 355(b) or (c))*	☐ 14. A patent certification with respect to any patent that claims the drug/biologic *(21 U.S.C. 355 (b)(2) or (j)(2)(A))*
☐ 15. Establishment description *(21 CFR Part 600, if applicable)*	☐ 16. Debarment certification *(FD&C Act 306 (k)(1))*
☐ 17. Field copy certification *(21 CFR 314.50 (l)(3))*	☐ 18. User Fee Cover Sheet *(PDUFA Form FDA 3397, GDUFA Form FDA 3794, BsUFA Form FDA 3792, or MDUFA Form FDA 3601)*
☐ 19. Financial Disclosure Information *(21 CFR Part 54)*	
☐ 20. Other *(Specify)*: _____	

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to, the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state, and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

31. Typed Name and Title of Applicant's Responsible Official	32. Date *(mm/dd/yyyy)*

33. Telephone Number *(Include country code if applicable and area code)*	34. FAX Number *(Include country code if applicable and area code)*	35. Email Address

36. Address of Applicant's Responsible Official

Address 1 *(Street address, P.O. box, company name c/o)*	
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City	State/Province/Region
Country	ZIP or Postal Code

37. Signature of Applicant's Responsible Official or Other Authorized Official	38. Countersignature of Authorized U.S. Agent
Sign	Sign

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Operations
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PRAStaff@fda.hhs.gov

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REFERENCES:

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3. Www.Internationalpatent.Com
4. Www.Indianpatentact.Com
5. Www.Thesisofpatent.Com
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7. https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/types-applications
8. https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-continued