CHAPTER - I

INTRODUCTION

PATENT SYSTEM
AND
PUBLIC DOMAIN IMBROGLIO

INTRODUCTION

Patent Law promotes the progress of science and technology by providing exclusive rights to inventors for a limited period of time. It operates on the principle of 'Quid Pro Quo' or 'Give and take'. An inventor gives an invention to the public and takes exclusive rights over it for a limited period of time.

The grant of exclusive rights provides incentives to invent, invest, design around and disclose. Possibilities of commercial benefits during the period of exclusive rights encourage inventors to invent and investors to invest. Incentive to design around springs out of the efforts of competitors to work around the technology, whose access is blocked due to existence of patents. As complete disclosure of the invention is a prerequisite to the grant of a patent, the inventor is incentivized to disclose his invention to the public in order to get a patent. These incentives operating together or individually promote the progress of science and technology.

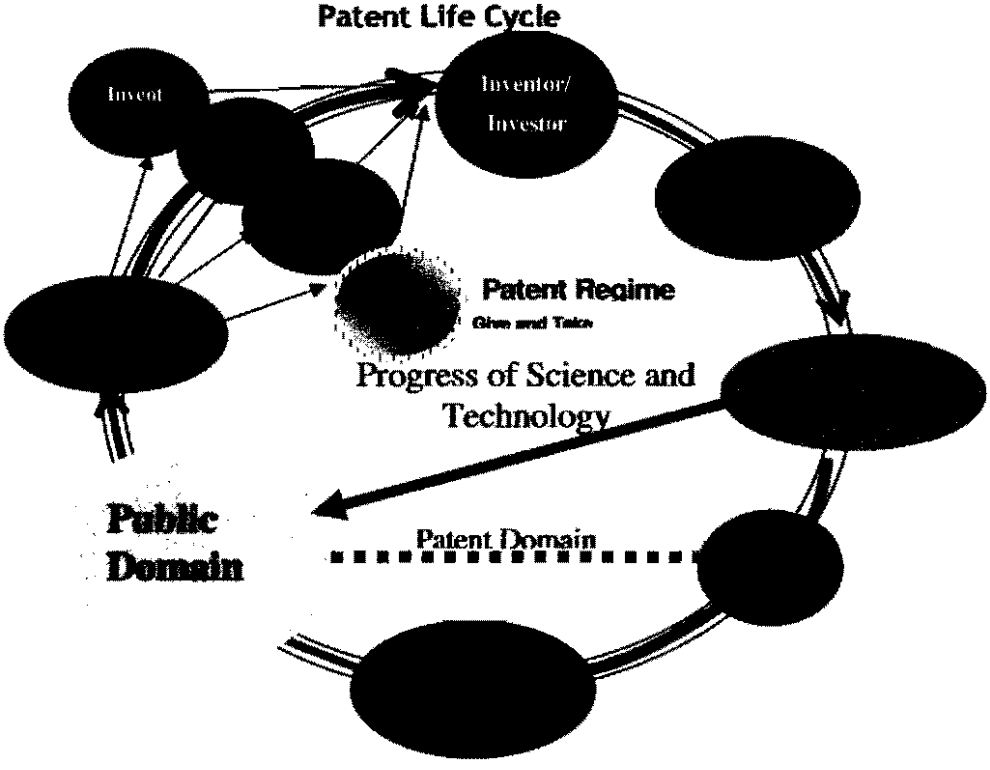

Figure 1.1 - Life cycle of a patent.

The basic objective of the patent regime as seen in the life cycle is creation of new inventions through economic incentives and enrichment of the public domain. By granting exclusive rights, the patent regime provides the aforementioned incentives, which in turn promote progress of science and technology by encouraging investment and invention through promise of financial benefits during the exclusive period. On being created and satisfying all requirements, an invention passes through the patent domain before getting into the public domain. The existence of a public domain is central to the purposes of a patent system, which aims to foster innovation. While a patent grant rewards and promotes inventiveness by conferring a limited monopoly upon an invention which meets certain criteria, a viable and vigorous public domain is indispensable to the process of invention itself[1]. Information in the public domain acts as a basis for further inventions by providing the knowledge necessary for future inventive activity. However, this does not apply to path breaking inventions, which are completely different from the existing knowledge and which open up a totally new field that is not dependant on information in the public domain.

Most provisions under patent law are in one way or the other related to and affects the patent life cycle. The objective of the patent system, which is to promote the progress of science and technology, can be achieved only if the patent provisions achieve a balance between inventions in "patent domain[2]" and information in the public domain. The determination of the ideal balance between patent and public domains is very tough because it varies based on the economic and social ideologies of each country. Any failure by a country to maintain the ideal balance could be counter productive to patent objectives resulting in slowing down of progress of science and technology.

[1] Dr. James Otieno-Odek, Public Domain in patentability after the uruguay round: a developing country's perspective with specific reference to kenya, 4 Tul. J. Int'l & Comp. L. 17 (Winter, 1995).

[2] "Patent Domain" shall include all inventions for which a patent has been granted, whose patent term hasn't expired and the right to utilization of which is limited to the patent holder.

One of the basic steps adopted by different governments to maintain such a balance is legislation of patentability requirements. By imposing various conditions in the form of legal requirements, the government tries to limit the types of inventions or number of inventions or both that can be granted a patent, leaving the other inventions within the public domain. Based on the stringency of criteria for patentability the number of inventions plummeting into public domain varies. It means that if the stringency of requirements for patentability are raised or lowered, the number and types of inventions that fall into the public domain will increase or decrease. Any flaw in the arrangement of patentability requirements has the potential of distorting the fine balance between patent and public domains, which would in turn slow down the progress of science and technology.

Patentability requirements

A patent is granted to an invention only if it satisfies the patentability requirements. These requirements are conditions imposed by the government to merely limit the grant of patents to competent inventions. Patentability requirements include patentable subject matter, usefulness, novelty, non-obviousness and specification. The requirements work like filters in tandem as shown in figure 1.2.

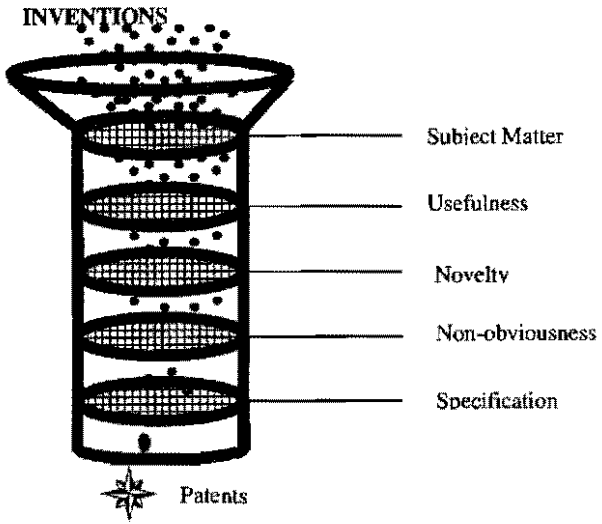

Figure 1.2 - Kalyan's Patent Filter Model

An invention will get a patent only if it passes through all the filters. Analysis of patentability is done step-by-step and filter-by-filter. To get a patent, the invention must pass through all filters one by one. An invention reaches second filter only after passing the first and the third filter after passing the second and so on. If the invention gets blocked at one of the filters, it means that it hasn't satisfied that requirement and is therefore not eligible for a patent. Grant of a patent is a result of the cumulative effect of all filters.

Configuration of each patentability filter differs from country to country based on social and economic conditions. However, each country has latitude to configure its filters only over and above certain basic standards that have to be followed as a result of their conformance with the International Agreements.

Basic Standards under Trips Agreement

The Agreement on TRIPS is a part of the Marrakesh Agreement signed by various nations establishing the World Trade Organization. This agreement aims at bringing about uniformity and harmonizing intellectual property laws. The agreement aims at providing adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights.

TRIPs Agreement provides for four patentability requirements to be satisfied by an invention in order to be eligible for a patent grant[3]. They are subject matter including product or process, novelty, inventive step and industrial application[4]. The agreement obligates member states to treat all fields of technology equally for grant of patents[5]. However, the agreement allows member countries to exclude certain inventions from scope of patentability for protecting public order or morality or animal or plant life or health or

[3] Article 27 Para 1, TRIPs Agreement 1994.
[4] Id.
[5] Id.

environment[6]. It also allows members to exclude medical methods, plants or animals except microorganisms and essential biological processes except microbiological processes[7]. Member countries have the latitude to configure their patentability filters only after fulfilling the aforementioned basic requirements provided in the TRIPs Agreement.

Role of **Patentability Filters**

Each patentability filter plays a role in determining the scope of inventions eligible to pass into the patent domain because it is the concerted affect of all filters that determines patentability.

Patentable Subject Matter

Subject Matter filter defines the types of inventions that are eligible for patent protection. It acts as an entry point for fundamental patentability analysis that will be done under the other filters. The government uses this filter to define the list of subjects it wants to promote and suppress under the patent regime. The subjects are defined in broad terms like any invention in Europe[8] or product or process as in India[9] or process, machine, manufacture of composition of matter as in USA[10]. Apart from defining the constitution of subject matter, some governments provide a list of exclusions that are prohibited from patent protection. Indian Patent Act has a long list of Non-patentable Inventions under Section 3 and USA has a list of judicially created exclusions.

[6] Article 27 Para 2 of TRIPs Agreement 1994.
[7] Article 27 Para 3 of TRIPs Agreement 1994.
[8] Article 52, European Patent Convention.
[9] Section 2(j), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005) or process, machine, manufacture, composition of matter or improvements as in USA. (35 USC Section 101 (2005).
[10] 35 USC Sec. 101 (2005).

In India, the list of exclusions includes the following[11]:

a. An invention which is frivolous or which claims anything obvious or contrary to well established natural laws[12];
b. An invention, the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment[13];
c. 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[14];
d. 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[15];
e. 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[16];
f. The mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way[17];
g. A method of agriculture or horticulture[18];

[11] Section 3, Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[12] Section 3(a), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[13] Section 3(b), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[14] Section 3(c), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[15] Section 3(d), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[16] Section 3(e), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[17] Section 3(f), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[18] Section 3(h), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.

h. 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[19];

i. 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[20];

j. A computer program per se other than its technical application to industry or a combination with hardware[21];

k. A mathematical method or a business method or algorithms[22];

l. A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions[23];

m. A presentation of information;[24] Method representing information in the form of signs symbols or in any other form; and

n. Topography of integrated circuits[25]; an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components[26].

Like India, Europe also has a long list of inventions that are not Patentable. The list includes inventions, which are

(a) Discoveries, scientific theories and mathematical methods[27];

(b) Aesthetic creations[28];

[19] Section 3(i), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[20] Section 3(j), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[21] Section 3(k), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[22] Section 3(ka), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[23] Section 3(l), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[24] Section 3(n), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[25] Section 3(o), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[26] Section 3(m), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[27] Article 52(2)(a), European Patent Convention.
[28] Article 52(2)(b), European Patent Convention.

(c) Schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers[29];
(d) Presentations of information[30];
(e) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body[31];
(f) Inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States[32] and
(g) Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof[33].

In contrast to the long list of exclusions under the Indian and European Law, the US Patent Law excludes only Laws of nature, physical phenomena, and abstract ideas[34].

Subject matter filter can be said to be an entry filter that screens inventions and paves way for fundamental patentability analysis under the other filters. An invention will pass through this filter only if it is included within the scope of eligible list of subjects and is not excluded by the scope of exclusions. However, if the invention falls outside the ambit of subjects or within the ambit of exclusions, it will not be qualified for a patent and will enter into the public domain. US patent subject matter has less exclusions and therefore, has a much broader scope when compared to the Indian or European subject matter. Many inventions that qualify as subject matter in USA are not eligible in India. For example: Computer programs and business methods are

[29] Article 52(2)(c), European Patent Convention.
[30] Article 52(2)(d), European Patent Convention.
[31] Article 52(4), European Patent Convention.
[32] Article 53(1), European Patent Convention.
[33] Article 53(2), European Patent Convention.
[34] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

patentable subject matter in USA but are not patentable subject matter in India. Furthermore, plants, animals and medical methods are patentable in USA but not patentable in India and partially patentable in Europe. Owing to the long list of exclusions from subject matter, less inventions enter the patent domain in India and Europe when compared to USA. Therefore, the size of public domain created by the subject matter filter in India is bigger than that created by the US filter which has only three exclusions.

Usefulness (Utility) or Industrial Application

An invention will be patentable only if it is useful or industrially applicable[35]. Though this has long been the easier filter of all to pass through it is beginning to become a little complicated. As no basic standards have been defined by the TRIPS Agreement, countries have the flexibility to configure this filter without any limitations. In USA, an invention will satisfy the usefulness requirement if it has substantial utility conferring to society some specific benefit in currently available form[36]. As per the utility guidelines issued in 2001, the usefulness of an invention should be specific, substantial and credible[37].

In India, an invention is patentable if it is capable of being industrially applicable[38]. Section 2(ac) provides that an invention is capable of industrial application if it is capable of being used in an industry[39]. The Manual of Patent Practice provides that Industrial application of an invention is determined by checking if the invention:

i. Can be made

ii. Can be used in at least one field of activity and

[35] Section 2(j)), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[36] Brenner V. Manson, 383 U.S. 519, 536 (1966).
[37] 35 USC Sec. 101 read with Utility Examination Guidelines, United States Patent and Trademark Office, Docket No. 991027289-0263-02], RIN 0651-AB09, 2001.
[38] Section 2(j) Indian Patent Act, 1970 as amended in 2005.
[39] Section 2(ac) Indian Patent Act, 1970 as amended in 2005.

iii. Can be reproduced with the same characteristics as many times as necessary[40].

Commercial utility of an invention is not relevant for the determination of Industrial Applicability.

In Europe, an invention will be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture[41].

The Indian and European utility filter is broader than that of USA, because it is easy to satisfy that an invention is capable of being made or used in an industry as required in India and Europe as opposed to the tougher requirement of substantial, credible and specific usefulness in USA. As a result, the size of public domain created by this filter is large in India and Europe than that in USA.

Novelty

Novelty and Non-obviousness filters are the most important patentability filters. Novelty filter confirms the newness of an invention for grant of a patent. Novelty means newness. An invention in order to be patentable should be new in the light of prior art that exists at the time the invention was made. Novelty of an invention is determined by analyzing it in the light of a single prior art reference. Patent Law of most countries provides a list of non-exhaustive circumstances that negate novelty of an invention. Under US Patent Law, an invention is not novel if the invention is:

(1) Known or used by anyone in the United States or printed or published in a foreign country[42]. Or

[40] Page 13, Para 2.4, Chapter II, Manual of Patent Practice and Procedures 2005.
[41] Article 57, European Patent Convention.

(2) In public use or on sale for more than a year before the filing date of patent application[43]. Or

(3) Abandoned[44]. Or

(4) Patented in a foreign country twelve months before the filing date of application in USA[45] or

(5) Derived from another person[46]. Or

(6) Invented by another person before the applicant provided the first inventor has not abandoned, suppressed or concealed his invention[47].

In India, an invention is patentable only if it satisfies the requirement of newness specified under section 2(j), which defines a 'new invention' as any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art[48]. The definition provides two circumstances that would alienate novelty of an invention and leaves it open for more situations. The two circumstances provided by the section are:

i. Publication of the invention before priority date anywhere in the world and

ii. Use of the invention before priority date, anywhere in the world.

It further goes on to say that the invention should not be a part of the state of the art i.e. public domain.

[42] 35 USC Sec 102(a) (2005).
[43] 35 USC Sec 102(c) (2005).
[44] 35 USC Sec 102(c) (2005).
[45] 35 USC Sec 102(d) (2005).
[46] 35 USC Sec 102(f) (2005).
[47] 35 USC Sec 102(g) (2005).
[48] Section 2(l), Indian Patent Act, 1970 as amended in 2005.

A list of non-exhaustive parameters that negate novelty under the Indian Law can be gathered from different sections in the Patent Act[49]. An invention is not novel in India if:

a. The Invention is publicly known or used in India before the priority date[50] of the claimed invention[51]; or
b. The Invention has been publicly displayed or published in a journal[52]; or
c. The invention has been publicly worked[53]; or
d. The claimed invention has been patented anywhere in the world[54]; or
e. The application in India is not filed within twelve months of its foreign application[55]; or
f. The inventor illicitly obtains the invention from another person[56]; or
g. The claimed invention forms part of a complete specification, which has been published or forms part of any publication before the claimed invention[57]; or
h. The invention forms part of a complete specification filed in India and having an earlier date of priority[58]; or
i. The invention forms part of knowledge, oral or otherwise available within any local or indigenous communities in India or elsewhere[59].

In Europe, an invention will be considered to be new if it does not form part of the state of the art, which comprises everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application[60]. The display of the

[49] Id. read with Section 29-34 and Section 64.
[50] Priority date is the date of filing of the first application relating to the invention.
[51] Section 25(2)(d), Indian Patent Act, 1970 as amended in 2005
[52] Section 31, Indian Patent Act, 1970 as amended in 2005
[53] Section 32, Indian Patent Act, 1970 as amended in 2005
[54] Section 25(2)(b), Indian Patent Act, 1970 as amended in 2005
[55] Section 25(1)(i), Indian Patent Act, 1970 as amended in 2005
[56] Section 25(1)(a), Indian Patent Act, 1970 as amended in 2005
[57] Section 25(1)(c), Indian Patent Act, 1970 as amended in 2005
[58] Section 64(1)(a), Indian Patent Act, 1970 as amended in 2005
[59] Section 25(1)(k), Indian Patent Act, 1970 as amended in 2005
[60] Article 54, European Patent Convention.

invention in an internationally recognized exhibition will not negate novelty in Europe, if the patent application is filed within 6 months of the display[61].

This filter has a very close interaction with public domain as the basic analysis under this filter is based on what exists in the public domain. Once an invention enters the public domain, it will not be able to pass through this filter. An invention, which is not new as a consequence of falling within any of the aforementioned circumstances is not eligible for patent domain and enters the public domain. The novelty filter can be said to be more demanding in India than in USA because the list of non-exhaustive circumstances in USA provide more latitude for patent applicants. For example, an invention is not novel for purposes of patent grant in India, if it is on sale even for one day before the priority date whereas in USA, sale of an invention for a period of twelve months before the date of priority will not negate the novelty of the invention. The same rule applies for publication before priority date. Due to its exacting conditions, when compared to USA, the Indian novelty filter is difficult to satisfy. Therefore, the number of inventions that fall into the public domain because of not qualifying the novelty requirement are higher in India and the Indian novelty filter creates a bigger public domain and smaller patent domain than that of USA. When it comes to Europe, it prima facie seems that novelty filter is broader than that of India and creates a larger patent domain than in India. This filter plays a very important role in determining and maintaining the size of public domain and the balance between public and patent domains.

Inventive Step/Non-obviousness

Inventive step or Non-obviousness is an extended version or advanced version of novelty. An invention to be patentable should not be obvious in the light of existing prior art at the time of invention. 'Prior art' is the science and technology or knowledge of science and technology, relating to the claimed

[61] Article 55, European Patent Convention.

invention, existing in the public domain, in the form of patents, publications, doctoral dissertations, etc. An invention is obvious, if a single prior art reference or a combination of prior art references as a whole, make the invention obvious to a person with ordinary skill in the art to which the invention belongs.

As per US Patent Law, an invention would not be patentable if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains[62]. While deciding upon the obviousness or non-obviousness of an invention the court or the USPTO has to determine the scope and content of prior art, ascertain differences between prior art and claims at issue and resolve the level of ordinary skill in pertinent art[63]. Secondary indicia such as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented and they may have relevancy in determining obviousness or non-obviousness[64].

In India, Section 2(ja) of the Patent Act provides that "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious, to a person skilled in the art[65]. The determination of inventive step as per the definition involves two steps:

i. Whether the invention involves a technical advance or economic significance or both and

[62] 35 USC Sec. 103 (2005)
[63] Graham v. John Deere Co., 383 U.S. 1 (1966).
[64] Id.
[65] Section 2(ja), Indian Patent Act, 1970 as amended in 2005.

ii. Whether the invention is Non-obvious to a person with ordinary skill in the art.

If the answer to both questions is affirmative, then the invention satisfies the requirement of inventive step. Existence of inventive step is determined through the eyes of a person with ordinary skill in the art. This person with ordinary skill is a ghostly person. He doesn't exist in reality. The patent examiner imagines a person and makes his determination by taking the person as a benchmark. The examiner combines all prior art references and checks if the invention as a whole constitutes inventive step in the light of the combination. Inventive step is determined by taking the date of invention as the point of reference. In India, it is the priority date[66].

The Manual of Patent Practice and Procedure provides that the following may be considered by examiner while determining inventive step[67]:

(a) Scope and content of the prior art to which the invention pertains
(b) Assessing the technical result (or effect) and economic value achieved by the claimed invention.
(c) Differences between the relevant prior art and the claimed invention
(d) Defining the technical problem to be solved as the object of the invention to achieve the result
(e) Final determination of non-obviousness, which is made by deciding whether a person of ordinary skill could bridge the differences between the relevant prior art and the claims at issue.

In Europe, an invention will be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art[68].

[66] Para 2.3, Chapter II, Manual of Patent Practice and Procedure, Indian Patent Office (2005)

[67] Para 2.3, Chapter II, Manual of Patent Practice and Procedure, Indian Patent Office (2005)

Inventive step/Non-obviousness filter is configured in such a way that it is difficult for any invention to pass through. This filter serves the purpose that nothing in the public domain enters the patent domain by looking at the obviousness of the invention after combining different prior art references. It brings in the concept of person with ordinary skill in the art, whose status and profile is based on the knowledge in public domain and analyzes the invention through his eyes. By doing so, it safeguards and maintains a proper balance between what goes into the patent domain and the size of public domain.

Though India, Europe and USA have certain common criteria to test Non-obviousness of an invention, they differ in their approach to economic significance. While economic significance of an invention is one of the basic tests for Non-obviousness in India, it is only a secondary consideration in USA and not considered in Europe. To elucidate this further, an invention can be non-obvious in India if it has a technical advance or economic significance in the light of prior art but in USA an invention can satisfy non-obviousness requirement only if it is different from the prior art and economic success of an invention can be used just to prove that fact. But in Europe, economic significance is not at all considered in non-obviousness determination. Therefore, the non-obviousness filter in India has more flexibility, is easy to satisfy and creates a bigger patent domain and smaller public domain when compared to that of USA and Europe.

Specification

The specification filter is a largely procedural filter. To obtain a patent, the inventor must file a patent application containing a specification[69]. The specification contains written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms,

[68] Article 56, European Patent Convention.
[69] Section 9(1) Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.

so as to enable a person with ordinary skill in the art to make and use the invention[70]. The specification shall also describe the best mode of carrying out the invention[71]. The written description may contain drawings where and when required to clearly describe the invention[72]. The specification concludes with one or more claims particularly pointing out and definitely claiming the subject matter of the invention[73]. The claims define the metes and bounds of the invention[74].

The objective of the specification filter is public notice and dissemination. The specification provides full details about the constitution and boundaries of the invention and describes the method of performing it. It allows the public to make and use the invention as soon as it enters the public domain after the expiry of the patent term. The claims in the specification provide notice to the public about what lies in the patent domain. Everything that falls outside of the scope of the patent claims is considered to be in the public domain. Furthermore, patent specifications contain valuable scientific information that patent data can be considered to be a powerhouse of scientific knowledge. The specification requirements in USA, Europe and India are largely uniform and therefore, the size of patent and public domain created by them is not highly variable.

It can be concluded from the discussion with regard to the patentability requirements and their impact on patent and public domains that each one of the filters plays a very important role in defining the size of patent and public domain. So, each one of the requirements play a very important role in defining the balance between patent and public domains, which is vital for optimizing progress of science and technology. The appropriate balance

[70] Sections 9 and 10, Indian Patent Act, 1970 as amended in 1999, 2002 and 2005 and 35 USC Sec. 112(2005).
[71] Section 10(4)(b) Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[72] Section 10(2) Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[73] Section 10(4)(C) Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[74] Section 10(5) Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.

required for promoting progress varies from field to field. While a field like software, which has inventions with short life span and require less R and D requires a specific type of balance and inventions relating to biotechnology with long life span and high R and D require a different balance. It is important for a country to identify appropriate balance that is required to promote optimal progress of science and technology in a specific field based on its social and economic conditions.

Genetic inventions and Patent Issues

Since inception patent law is being customized and fine tuned by governments to meet the needs of evolving technologies. Strong basic principles have evolved to cater to the needs of traditional fields of science and technology and they have been working well in promoting progress. However, the basic principles have utterly failed in a number of ways, when it comes to their application to Modern Biotechnology and specifically gene based inventions. The unique nature of the science of genetics is the main reason for the failure.

Genetic research promises more efficacious drugs, medical treatment tailored to the individual patient's biological make-up, new crops, new industrial processes and much more. It has the potential to transform humanity provided humanity wishes to be transformed (Geoffry Carr). Biotechnology companies invest hundreds of millions of dollars and sometimes decades to develop a product. Patents provide the needed assurance for investors to risk the capital necessary in the long development process, so that investment can not only be recouped but also generate a profit. In the absence of effective patent regime, investors would not be interested in investing millions on long term R and D because research output could be exploited by any person, which would jeopardize their returns and profits. In this context, genetic research assumes very high importance when seen in the light of the patent regime because of its research and investment intensive nature and so the patent regime plays a very

important role in encouraging the progress of genetic science. However, the application of the patent system to genomics as a field is fraught with uncertainty and ambiguity because of its unique nature.

One of the unique characteristics of genetics as a field is the immaturity and unpredictability of the field. As the field is largely not predictable and most research is based on trial and error, it becomes a great challenge to coin patent provisions that can be applied to it for optimal progress. If a provision is not properly designed, it will give rise to an imbalance between the patent and public domains, thus resulting in slowing down of the progress of the field. Patentability requirements such as utility, novelty, non-obviousness and enablement are based on the predictability of a field and common general knowledge, that it becomes a great challenge to coin these provisions to suit the needs of genetic inventions.

As genetics deals with life, it gives rise to moral, ethical and religious issues. Most issues in genetics, from patenting of genes or genetically modified crops to patenting life are confronted with moral, ethical and religious controversies. As a result, public consciousness has for long been intertwined with the progress of genetic science and policy framers have had difficulty in creating a patent regime to promote a field that has the potential of disturbing ethics and values that have been built into the society. Furthermore, there is fear among the public that genetic research might result in environment hazards. Fear of environmental hazards shape in the form of lot of controversies. One issue that raised moral, ethical and environmental controversies is the rDNA controversy, which leads to promulgation of safety guidelines for genetic research. In such a scenario, while genetic research promises great medical benefits, there is fear among the public that it might lead to medical disasters due to unknown factors. The aforementioned issues make the challenge for framing patent law for genetic inventions very challenging.

In the light of the aforementioned unique characteristics of genetics, this thesis discusses the variances in the size of patent and public domains as a

result of differences in substantive patentability requirements (including patentable subject matter, utility, novelty, non-obviousness, written description and enablement) and certain other provisions such as morals and research exemptions under the patent law. It points out the existing balance between patent and public domains in relation to genetic inventions and their role in promoting or impeding progress. It further goes on to propose a patentability model that would bring about an ideal balance in patent and public domains to enable optimum progress in the field based on social and economic conditions of India.

Research Issues

All research issues are studied from the patent and public domain point of view in the light of patent laws in USA, Europe and India.

a. Patentable subject matter and its influence on progress of genetic inventions: How is the patent and public domain balance in USA, Europe and India? Is the patent and public domain balance in India proper for optimal progress of gene based inventions? What are the changes required?

b. Utility of genetic inventions: What are the standards for utility relating to gene based inventions in USA, Europe and India? Does Indian utility requirement bring about a patent/public domain balance?

c. Novelty: What are the novelty standards for genetic inventions in USA, Europe and India? How is the patent/public domain balance and does India need a change?

d. Non-obviousness of genetic inventions: What are the principles governing non-obviousness requirement in USA, Europe and India for gene based inventions? Is there a public/patent domain balance and does India need a change to promote optimal progress?

e. Written Description and Enablement: Do different countries have different standards for written description and enablement of gene based inventions? What are the differences and how do they impact patent grants and sizes of patent/public domains? What are the standards India needs to adopt?

f. Morality: Is morality considered for granting patents to genetic inventions? How are moral standards defined and how do they influence sizes of patent and public domains?

g. Research exemptions and genetics: What is role of research exemptions in various countries in defining the public/patent domain balance for gene based inventions? Do research exemptions interface appropriately with patentability requirements?

h. Do Indian patentability requirements for gene based inventions bring about a balance between patent and public domains to promote rapid progress? What is the appropriate patent model for India to promote progress of genetic inventions in an optimal manner?

The research thesis explores the patent and public domain balance in USA, Europe and India with regard to gene based inventions in the light of various patent provisions. It elucidates the differences in law and their impact on patent and public domains with the help of examples through comparative studies. The thesis analyzes the impact of the provisions on the progress of genetic science in the light of patent and public domains. It finally proposes a patent model for India, which would ensure a balance between patent and public domains and would promote rapid progress of genetic inventions.