CHAPTER-III
3.1 Introduction

Almost every country has a patent law that gives an inventor the exclusive right to something he has invented and consequently rewards him for his industry and creativeness. While rewarding the inventor may be just, the primary purpose of patent laws is to benefit society by encouraging creativeness, inducing the investment of capital in untested areas, and providing an incentive to disclose new technology. The substantive requirements of various patent laws are designed to ensure these ends; thus in every patent law novelty, industrial usefulness, and nonobviousness are prerequisites to patentability. Novelty, usefulness, and Nonobviousness are determined by a search of what is known as "prior art." Prior art is the existing body of knowledge from which patentability is measured and is composed of patents, publications, and prior use. Each country’s patent law determines the extent to which prior art draws upon foreign patents, publications, and prior use. After the body of prior art is assembled, patentability is determined by examining and comparing the prior art with the invention to discover whether the invention is truly new, useful, and nonobvious, as defined by the country’s substantive patent law and court decisions. Assuming an accurate search of the prior art, novelty can be ascertained with some accuracy. Usefulness also is not too difficult to determine.

Nonobviousness, however, requires a highly subjective appraisal. If an invention is obvious to a trained practitioner in the art, issuance of a patent for it fails to promote, and in fact may hinder, the ends of a patent system. The idea of granting an exclusive right to the direct profits from an invention is not a recent one. In 1421 the first known patent for invention was granted by private statute of the Republic of Florence to Filippo Brunelleschi, an architect, for his invention of "a kind of ship." The grant was for only 3 years and prevented the use of any other novel means of water transportation in Florentine territory. The Republic of Florence did not develop the patent notion any further. During the same period, however, the Venetian Republic, possibly influenced by
Brunelleschi's patent, established the first public patent statute, which rewarded any invention that improved or accelerated the process of silk making. This was a forerunner of the first known general patent statute, passed in 1474 by the Venetian Republic. This statute offered protection for a 10-year period to inventors in all fields, required local novelty and usefulness, and specified the punishment for infringement. Except for its limited territorial scope, this Venetian statute contained all the elements of a modern patent statute. The patent concept that slowly developed in the rest of Europe was less distinctly defined than that of the Venetian statute. The European concept was based on the 'literae patentes', or "letters patent," which were issued by sovereign grace to proclaim a special privilege, title, or monopoly. In England letters patent were used by the Crown to control trade, but the system was abused by court favorites who made fortunes from patent-based monopolies in such industries as salt, tin, starch, and paper. The abuse became so flagrant that in 1623 Parliament passed the Statute of Monopolies, which declared all monopolies void except those granted for new and useful device.

The concept of the patent as an act of grace survived until the advent of the Industrial Revolution and the idea that individual enterprise should be rewarded by the state as a matter of course. This modern patent concept appeared United States' in 1790 first patent law, which provided patent protection after an examination to determine the novelty of the particular invention. This statute extended patent protection to "any useful art, manufacture, engine, machine or device or any improvement therein not before known or used." The requirement of an examination to determine novelty was abandoned in 1793, only to be added again in 1836 with the passage of a patent act that is the direct antecedent of our present patent law. Why the end of the 19th century most developed countries had begun to adapt their patent systems to this modern concept.

3.2 National Patent Systems

At present there is no unified, international patent system. Fundamental differences regarding the nature and extent of the rights that should be granted by patents have led to wide dissimilarities among the various national patent systems. At one
extreme is the United States, which grants a property right to the inventor and, in most instances, leaves its exploitation to his discretion. At the other extreme is the Russia, whose Inventor's Certificate does not convey or recognize any exclusive property right, the state simply grants to itself a monopoly to utilize inventions. Most nations follow a middle course, they grant a property right to the inventor to exclude others from making use of the invention, but do so only if the invention is put to commercial use in that country within a reasonable period of time and only if periodically paid. This tends to decrease the retention of unused or uneconomic patents.

Further, many countries have compulsory licensing, which requires the patentee to license his invention under stipulated conditions to certain applicants who then can utilize the invention. Similarly, the protection that a patent offers differs among countries. Most nations, including the United States, the Scandinavian countries, West Germany, the United Kingdom, Canada, Australia, and Japan, have examination systems. France and Italy, among others, have registration systems. An examination system tries to ascertain if the invention meets some statutory definition of patentability and gives a presumption of validity to a granted patent, while a registration system leaves the question of validity wholly to the courts. But the difference between these systems is not as great as one might think. To illustrate, Switzerland examines with regard to certain areas of technology only. France has started a novelty search in areas of medical research and is considering a plan to extend it. The Netherlands and West Germany have each enacted a compromised referred-examination system that grants a patent of limited duration upon application and examines only if the patentee or a third party considers the validity or scope of the patent of such commercial concern that it justifies his bearing the cost of the examination required to extend the patent's life.

Further, even in a country with a pure examination system, such as the United States, the presumption of validity may be fairly weak. In the United States, for example, almost 60 percent of all patents considered by the courts are wholly or partially canceled. Two further points of difference among patent systems are the first-to-invent criterion and the method of defining the invention's subject matter. First, if there is any conflict
between two inventions in, for example, the United States, the inventor who can prove he was the first to invent the discovery will prevail. In most other countries there is no attempt to determine the first to invent, for the party who first filed his application will win." Second, patent systems differ with respects to the specificity required in the inventor's claims his definition of the subject matter of the invention. A strict definition, such as that required by the United States, involves a much more detailed description of the invention than is necessary in most European countries. The differences between the various national patent laws even extend to such minor, but nevertheless vexing, matters as the size of the paper on which an application is printed. These various dissimilarities, coupled with the principle of territoriality, which says that the exclusive right granted by the patent is only good within the state that conferred it and that all legal dealings in connection with the patent must be determined by the laws of that state, place a tremendous strain on companies that wish to do business internationally and on the various countries that search and examine applications. For example, in 1966 approximately 611,000 patent applications were filed worldwide; of these more than half were duplicates and multiple filings." Since each duplicate application involves a separate application form and (in examining countries) an independent search and examination, a tremendous waste of manpower and economic resources is involved. This problem is particularly acute in most European countries, where the majority of patents granted are filed by foreigners.

3.3 USA

The three basic requirements found common in all patent laws, in US Code 35, the three consecutive sections 101-103 deal with patentable inventions, Novelty, Nonobviousness and Utility. We look these provisions with the help of case study which is the only way to have a crystal clear understanding of modern technology patenting.

3.3.1 Patentable Inventions

These are defined as any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. The requirement that
the invention be useful is rather stronger that the EPC requirement that it be capable of industrial application. Court decisions relating to living organisms, software, and methods of doing business have expanded the above definition so broadly that it now seems that there is no kind of human activity that is clearly excluded from patentability in the USA. Naturally occurring compounds and organisms are also regarded as patentable inventions if they are isolated from their natural environment and found to be useful. Nevertheless, some have challenged this view, and argue that products or nature fall outside the above definition and are not patentable subject matter no matter how novel, non-obvious, and useful they may be. As their arguments also apply to DNA sequences, and would have devastating consequences for the US biotech industry if they were put into practice, it is unlikely that the present situation will change.

3.3.2 Patent - monopoly

A patent is literally a monopoly, as a patent owner enjoys the right of exclusive sale for the term of the patent. The right to a monopoly has been said to be "the very foundation of the patent system. The essence of a patent owner's statutory monopoly has been said to be the right to invoke the state's power to prevent others from utilizing the invention without the patent owner's consent.

Although Thomas Jefferson was a strong advocate of the patent system, having himself, in effect, been the first patent examiner in his capacity as Secretary of State, he viewed the grant of patent rights in an idea already disclosed to the public as akin to an ex post facto law, "Obstructing others in the use of what they possessed before Jefferson's aversion to monopolies was so intense that he apparently advocated incorporation in the Constitution itself an express prohibition against monopolies for subject matter other than productions in literature and inventions in the arts. In an 1870 opinion, the Supreme Court endeavored to distinguish between patents and monopolies as follows

Letters patent are not to be regarded as monopolies, created by the executive authority at the expense and to the prejudice of all the community except the persons therein named as patentees, but as public franchises granted to the inventors of new and useful improvements for the purpose of securing them, as such inventors, for the limited term therein mentioned, the exclusive right and liberty to make and use and vend to others to be used their own inventions, as tending to promote the progress of science and the useful arts, and as matter of compensation to the inventors for their labor, toil, and expense in making the inventions, and reducing the same to practice for the public benefit, as contemplated by the Constitution and sanctioned by the laws of Congress.

Courts, in rationalizing the constitutional power of Congress to authorize the grant of patents for useful inventions, have repeatedly stressed that, inasmuch as the sine qua non of a valid patent grant is the novelty of its subject matter, the public by virtue of a grant of letters patent is not deprived of anything it enjoyed prior to such a grant. For example, in 1933, the Supreme Court stated

The term "monopoly" connotes the giving of an exclusive privilege for buying, selling, working, or using a thing which the public freely enjoyed prior to the grant. Thus a monopoly takes something from the people. An inventor deprives the public of nothing which it enjoyed before his discovery, but gives something of value to the community by adding to the sum of human knowledge.

To the foregoing rationale must be added the fact that to be the subject of a valid patent, the invention must not only be new and useful, it must also represent more than a routine advance, i.e., it must not have been obvious to a person of ordinary skill in the art at the time the invention was made

In a 1964 opinion, the Supreme Court alluded to the abusive grants of monopoly made by Tudor monarchs, distinguishing there from grants of letters patent for useful inventions in the following terms
Patents are not given as favors, as was the case of monopolies by the Tudor monarchs, but are meant to encourage invention by rewarding the inventor with the right, limited to a term of years fixed by the patent, to exclude others from the use of his invention.

On yet another occasion, in an attempt to reconcile patents and monopolies, the Supreme Court stated "At the same time, a patent is an exception to the general rule against monopolies and the right to access to a free and open market."

The novelty requirement for a patent grant has also been cited in reconciling the philosophies underlying federal antitrust law and federal patent law. In practice, courts have made patents compatible with the antitrust laws by closely confining the exclusivity of a patent grant to the scope of its claims and by carefully scrutinizing patent validity. The Supreme Court has held that a patent procured by fraud has no immunity from a charge of monopolization under antitrust law. Because a patent is deemed a monopoly, some courts have regarded it as a "public service" to strike down an invalid patent, characterized as a "trespass upon the public domain."

The cry of inequitable conduct before the Patent & Trademark Office, often coupled with a cry of unlawful "monopoly" and/or "restraint of trade," has frequently been raised by accused infringers. According to Warren Burger, Chief Judge of the District of Columbia Circuit court:

The fact that "monopoly" power exists in the patent system does not mean, ipso facto, that it should be treated as an evil in the antitrust sense. While exclusivity commands scrutiny, it must be recognized that this temporary "monopoly" is a deliberate creature of the Constitution and one long implemented by Congress to promote technology and encourage progress.

The Federal Circuit avoids use of the word "monopoly" in connection with patents, having characterized as an "obfuscation" description of a patent as an exception to the general rule against monopolies and as "pejorative" referring to a patent owner as a "monopolist. Chief Judge Markey has pointed out that neither the Patent Act, nor any
other federal statute, characterizes a patent as a "monopoly." It should be pointed out that neither the U.S. Constitution, nor the Declaration of Independence, employs the term "democracy." The Federal Circuit has also pointed out that a patent is not per se a monopoly in the antitrust sense. It should be noted that in an antitrust case, the Supreme Court stated. "Patents, on the other hand, furnish the most familiar type of classic monopoly."

Taking a hint from a Federal Circuit judge, courts have drifted away from the feeling that it will usually be the better practice to inquire fully into the validity of the patent in litigation. Worthy of mention here, as elsewhere is that a patent, albeit a monopoly, may actually promote competition, as by facilitating market entry in a concentrated industry. Federal legislation now allows arbitration of patent infringement and interference issues, something that had been previously been prohibited on antitrust grounds.

3.3.3 Novelty

A US patent is granted to the first to invent and not the first to file, and as a result the novelty requirements in the USA are far more complex that those in systems in which the filing date is crucial. The first requirements are that the applicant must himself have invented the subject matter of the application, and must not have abandoned it at any time. If the invention is not novel, before the applicant's invention date, the subject matter was invented by someone else — hence the need for interference proceedings to determine priority of invention in the case of conflicting patent applications; Described in a US patent application, which is subsequently granted; note, however, that if the US application claims priority from a foreign filing, the effective date of the reference is not the priority date, but the US filing date. This is a form of discrimination against non-US applicants, which is generally regarded, outside the USA, as being in violation of TRIPs.

2 35 USC (United States Code) 102(g).
3 35 USC 102 (e).
4 In re Hilmers 149 USPQ 480 (CCPA 1966).
For PCT applications, however, the relevant date is the international filing date, and not the date of entry into the National Phase in the USA:

Known or used by others in the USA or patented or described in a printed publication anywhere in the world; i.e., what we have described earlier as ‘mixed novelty’ requirements. The term ‘printed’ was at one time taken literally, but now is applied also to photocopies or to documents in electronic form, if they are publicly available. A document made available to the public by being put on an Internet website, for example, is a ‘printed publication’ but as such documents may be changed later it may be difficult to prove what was actually published at a certain date.

For all of these criteria the invention date can be established by evidence such as laboratory notebooks, and since 1996 this may be done not only for inventions made in the USA, but also for those made in other countries also. For inventions made outside the USA before 1st January 1996 only the US filing date or the date of a convention priority filing can be used.

The matter does not rest there, however, because where the invention date is more than one year before the US filing date there are the addition requirements that the invention must not have been in public use or on sale in the USA, or patented or described in a printed publication anywhere more than one year before the US filing date, and that it must not have been the subject of a patent application made abroad more than one year before the US filing date and granted before the US filing date. The first of these requirements means that a US inventor may publish his invention or put it on public sale and still be able to obtain a valid US patent, so long as the patent application is filed with one year. This is often referred to as a ‘grace period’ although this is not strictly correct. Publication by another less than 12 months prior to the filing date also does not affect the validity of the application, but here it is necessary to show that the

5 35 USC 102(a).
6 35 USC 102 (b)
7 35 USC 102 (d)
Anticipation

Patent invalidity based on lack of novelty is often called "anticipation." To demonstrate invalidity based on lack of novelty requires that the same invention, including each element of the claims, was known or used by others before the patentee invented it. To avoid anticipation and satisfy the novelty requirement, it has been generally held that the degree of physical difference, which must exist between that which sought to be patented, and the prior art need be only slight. Any degree of physical difference, however slight, invalidates claims of anticipation. So long as the physical structure of the invention sought to be patented is not identically disclosed, novelty very likely is present. That a mechanical equivalent is prior art does not render the invention anticipated thereby, although it may render it obvious in view thereof. By this standard, even mere colorable or trivial variation of prior art structures would literally possess novelty. Thus, it has been said that novelty has been called a fairly liberal test of patentability.

Identity of invention is a factual question, which requires that every element of the asserted claim exists, either expressly, or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device. Patent claims in which there is no cooperation between the constituent elements and no cooperative result produced other than the sum of the element's independent functions have been deemed invalid for lack of novelty. Since
physical identity is the test of novelty and anticipation, it should follow that the mere existence, anywhere in the prior art, of physical structure identical in description with that claimed would constitute anticipation.

To constitute anticipation, all the claimed elements must be found in exactly the same situation and united in the same way to perform the identical function in a single unit of the prior art. When the assertion of loss of novelty is based on printed publication, a finding of anticipation must show that the publication describes the same invention with all the elements of the claim arranged in the same way as they are in the patent claim. Anticipation can only be established by a single prior art reference, which discloses each and every element of the claimed invention. An infringer may argue that the differences between the claims and the prior art are "insubstantial" and that the missing elements could be supplied by one having ordinary skill in the art, but these arguments have been held ineffective to establish anticipation. Prior art, which directs the public away from the claimed invention, has been said to be the antithesis of anticipation. However, a reference is no less anticipatory, if after disclosing the invention, the reference disparages it. Thus, the question of whether a reference teaches away from the invention is inapplicable to an anticipation analysis. This standard is not satisfied where the prior art reference merely discloses the "concept," "essence," "key," or "gist" of the patented invention; "concepts do not anticipate." Moreover, anticipation cannot be predicated on teachings in a reference that are vague or based on conjecture. Additional references may be used only to interpret the allegedly anticipating reference. A reference anticipates a claim if it discloses the claimed invention so that "a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention. Anticipation can be found only if a reference shows exactly what is claimed; where there are differences between the reference and the claim, a rejection must be based on obviousness under 35 USC sec 103. That information extrinsic to a piece of prior art but available from a second source, which is within an expert's common knowledge, may be needed to practice the invention otherwise disclosed in such piece of prior art does not preclude that piece of prior art from constituting an anticipation. A printed publication may not explicitly disclose one or
more elements of the patent's claims, but this publication may still be "anticipating" if a person of ordinary skill in the art would understand the publication as showing the missing element. This modest flexibility in the rule that anticipation requires every element of the claims to appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges.

Oral testimony to establish the existence of allegedly anticipatory devices has long been viewed with skepticism. Uncorroborated oral testimony by a witness speaking only from memory in regard to past transactions, in the absence of contemporaneous documentary or physical evidence, is insufficient to show anticipation of an issued patent. Oral testimony of anticipation has been deemed unsatisfactory because of the forgetfulness of witnesses, their liability to mistakes, and their proneness to recollect things as the party calling them would have them recollect them, aside from the temptation to actual perjury. Even where a witness is of the highest character, the possibility of his being mistaken as to the exact device used, which, though bearing a general resemblance to the one patented, may differ from it in the very particulars, which make it patentable. Commercial success has cast doubts that the identical product was previously "known and used."

Anticipation has been characterized as a "narrow technical defense" that does not raise for consideration all that the prior art disclosed, but occurs where the same or virtually identical device or invention has previously been disclosed. The prior art is to be more broadly construed in determining obviousness than in deciding whether there has been anticipation.

Claims of issued patents tend to be construed more rationally, the courts often going behind their literal wording and considering the inventive thought that underlies and which motivated the claims. Thus, a court may discount as an anticipation, structure from an art totally unrelated to that to which the invention under consideration is
directed, even though such happens to read literally upon one or more of the claims. Incidental anticipations, which are temporary and transitory, have been deemed not to negate novelty.

Anticipation and infringement are reciprocals, i.e., it is an elemental principle of patent law that a structure in a prior art reference which would infringe the patent if later in time, anticipates it if earlier in time. The basic test for anticipation has been said to be "that which infringes if later anticipates if earlier."

Anomalous though it may seem, a written description may be adequate to anticipate a claim and yet be insufficient to support a patent. For example, description of a single embodiment of broadly claimed subject matter constitutes a description of the invention for anticipation purposes, but the same information in a patent specification might not alone be enough to provide a description of that invention for purposes of adequate disclosure. Similarly, a description of a compound lacking a statement of use therefore would suffice as an anticipation of a claim thereto and yet is deemed an insufficient disclosure to support a patent. A description of a compound is deemed to constitute anticipation even though such description does not disclose a utility for that compound.

Anticipation has been said to require not only identity of invention but also enablement. A reference cannot anticipate that which it does not enable. The description of a composition of matter may constitute anticipation thereof even though such description does not disclose how to prepare the same, provided that it would be within the skill of the art to do so. A related question is whether, and under what circumstances, a prior art description can constitute an anticipation of a claim. While in the final analysis, each case turns on the precise form and content of the prior art disclosure, it seems safe to state, on one hand, that to constitute an anticipation the prior art need not describe and, on the other hand, the prior art disclosure must at least substantially identify the its properties to constitute an anticipation. If it is possible to derive a class of
compounds of lesser scope than the disclosed in a prior art reference on the basis of preferences ascertainable from the reference, anticipation may be found.

An accidental, unintended, and unappreciated duplication of an invention has been said not to defeat the patent right of one who, though later in time, was the first to recognize, that which constitutes the inventive subject matter. A prior accidental and unappreciated combining, which would not amount to anticipation, would not entitle a party to an adjudication of priority of invention. An accidental or unwitting duplication of an invention cannot constitute anticipation; at least where the earlier inventor was not aware of what he was doing or how he did it. Should there be any conflict between the line of cases indicating accidental and unappreciated results, on the one hand, and the doctrine of inherency, on the other hand, the doctrine of inherency should prevail, insofar as whether the prior art constitutes an anticipation. Lack of appreciation of a result by prior art remains material in priority contests and is relevant to the issue of obviousness.

Another's experiment, imperfect and never perfected, will not serve either as anticipation or as part of the prior art, for it has not served to enrich the prior art. Rudimentary or unsuccessful experiments with isolated elements of a combination do not anticipate an invention, which successfully combines those elements. It is well settled that an invention set up in defense of infringement must have been complete and capable of producing the desired result. Patents for useful inventions ought not to be invalidated and held for naught because of such excursions into the bone yard of failures and abandoned experiments. A "failed" experiment renders it irrelevant as prior art. A distinction, however, is drawn between a mere failed "experiment," on one hand, and an invention that has fallen into disuse, on the other hand. Whether an invention has fallen into disuse or not if in fact it has been in public use, the invention may not be patented by a subsequent inventor.

A structure that was altered to meet a customer's specifications, then abandoned and thereafter never published or otherwise developed, compels its elimination from consideration as a branch of prior art. Similarly, an unexplained, miss-designated
representation was deemed not to be effective prior art. Nor is an abandoned experiment effective prior art. A prior art patent may properly be considered anticipation even though it has never been commercially made.

3.3.4 Non-obviousness

As we have seen, there has tended to be a very high standard of inventiveness set by US courts, are even though this has been somewhat relaxed, it is still a formidable undertaking to convince the USPTO and courts that the average invention is not obvious. One of the greatest difficulties is that, in contrast to British and EPO practice, it is permissible in the US to 'mosaic' together any number of prior art documents and, often with a generous measure of hindsight, to piece together the invention as a sequence of logical steps. Another problem is that, whereas in the EPC the whole contents of an unpublished application of earlier date can be used to attack novelty but not to allege obviousness, is the USA an earlier-field application can base both type of attack.

Following the change in the US Patent Law in 1952, it was not until 1966 that the US Supreme Court ruled on the issue of obviousness. The principles laid down in the case of Graham Vs John Deere⁸ are very similar to those of the English Windsurfer Case, discussed above. In considering obviousness, the court must make factual enquiries as to (i) the scope and content of the prior art; (ii) the differences between the prior art and the claims at issue; and (iii) the level of ordinary skill in the pertinent art.

The determination of obviousness is then a matter of law based upon facts.

3.3.4.1 Invention - Ideas

Perhaps the deepest-rooted misconception about patents pertains to "the patentability of ideas." Thus, not infrequently, a certain idea will be spoken of as being "patentable," another idea, as being "unpatentable." Even the Supreme Court, on

⁸ 148 USPQ 459 (Sup. Ct. 1966).
occasion, has spoken in these terms. Ideas nurture the patent system; they are its pabulum. Strictly speaking, however, naked ideas are not patentable.

In many cases US Supreme Court has explicitly recognized that one may not patent an idea. Other federal courts have echoed this position. Those acquainted with the mysteries of patent law often employ the word "idea" as a shorthand substitute for "invention" or for the physical exploitation or embodiment of an idea. Perhaps this is so because there is no requirement that an invention be reduced to actual practice before the patent thereon issues or before a patent application therefore is filed, it being sufficient that the patent specification contain a description adequate to enable one skilled in the art to which it pertains to reduce it to practice. Actual reduction to practice may, however, be material in determining priority of invention. While ideas are not patentable, an idea is often the inspiration for an invention. For example, James Watt's monumental improvement of the steam engine was built around the idea of employing a separate chamber to condense the steam. When a patent attorney speaks of the patentability of an idea, he means the patentability of an invention and its exploitation in tangible form. To the uninitiated, however, this causes confusion and misunderstanding. It projects an erroneous image, tending to leave laymen with the impression that patents somehow interfere with the freedom of thought.

No patent confers a right to exclude others from the underlying idea, which gave rise to the invention. The monopoly conferred by a patent attaches only to the embodiment of an idea in tangible form. Patent rights and rights in physical objects, which possess the physical attributes called for by the claims of a patent are entirely distinct.

The very motivation for having a patent system is to enlarge the fund of knowledge freely accessible to the public. The patent system fulfills this objective by

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offering monopolies, for limited times, upon the exploitation, in tangible form, of ideas in exchange for public disclosure. Immediately upon the granting of a patent, the ideas disclosed in the patent specification become available to the public. Everyone is free to think about any patented invention, even during its ephemeral life. The patent system imposes no constraints upon thought: it certainly encourages the free exchange of ideas.

However, they are introduced as pristine legal concepts, the state of the popular mind having been largely ignored. In what follows, special effort has been made to relate these and other concepts indigenous to patent law to common experience, hopefully thereby facilitating the dissipation of misconceptions surrounding them. The author, however, has no illusions about the efficacy of this presentation. He appreciates the fact that these misconceptions are so deeply ingrained that only with the conscious, constant, and concerted efforts of the readers can they be dispelled and relapse prevented. Similarly, naked ideas are not copyrightable, as the attribution to an egg of qualities normally possessed by humans. Only the expressions of ideas are copyrightable. A parallel prohibition applies in regard to trademarks, in that a general marketing theme, as such, is not protectable. Another manifestation of the confusion between ideas and intellectual property rights is the association of such rights with metaphysics.

The set of judicial pronouncements on the subject was often referred to as the "negative rules of invention." A list of the more significant of these negative rules follows:

1. The exercise of ordinary mechanical skill does not amount to invention.\(^{11}\)
2. Mere perfection of workmanship does not amount to invention.\(^{12}\)
3. Which is logically deducible from the teachings of the prior art does not amount to invention.
4. The mere carrying forward of an old idea does not amount to invention.\(^{13}\)

\(^{11}\)Hotchkiss v. Greenwood, 52 US (11 How) 248 (1850)
\(^{12}\)Reckendorfer v. Faber, 92 US 347 (2 Otto) 347, 356 (1875).
\(^{13}\)Smith v. Nichols, 88 US 112, 119, 22 L. Ed. 566 (1875)
That which would have been obvious to persons skilled in the art to which the subject matter relates does not amount to invention.\textsuperscript{14}

The substitution of a known equivalent for one of the elements of an old structure does not amount to invention.\textsuperscript{15}

Mere enlargement or change in size, degree, or form does not amount to invention.

Unification or multiplication of parts does not amount to invention.

Omission of an element and its attendant function, unless the omission produces a new result, does not amount to invention.

The application of an old process or machine to an analogous subject, with no change in the manner of application, and no new result, does not amount to invention.

Merely carrying out a prior art process in a continuous manner is not invention.

Absent a new or different result, a combination of old elements is not invention.

The mere substitution of one material for another is not invention.

One may not patent as an invention the making into one part of what formerly was in two.

There was no statute mandating these applications, but all are extracted from judicial pronouncements. One difficulty in applying them to concrete situations lay in casting a contribution in terms of such indicia as "a change in degree," "a new result," etc. What constitutes ordinary skill in a given art? What might be obvious to one person might be nonobvious to another. Moreover, from time to time the courts invoked even more elusive and abstruse criteria. For example, on occasion, judges, including Justices of the Supreme Court, in Chakrabarty's case and Bergy's case and now in K.S.R.'s case. But we should not go with facts, must understand with the principle behind.

3.3.4.2 Nonobviousness with Novelty and Utility

There are people who think inventions as miracles; there might be such formerly, but they are ceased. With these, every one who offers a new invention is deemed a

\textsuperscript{14} Diamond Rubber Co. of New York v. Consolidated Rubber Tire Co., 220 U.S 428, 434-35, 31 S. Ct. 444, 55 L. Ed. 527 (1911)

\textsuperscript{15} Morley Sewing Mach. Co. v. Lancaster, 129 U.S. 263, 9 S. Ct. 299, 32 L. Ed. 715 (1889)
pretender; he had it from some other country or from some book. A man of their own acquaintance, one who has no more sense than themselves, could not possibly, in their opinion, have been the inventor of any thing. They are confirmed, too, in these sentiments, by frequent instances of pretensions to invention, which vanity is daily producing. That vanity too, though an incitement to invention, is, at the same time, the pest of inventors. Jealousy and Envy deny the merit or the novelty of your invention; but Vanity, when the novelty and merit are established, claims it for its own... . One would not, therefore, of all faculties or qualities of the mind, wish, for a friend, or a child, that he should have that of invention. For his attempts to benefit mankind in that way, however well imagined, if they do not succeed, expose him, though unjustly, to general ridicule and contempt; and if they do succeed, to envy, robbery, and abuse.

The rationale for nonobviousness as a requisite of patentability has been sketched, in broad outline, Invention, by its very nature, defies positive definition, for if invention could be precisely defined, there would be no such thing as invention. This paradox, no doubt, has lent a certain aura, if not mystery, to the subject. The reality of invention and its contributions to the amelioration of our civilization, however, are everywhere evident.

Once an invention has been disclosed, little mystery about it remains. There has not been an invention yet made which defies a law of nature. Humans do not create from nothing; they must employ the principles of engineering, physics, chemistry etc and their experience. It cannot be the law that the only inventions patentable are those that cannot be explained by any known principles of engineering or physics. As courts have noted, all machines function according to the laws of physics. Even second-rate scientists can formulate accurate theoretical explanations, in terms of known and accepted physical laws, of why an invention works, once its efficacy has been demonstrated. There is a distinction between making and doing something, on one hand, and offering an explanation therefore, on the other. The trick to making an invention is to so combine existing structures and/or operations as to yield a new and different effect or result.
Although it is not possible to define, in positive terms, all of the elements sufficient to constitute an invention, it is possible to specify some that are necessary and indispensable therefore. Prominent among these are novelty and utility. The law, however, has segregated novelty and utility from whatever else of substance it deems necessary to constitute a patentable invention and has elevated this something else to the status and dignity of a discrete and independent condition of patentability, to which the confusing title "invention" had been applied, and which has been characterized as the "sine qua non of patentability."

The rationale for the imposition of this tertian quid is that all that is novel and useful may not be worthy of patent protection. The difference between what is old and what is merely technically or literally new may be so slight and trivial as to be readily, and perhaps even spontaneously, deducible upon demand from what is old and already known. There is a distinction between being different merely for the sake of being different and being different for a purpose.

While novelty and utility are requirements of patentability separate and apart from invention, these three qualities so overlap, and are so interrelated, as to be incapable of being entirely segregated from one another. Justice Sandra Day O'Connor, writing for a unanimous Supreme Court has stated that "taken together, the novelty and nonobviousness requirements express a congressional determination that the purposes behind the Patent Clause are best served by free competition and exploitation of either that which is already available to the public or that which may be readily discerned from publicly available material. Lack of novelty has been characterized as the epitome or ultimate in obviousness. Anticipation and obviousness are related, obviousness being a broader, more general condition of patentability. Obviousness has been said to follow \textit{ipso facto} from anticipation, although they are separate and distinct concepts.

Invention anticipated by prior art are necessarily obvious in view of that prior art. A patent claim that is invalid due to anticipation under 35 USC Sec 102 would also be invalid due to obviousness under 35 USC Sec 103. Indeed, some have suggested equating
invention with the degree or quantum of novelty required for patentability. There is no authority in 35 USC Sec 103 for treating "improvement" inventions, or inventions differing from the prior art only "in matter of degree," any differently from other types of inventions. While there are no degrees of obviousness i.e., claimed subject matter is either obvious or nonobvious the magnitude of any differences bears on whether the claimed invention, as a whole, is nonobvious. While how different from the prior art that which is novel must be to be patentable is definitely a factor in determining whether invention is present, the degree of difference is not to be measured by structure alone. Caution should be used in applying such a yardstick, for experience has taught that many of the very greatest advances differed structurally only very slightly from the prior art. Edison's incandescent lamp, the Wright brothers' airplane, and Bell's telephone are but a few of the many, many illustrations of this phenomenon. Laws, be they of physical or judicial origin, are but generalizations drawn from empirical observations and intuitive notions. To be acceptable, they must conform to these realities. Accordingly, the doctrine of small structural or physical change evolved. It was best articulated by Justice Learned Hand in the following words:

"Very slight structural changes may be enough to support a patent, when they presuppose a use not discoverable without inventive imagination. We are to judge such devices, not by the mere innovation in their former material, but by the purpose which dictated them and discovered their function."

The degree of difference is necessary to endow novel structure with patentable status may also be affected by the technological field involved. The Court of Customs & Patent Appeals noted on more than one occasion that progress is as important in crowded arts as in those, which are in the pioneer stage, and that progress in crowded arts is usually made in small increments. The courts recognized that as "unoccupied places ... become narrower, ... the inventor's contribution may be, and often is just as outstanding and just as important and valuable as it would be if the field were a virgin one, and the invention, the first to appear. That court then remarked: In fact an invention in a crowded art may be like a fertilizer on exhausted soil. It gives new life to a dying industry."
Claims drawn to an alloy which call for the inclusion of a small but specific amount of a metallic element in an otherwise old composition whereby there is a substantial improvement in one property without sacrifice of other desirable alloy properties were held patentable. The doctrine of small structural change has been held to be inapplicable in regard to the use of commonplace materials applied in a commonplace, long-established manner.

The proposition that perceiving a solution does not entail the recognition of a problem is unacceptable. The failure of others to discern the concept in the prior art is not preclusive evidence of nonobviousness. If it were, the distinction between novelty and nonobviousness would be blurred.

It is not the difference, but the difference makes that counts. This formulation suggests an interrelation between the elements of novelty ("the difference") and utility ("the difference the difference makes") with nonobviousness. It indicates, moreover, that "the difference" is to be placed in the perspective of the prior art. While suggesting that "the difference" must be significant, the foregoing illustrations and abstractions drawn there from offer no concrete clues as to the way or ways in which "the difference" must be significant. This is the point at which invention eludes more precise analysis in positive terms. What it takes to make that which is both new and useful as an "invention" has been characterized by some courts as that "impalpable something."

Although the great majority of countries now grant patents for chemical compounds per se, and this is one of the main requirements of TRIPS, this has been a relatively recent development in many cases. Even countries such as Germany, Japan, Netherlands, and Switzerland made this change only in the decade 1968-78 and Scandinavian countries, Austria, Spain, and Greece did so only within the last 10 or 20 years. Countries, which still do not grant patents of this type generally, allow only claims to processes for the production of chemical compounds; even if the processes themselves
are conventional, they are considered patentable if the end product is new, useful and non-obvious.

How useful process patents are depends chiefly upon two factors; whether or not there is derived product protection and whether or not there is reversal of the onus of proof. In any country in which there is product-by-process protection sale of the product will infringe the patent if the claimed process has produced it. The difficulty here is that, the patentees is usually not in a position to prove that the product has been manufactured, by his process unless perhaps careful analysis can detect traces of a characteristic starting material or by product. This is where reversal of onus of proof means that where the compound is new the court will assume that it has been produced by the patented process unless the person accused of infringement can prove otherwise. This is now one of the requirements of TRIPS\textsuperscript{16}

In any case, no matter how strong the process patent may be, it will normally cover only one method of making the compounds in question, and cannot be used to stop anyone from making the compounds by a completely different method. This may not be a serious problem for certain types of compounds for which there is only one commercially feasible manufacturing process, but for most classes of compound there will be many different synthetic routes available. If the inventor can think of ten different processes, then to cover all of these would, in most process protection countries, require ten separate patents, and then someone else will come along with an eleventh. For this reason complete protection is seldom possible in a country, which does not grant product \textit{per se} protection, and this is why TRIPS is so important to the chemical industry.

Before TRIPS, and still for countries, which are not yet in conformity with TRIPS, special rules applied in many countries for inventions of a new chemical compound useful as a pharmaceutical. An understandable concern for public health has often led to the conclusion that patents for medicines are contrary to public policy and that medicines

\textsuperscript{16} Art. 34, TRIPS

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would be cheaper and more readily available if they could not be patented. As we shall see, such evidence as there is tends to the opposite conclusion.

Some countries, which normally had product, per se protection allowed only produce-by-process protection for pharmaceuticals. Such was the situation for example in Canada, Norway, and Finland. At the other extreme, some countries had no protection whatsoever for pharmaceutical inventions; for example Italy (until 1978), Brazil (until 1997), and Turkey (until 2000).

For many years Italy had a law prohibiting patent protection for pharmaceuticals, which made the country a heaven for small pharmaceutical companies whose products imitated those of research-based companies, which were, still patented elsewhere. In 1978, as Italy was debating how best it could change this law I order to be able to ratify the EPC (for which at least process protection for pharmaceuticals would be necessary), a surprise decision of the Constitutional Court held that the old law was unconstitutional field. Thus whereas most people had expected a lengthy transition period of process protection for pharmaceutical in Italy, the country went in one step from no protection at all to full product per se protection together with protection for a new pharmaceutical use of a known compound.

Countries, which allowed only product-by-process or process-only protection for pharmaceuticals often had further special provisions such as shorter terms for pharmaceutical patents or compulsory licenses. Until the 1977 Act came into force in Britain, compulsory licenses could be granted at any time on pharmaceutical patents. However, the more recent licenses, which were granted, had the royalty set by the courts at high levels, which took into account the patentee's investment in research. More to the liking of the implicitness was fixed at a maximum 4 percent of net sales price of the finished product, and in India, where the figure was 4 percent of the ex-factory bulk price of the active ingredient, which is practically nothing.
3.3.4.3 Microbiological Inventions

Although the TRIPs agreement allows the exclusion of patents for plants and animals, this exclusion does not extend to patents for microorganisms and microbiological processes. Nevertheless, microbiological inventions, which involve the use of a new strain of microorganisms, produced by artificially induced random mutation, or transformed by recombinant DNA technology, present special problems. The requirements of a full and sufficient disclosure of the invention are interpreted by most countries to mean that the new strain must be deposited in a recognized culture collection and made available to the public. From the point of view of the inventor, this loss of control of his strain may outweigh the advantages of obtaining patent protection in certain cases. For inventions involving recombinant DNA technology, a written description of the relevant DNA sequences can be given and this usually makes deposition of a transformed organism or vector unnecessary. However, information on DNA and amino acid sequences must be provided to the European, US and Japanese patent Offices in electronic form in a standard format, to allow computerized searching.

Perhaps computer hardware can of course be patented in the same way as any other electro-mechanical invention, computer programs as such, are excluded from patentability, both by the EPC\(^1\) and India. Nevertheless, software-related inventions have been held patentable when they are considered to provide a technical effect, for example to control an external technical process, or even to increase the working memory of the computer running the program. Whereas a computer programmed in a certain way would be patentable if there was such an effect, it was not generally possible to patent the actual program itself, whether in abstract form or as written onto a disc. The situation in the USA was more favourable to the patenting of software inventions. Following court decisions holding such inventions patentable, the discs and CD ROMs carrying a computer program to be patented as articles of become generally patentable. The EPO is

\(^{1}\) Art. 27(3b), TRIPs.
\(^{1}\) Art. 52(2), EPC.
now moving in the same direction, and although business methods generally remain un-patentable, claims to computer programs on recording media have been granted.

Just as in the early days of biotechnological inventions, the lack of experience of many examiners with this new field has led to many software patents being granted which on their face appear to be excessively broad, and in particular to cover many ways in which the Internet is currently being used. Attempts by some companies to enforce such patents will no doubt give rise to court decisions establishing their valid scope, but there will be some years of confusion before the position becomes clear.

3.3.5 Utility

Utility, long a requirement to obtain a patent in American law, means that an invention must perform some function of positive benefit to society. A person cannot obtain a valid patent for an invention that will not in fact operate to perform its designated function or that will only perform mischievous or harmful functions. The purpose of the utility requirement is to assure that society obtains a “quid pro quo” in the form of a “substantial utility” and “specific benefit in currently available form” before granting a monopoly to an inventor. The requirement is easily met with most mechanical devices and processes but is a frequent problem with chemical compounds and processes—particularly pharmaceutical compounds (drugs). To comply with the utility requirement, an invention need not be superior to existing products or processes. However, it must meet three tests. First, it must be operable and capable of use. It must operate to perform the functions and secure the result intended. Second it must operate to achieve some minimum human purpose. Third, it must achieve a human purpose that is not illegal, immoral or contrary to public policy.

Minimum Utility: To be useful, an invention must be capable of some beneficial use in society. It must be more than “a mere curiosity, a scientific process exciting wonder yet not producing physical results, or frivolous or trifling article or operation not aiding in the progress not increasing the possession of the human race.
Generally, it is an easy matter to demonstrate a sufficient human purpose for mechanical products and processes. For example, recreation and amusement is a beneficial purpose, and hence games have been held patentable. The problem of finding sufficient purpose is encountered most often with chemical compounds and processes.

3.3.6 Utility and operability

In order to meet the utility requirement, a new product or process must be shown to be ‘operable’; it must be capable of being used to affect the object proposed. Operability is also an element of the disclosure requirement. U/s 112 the inventor must disclose in the specification how to use the invention in detail sufficient to one with ordinary skill in the art.

Operability is also an element of the rules on priority of invention. In interference between different inventors each claiming the same subject matter, a party must show possession of an operable product or process to establish prior actual reduction to practice.

3.3.7 Utility of Processes

Often a chemical inventor will discover a new compound or a new process to make a compound without discovering a specific practical human purpose to which the compound can be applied. The inventor may believe that a particular use can be made of the compound but not be able to meet the requisite standard of providing such use. It is now clear that such an inventor cannot obtain a patent on a compound or a process to make a compound unless he can show some specific utility for the compound. Discovery of some such utility is required before the invention is completed, that is, “reduced to practice,” actually or constructively. It is less clear what constitutes a sufficient minimum purpose served. For sufficient utility if the compound produces effects in
laboratory animals or functions as an intermediary to produce other compounds of known utility.

The utility requirement with respect to inventions relating to compositions of matter and to processes making the same is not quite so liberal. As held by the Supreme Court in *Brenner v. Manson*, some practical utility for the product of a chemical process must either be apparent to one skilled in the art or be disclosed in the specification for a patent application with claims directed to such process to satisfy the utility requirement. This rule applies a fortiori to product claims. It also applies in regard to the right of foreign priority under 35 USC sec 119, the benefit of an earlier foreign filing date not being accorded where the foreign application lacks a teaching of how to use a product claims.

The Federal Circuit upheld a Patent and Trademark Office rejection of patent claim for purified nucleic acid sequences encoding proteins and protein fragments because the claimed invention lacked a "specific and substantial utility." The court cited the Supreme Court's decision in *Brenner v. Manson* and stated:

the claimed ESTs (genetic sequences) act as no more than research intermediates that may help scientists to isolate the particular un-lying protein-encoding genes and conduct further experimentation on those genes ... the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit.

By "practical utility" is meant a specific and substantial utility. The Manual of Patent Examining Procedure provides the following guidance:

A "specific utility" is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

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Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition.

A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use.

The requirement that a specific utility must be disclosed is directed to one skilled in the art, so that a specific utility need not be expressly stated in the specification if such would be obvious to a person skilled in the art. Thus, a statement that the compounds claimed have "a better action and a better action spectrum as anti-tumor substances" coupled with favorable comparative test results showing the claimed compounds to be highly effective against two lymphocytic leukemia "tumor models" was deemed by the Federal Circuit as at least an implicit assertion that the claimed compounds are highly effective against lymphocytic leukemia, although the "tumor models" are not diseases--as the only way an animal can get sick there from is by direct injection of the cell line. Tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use. Adequate proof of any such activity constitutes a showing of practical utility. A well-known example of such a rejection occurred in a case where the inventor tried unsuccessfully to claim an "Energy Generation System Having Higher Energy Output than Input." Merely stating that the class of compounds claimed process "high biological activity" is insufficient to satisfy the utility requirement.

Evidence merely of inhibition of production of collagens in synovial cell cultures derived from arthritic rabbits was deemed insufficient to establish asserted practical utility in treating arthritis, evidence correlating such inhibition of collagens production and amelioration of an arthritic condition being lacking. Apparently, reliance cannot be
placed upon in vitro experiments unless the record of the case demonstrates an established correlation between such in vitro experiments and practical utility. Mere usefulness in further chemical research will not suffice to satisfy the utility requirement.

Accompanying the Guidelines for Examination of Biotechnology Applications is a narrative "Overview of Legal Precedent Governing the Utility Requirement." This overview contains a section on in vitro and animal testing, which states:

Data generated using in vitro assays and testing in animals almost invariably will be sufficient to support an asserted therapeutic or pharmacological utility. In no case has a Federal court required an applicant to support an asserted utility with data from human clinical trials.

If an applicant provides data from in vitro and animal tests to support an asserted utility, the Examiner should determine if the tests, including the test parameters and choice of animal, would be viewed by one skilled in the art as being reasonably predictive of the asserted utility. If so, and the data supplied is consistent with the asserted utility, the Examiner should not maintain a rejection under 101. This approach is to be followed not only in cases where there are art-recognized animal models for assessing utility in human disease and treatment, but also where no such validation of a specific test has been performed. Thus, if one skilled in the art would accept the animal tests as being reasonably predictive of utility in humans, they should be considered sufficient to support the credibility of the asserted utility. Examiners should be careful not to find evidence unpersuasive simply because no animal model for the human disease condition had been established prior to the filing of the application.

The Patent & Trademark Office had previously been criticized for its reluctance to accept in vitro and animal testing as proof of utility for an invention related to treatment of human disorders.
The mere discovery of an end use (as abrasive articles) for a composition of matter which in the prior art was used only as an intermediate (in the production of abrasive articles) does not entitle the discoverer of that end use to a patent on the composition. The Supreme Court held as failing to satisfy the utility requirement a patent application directed to a process of making a chemical compound for which there was no known specific utility. A chemical process must produce a useful product. The utility must be related to the composition's specific chemical structure; for all matter is useful, if only to the extent that it occupies space and possesses inertia. Where a chemical process generates several compounds, it is not necessary in order to satisfy the utility requirement with respect to such process that a specific utility be recited for each and every conceivable compound that may be produced thereby. Compositions within a claim need not have the same degree of utility.

The Court of Customs & Patent Appeals sustained a finding of utility by the Board of Appeals adequate to support an interference count to: "Crystalline micro spheres consisting essentially of uranium mono-nitride having a density of at least 90% of theoretical," based solely upon publications indicating that a number of installations had been studying uranium mono-nitride as a nuclear fuel with promising results. Apparently the publication relied upon said nothing about uranium mono-nitride in the form of crystalline micro spheres. Moreover, the utility must be practical. This is in contradistinction to "usefulness" in the sense of being only an object of scientific research, and this is true whether that research be directed to (1) the production of other compositions which do possess demonstrated practical utilities; or (2) the finding of a practical utility for the composition which is claimed or is produced by the claimed process. Evidence merely warranting further study does not establish patentable utility.

Not only must the requisite utility exist, but this must either be disclosed in the specification or be predictable. The Supreme Court found as insufficient the fact that another compound of the same class to which that under consideration belonged was known to possess tumor-inhibiting properties. Where an allegation of a specific utility is not mentioned in the specification and such is unknown to the prior art, the Patent &
Trademark Office may refuse to consider evidence thereof, on the ground that it would constitute new matter. Recitation of an intended use of a composition is not required in the claims, particularly when the written description of the specification is fully adequate in teaching a skilled worker how to utilize the claimed composition.

Where an allegation of a specific utility has been made in the specification, an applicant may submit evidence to prove such statements. When properly challenged by the Examiner, the applicant can provide evidence supporting the allegation of specific utility.

Where a specification contains a description of utility which corresponds in scope of the subject matter sought to be patented, it must be taken as sufficient to satisfy the utility requirement of 35 USC sec 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope. While the scope of a claim and the number of compounds included within the scope are not irrelevant to a 35 USC sec 101 and/or 35 USC sec 112, first paragraph, analysis, a claim is not unpatentable under 35 USC sec 101 or 35 USC sec 112, first paragraph, merely because compounds within its scope have different re-activities.

Where extra agent or incredible allegations of utility have been made in the specification, the applicant may be required to submit proof thereof. The Patent & Trademark Office has the initial burden of challenging a patent applicant's presumptively correct assertion of utility. If the Office provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility; as by providing references indicating that those skilled in the art would "reasonably doubt" the asserted utility and operability, the burden shifts to the applicant to submit evidence sufficient to convince such a person of the invention's asserted utility.

A method of vaccinating humans or animals to achieve immune protection against pathogenic E. coli was deemed sufficiently unusual in 1987 to justify an Examiner's requiring substantiating evidence. The mere fact that the art of cancer chemotherapy is
highly unpredictable places the burden on applicants to provide a basis for believing speculative statements that applicants place in the specification in the form of positive assertions. Noting that contemporary knowledge in the art of cancer therapy has far advanced since the days when any statement of utility in treating cancer was per se "incredible," a panel of the Patent & Trademark Office Board of Patent Appeals & Interferences has held that asserted improvement in the known effectiveness of interferon in the treatment of certain neo-plastic conditions by substantially simultaneous administration of another compound which inhibits a substance known to denature interferon does not amount to an incredible statement of utility. While incredible allegations of utility must be supported by evidence, proof of absolute safety or effectiveness is not necessary to satisfy the utility requirement. Amelioration of the symptoms or even cure of cancer is no longer considered to be "incredible." Whatever might have been the case earlier in the 20th Century, in 1992, the notion that a chemical compound may be useful in treating cancer was not inherently incredible. Cure for both the symptoms and the cause of arthritis involving merely placing a solution of lactic acid and water on one's skin is, on its face, "incredible." Nonetheless, decisional law would seem to indicate that such utility is sufficiently unusual to justify an examiner's requiring substantiating evidence.

Whether or not testing of an invention is required to establish utility, and if so, the nature and extent of such testing, depends on the facts of the particular case. No a priori rules can be formulated to meet the exigencies of each case. However, evidence merely warranting further study is not equivalent to evidence showing the type of utility required by 35 USC sec 101.

The examiner may require further assurance of usefulness where a reasonable doubt exists as to whether the invention will function as stated notwithstanding the asserted utility. It is proper for an examiner to ask for substantiating evidence when utility as a drug, mendicant, or the like in human therapy is alleged, unless one with ordinary skill in the art would accept allegations of utility as obviously correct. Where the Patent & Trademark Office alleges that the stated utility is of such an unpredictable
nature that one could not be certain that all animals and compounds within the scope of the claims would react in the stated manner, it is incumbent upon the Patent & Trademark Office to explain why it doubts the truth or accuracy of any statement in applicant's disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

It is not proper for the Patent & Trademark Office to require clinical testing in humans to rebut a prima facie case for lack of utility when the pertinent references which establish the prima facie case show in vitro tests and when they do not show in vivo tests employing standard experimental animals. It has been said that utility, particularly therapeutic utility, cannot be established by analogy. Whether in vitro or in vivo tests are needed depends on the facts of each case.

It is interesting to note that while product claims are distinct from those directed to the use or method of using the product, a use for the product is an indispensable part of a process patent.

By virtue of the Federal Food, Drug and Cosmetic Act, the Federal Food & Drug Administration requires that it be demonstrated to its satisfaction that all new drugs, before the same can be marketed, are safe and effective for their intended uses. So as not to prejudice the results, the testing protocol required by the Federal Food & Drug Administration is generally "double blind," i.e., neither the persons administering the drug nor the persons receiving the drug knows exactly what is being administered. It may be the drug, another drug that is believed the equivalent thereof, or a placebo. In single-blind tests, it is only the patient that is unaware of the exact nature of what is being administered. Double-blind tests are not necessary to establish the utility required by the Patent Act. The United States Court of Customs & Patent Appeals rejected attempts by the Patent & Trademark Office to equate the utility requirement of the Patent Act with the safety and effectiveness standard of the Federal Food, Drug and Cosmetic Act. However, a disclosure that lacks any information as to the host, the dosage level, mode or
routes of administration, or how to prepare the composition for administration would not satisfy the enablement requirement of 35 USC sec 112, first paragraph.

Having found that a claimed composition has utility as contemplated in the patent specification, 35 USC sec 101 is satisfied, and it becomes unnecessary to decide whether it is in fact useful for other purposes indicated in the specification.

The Federal Food & Drug Administration standard of effectiveness is the marketability standard and not the invention standard. The drug Thalidomide, while patented in the United States, never received marketing approval from the Food & Drug Administration. Pharmacological tests on animals are only done as screening devices to determine whether a drug has sufficiently low toxicity and some type of activity to provide a rationale for going on to test the drug on man. While human clinical data is far more significant to a determination of the effectiveness of a human drug than is animal data derived from testing on healthy animal preparations, pharmacological tests on animals are adequate to make a judgment with respect to patentability. Human clinical data are not required in assessing patentable utility.

Certainly if human use is not alleged, it need not be proved, veterinary utility being sufficient, even where the animals on which the tests are conducted are not generally used either for food or as pets. Substantiating evidence may be in the form of animal tests that constitute recognized screening procedures with clear relevance to utility in humans. In vitro experiments may suffice to establish patentable utility provided the record demonstrates a correlation between such in vitro experiments and a practical utility. When an applicant for a patent has alleged in his patent application that a new and unobvious chemical compound exhibits some useful pharmacological property and when this property has been established by statistically significant tests with "standard experimental animals," sufficient statutory utility for the compounds has been presented. Claims drawn to a composition of matter would entitle the patent owner to exclude another from any use of such composition even though the use is neither disclosed nor claimed in the patent specification. If existence of any substantial basis for an assertion of
human utility at the time the patent application is filed, it may be unwise not to mention such utility in the specification, as not to do so might endanger a charge of failure to comply with the best mode requirement. Failure adequately to document human utility would at worst result in a requirement by the Patent & Trademark Office to cancel its mention. It is not entirely settled whether or not in vitro tests are sufficient to establish therapeutic utility, at least where the claims recite in vivo use. Mere in vitro testing or mere testing on animals may suffice to establish utility in human treatment. That the tests are conducted outside the United States does not ipso facto make them unacceptable.

A certain minimum level of safety must be demonstrated even to satisfy the utility requirement of 35 USC sec 101. Basically this standard is that there should be no harmful side effects when the claimed composition is properly used. Proof of safety is required by the Patent & Trademark Office only in those cases where adequate reasons can be advanced by the Examiner for believing that the drug is unsafe, and the evidence submitted will be accepted if it establishes a reasonable probability of safety. The documentation required by the Food & Drug Administration would seem to far exceed that necessary to establish utility. The Patent & Trademark Office may request information on the conduct of research relating to drugs, with respect to patent applications, from the Secretary of Health & Human Services. Accordingly, it is possible to patent a drug and yet be unable to market the same as such, for failing to meet the standards of the Federal Food & Drug Administration.

3.4 EUROPE

3.4.1 European Patent Convention

There are three simple requirements for a patentable invention as set out in the European Patent Convention and in the laws of those countries which have acceded to it; as for example in the British Patents Act 1977. These are that the invention must be new; that it must involve an inventive step; and that it must be capable of industrial application. The same three requirements are met with in one form or another in the USA, Japan, India and indeed in practically every country, which has a patent system at
all. There are in addition certain matters, which are specifically excluded from patent protection, which are allowed by the provisions of TRIPs. These exclusions are not necessarily to be found in the laws of other countries, for example the USA and more extensive lists of excluded subject matter may be found in the laws of countries, which have not yet fully adapted their laws to TRIPs.

3.4.2 Novelty

The first and clearest requirement is that nothing can be patentable which is not ‘new’. If a patent were to be granted for something already known, then, on the classical theory of patent protection in exchange for disclosure, the patentee would be receiving something for nothing; there would be no consideration for the grant. Quite independently of this theory of the patent system, if the public at large, or even any part of it, knew of the information and were free to use it, then the grant of a patent in respect of this information would deprive the public of rights, which it previously had. Such a patent monopoly would be unjust for the same reason as Queen Elizabeth I monopolies on salt and playing cards.

Considering that the concept of novelty is so basic to patentability, it may seem odd that there are several different concepts of novelty, which have been applied to inventions. The most straightforward is that of ‘absolute novelty’ applied by the EPC that is, that an invention is new if it is not part of the ‘state of the art’, the state of the art being defined as everything that was available to the public by written or oral publication, use or any other way, in any country in the world, before the priority date of the invention.

Although some countries, for example France, have applied the absolute novelty criterion for many years, this concept was added by British patent law 1977 in India after TRIPs. Under previous patents Acts, ‘local novelty’ was the rule, which meant that a prior publication or use had to occur within that country in order to damage the novelty of a patent application. This concept goes back to the early days of patent, when patents
were frequently granted for inventions, which, although known abroad, were brought into
the kingdom for the first time by the patentee. Under the 1949 Act, it was still possible to
apply for a patent as an inventor by importation; for example, a person in the UK to
whom an invention was communicated from abroad has the right to apply for a patent.

Under the old British rule of local novelty, it was fairly well established that it
was enough to destroy the novelty of a later patent application if only one person in the
UK was in possession of information amounting to a description of the invention and that
person was free to do whatever he liked with the information. This remains true under the
1977 Act, and is also the law as applied in the European Patent Office by the Boards of
Appeal. Now it seems clear that a prior publication in, for example, a local newspaper in
'Daynic Bhaskar' would destroy the novelty of a British patent application even if the
publication was never read outside Rajasthan, India; a situation just as anomalous as that
under the old law according to which a printed US patent could be an effective
publication only from the day on which copies of it or its abstract arrived in the UK.

Some countries also have, or have had, a system intermediate between absolute
and local novelty. According to this 'mixed novelty' system, which is still the law in the
USA, a later patent application is rendered invalid by written publication anywhere in the
world but by use of the invention only in the home country; that is, prior use in foreign
country would not invalidate if there was no written description. This has sometimes
given rise to problems when patent applications have been filed in the USA relating to
aspects of traditional knowledge in countries such as India. A classic example in
USPTO, two patents was granted20 (to two Indian nationals resident in the USA) for the
use of turmeric in wound healing, something that had been known in India for thousands
of years. The use of the invention in India was not itself prior art in the USA, and
although there must have been some written descriptions of the invention, the search
carried out by the USPTO examiner did not find them. The patent was revoked in re-
examination proceedings instituted by the Indian government research organization
CSIR.

20 USP 5,401,504.
Japan has had all three types of novelty requirement within a relatively short time. Up to 1987, local novelty was the rule, then a mixed novelty system applied, and finally since January 2000, the law requires absolute novelty.

Under the absolute novelty system which is now the law under the EPC, prior use of an invention anywhere in the world would invalidate European patent application, if that use made the invention available to the public. The situation is clear if the invention is a machine, a gadget, or a chemical compound or composition, which can be analyzed and reproduced by the skilled person 'without undue burden'. In this case, sale makes the invention available to the public, and it is immaterial whether in fact anyone did investigate the workings of the machine or analyze the compound, or even whether or not anyone would have any motivation for doing so. However, the use, or even the wide spread sale to the public, of a complex mixture which cannot be precisely analyzed may to be held to make the invention which it represents available to the public. For example, it was held by a technical Board of Appeal that a control program stored on a microchip had not been made available to the public, although the chip had been sold because it would take man-years of effort to analyze it. However, in a later case it was held that the concept of 'undue burden' did not properly belong to the determination of novelty and that even if the commercial product could not be precisely analyzed, it would destroy novelty if the analysis enabled the production of anything falling within the claim.

A special situation is that of so-called 'selection inventions' in which an earlier publication discloses a broad class and the invention is, or is characterized by, a narrower subclass. This situation may occur in mechanical inventions in which the class in a group of structural elements, one of which is selected as being particularly useful. More usually, however, selection inventions are found in the field of chemistry, where a narrow group of compounds is selected from a known broad group. So long as no members of the narrow subgroup are specifically disclosed in the publication, it is generally considered, at least in USA and the EPO, that the compounds are novel, even though they may have been described in general terms. The narrow subgroup of compounds will,
however, only be patentable if it has some non-obvious advantage over the other members of the broad class, that is, if there is an inventive step in choosing that particular subgroup from all those generally disclosed.

An important question in considering novelty and inventive step is the position of earlier patent applications, which were not published at the priority date of a later application. Unpublished patent applications are not available to the public; and on the basis one would expect that they should not be considered as part of the ‘state of the art’. On the other hand, it has been a principle of patent law from the earliest times that not more than one patent should be granted for the same invention, since if this were not the rule, licensees could be forced to pay twice over to obtain the same rights, and the term of patent protection for one invention could be extended beyond the statutory period.

In the old British law and USA laws, this problem of ‘double patenting’ was dealt with by making it a separate ground of invalidity of a patent if the invention as claimed had been claimed in a granted British patent of earlier priority date. This approach was sound in theory, but in practice gave rise to a great deal of uncertainty. The situation often arose where the disclosure in the specification of an earlier application would clearly have been anticipation if it had been published before the priority date of a late application, but where the invention was claimed in somewhat different terms in the two applications. There were a number of cases in which the courts held that there had to be substantial identity between claims in order for this objection of prior claiming to be established, which greatly reduced the effectiveness of this approach.

Under the EPC the ‘whole-contents’ approach is adopted. Under this system, the whole contents (not only the claims) of an earlier unpublished application are considered. This is brought about by the simple expedient of defending the state of the art to include unpublished patent applications of earlier date, this greatly simplifies the situation.

In the EPO, an earlier unpublished European application is prior art against a later one, so long as it is not withdrawn before publication, and to the extend that it validly
designates the same countries. This means that the earlier application may be effective in respect of some states designated in the later application, but not against others. Unpublished European patent applications designating the UK can be prior art against a later British national application, and an earlier unpublished British application is prior art against a granted European patent (UK) under British law.

Although under the whole-contents approach the earlier unpublished application is considered to be part of the state of the art, this applies only to considerations of pure novelty, and not to the question of whether or not there is an inventive step. The existence of an earlier unpublished application can destroy the novelty of an invention, but cannot be used to argue that the invention is obvious. This possibility means that lack of novelty and obviousness must be clearly distinguished from each other. Nowadays the term 'anticipation' is normally used to mean lack of novelty, and is considered to occur when a piece of prior art (that is, a publication or use which was part of the state of the art before the priority date of the patent application in question) either is or describes something which would be an infringement of one or more of the claims in the application. That is, the test for anticipation is essentially the same as the test for infringement, and is met in the case of a written publication if the publication clearly describes something having every feature of the claim, or gives instructions to do something, which if carried out would give something falling within the scope of the claim. Thus a claim to a chemical compound may be anticipated by a description of a process if carrying out the process will inevitably give that compound, even if the compound itself was not described. However, anticipation requires 'more than a signpost upon the road to the patentee's invention... the prior inventor must be clearly shown to have planted his flag at the precise destination'.

Japan also has a system in which earlier unpublished Japanese applications are part of the state of art, but with the difference that earlier unpublished applications of the same applicant are excluded. In the USA a pending patent application of earlier date is a prior art against a later application, unless the later applicant can show that he had an

21 General Tire V. Firestone (1972) RPC 457 (CA).
invention date earlier than the date of filing of the earlier application. If it is prior art, it can be applied to attack both novelty and inventive step.

A disclosure formed by combining two documents together is not novelty destroying, although it may be relevant to the question of inventive step. Indeed, it is not even permissible in the EPO to attack novelty by combining two different embodiments described in the same document, unless the document itself indicates that they should be combined. Nevertheless the prior art document must be interpreted in the light of the common general knowledge of the skilled worker in the relevant field as of the date of publication, of the document. Needless to say, there is a gray area between what is clearly common general knowledge and what is simple another publication.

3.4.3 Inventive Step

The concept of novelty should be basically a simple matter, which should be capable of being tested rather easily once the claim in question has been ‘construed’, that is, has been logically analyzed to determine its scope. The question of whether or not something for which a patent is applied for involves an inventive step is one that is intrinsically much more difficult, since to some extent judgment of what is or is not obvious must be a subject matter.

Because the question is such a contentious one, there have been a great many patent cases in which obviousness has been at issue, and a great many judges have tried at various times to define what is meant by ‘obviousness’, or to pose questions such as ‘is the solution one which would have occurred to everyone of ordinary intelligence and acquaintance with the subject matter who gave his mind to the problem?’ or, more bluntly, was it ‘so easy that any fool could do it’?

23 Edison Bell v. Smith (1894) 11 RPC 457 AT 497 (CA).
The leading English case on obviousness probably is still the *Windsurfer case*,\(^\text{24}\) which although it was decided under the Patent Act, 1949, remains good law. In this case, the court of Appeal identified four steps which must be taken in the analysis of obviousness, namely:

Identifying the inventive concept embodied in the patent;

Imputing to a normally skilled but unimaginative addressee what was common general knowledge in the art at the priority date;

Identify the differences if any between the matter cited and the alleged invention; and

Deciding whether these differences, viewed without any knowledge of the alleged invention, constituted steps, which would have been obvious to the skilled man or whether they required any degree of invention.

With all respect, this circumlocution merely brings us back to the phrase ‘would have been obvious’ and does not really help us to decide when something is obvious and when it is not.

Finally, the matter should come down to the simple dictionary definition of obvious, i.e., ‘very plain’, bearing in mind that the reason for requiring the presence of an inventive step before granting a patent is that the ordinary worker in that field should remain free to apply his normal skills to making minor variations of old products.

Thus the person to whom the invention must be non-obvious if it is to be patentable is ‘the person skilled in the art’; a competent worker but without imagination or inventive capability. In the days when the great majority of patents were for relatively simple mechanical devices it was common to describe the person skilled in the art as ‘ordinary workman’. This is no longer appropriate in view of the increasing technical sophistication of industry. For chemical patents the person skilled in the art may normally be considered as the average qualified industrial chemist, and for complex inventions such as in the field of biotechnology, the notional addressee of the patent specification, the, person skilled in the art’ may be considered to be a team of highly qualified scientists.

It does become somewhat of a legal fiction to suppose that such a team could be competent but non-inventive, considering that its members would if employed in industry be expected by their company to make inventions as part of their normal duties, and if academic scientists would be expected by their university to produce original scientific work, which amounts to much the same thing. The point is that, obviousness should be judged by someone with average qualifications and imagination for those in the field. It is tempting for a party attacking a patent on the ground of obviousness to use an expert witness with the highest possible qualifications, but it is not very helpful to have a Nobel laureate testify that something is obvious. It may be obvious to a genius, but if it is obvious to the normal worker in the field, then obvious.

Among the principles which have been established in the course of the many cases obviousness are those there is no quantitative restriction on the size of the inventive step; i.e., the invention is patentable if it involves any inventive step, no matter how small. How the invention was made, whether as a result of planned research, a flash of inspiration, or even pure chance, is not relevant to the question of obviousness. An invention may be simple without being obvious, indeed producing a simple solution to what appears to be a complex problem is often highly inventive. It is often very easy to reconstruct an invention with the benefit of hindsight, as a series of logical steps from the prior art, but it does not necessarily follow that the invention was obvious, especially if there is evidence that the invention was commercially successful, or supplied a need. The question ‘if the invention was obvious, why did no one do it before?’ is usually a relevant one to ask, although there may often turn out to be a good reason why no one would bother to try.

The practice in the EPO is to apply the ‘problem and solution approach’ to inventive step. This derives from Rule 27(1) (c), which states that the invention is to be disclosed, in such a way that the technical problem (even if not expressly stated as such) and its solution can be understood. Having established what is the closest prior art, the examiner is supposed to determine what was the technical problem solved by the
invention, and then to judge whether or not the solution would have been obvious to the person skilled in the art. This procedure is supposed to make the evaluation of inventive step more objective, and to rule out ex post Facto analysis, but the difficulty is that the ‘problem’ is determined with hindsight in full knowledge of the invention as well as of the prior art, and may have had nothing to do with the problem the inventor was trying to solve.

In considering obviousness, anything in the state of the art, other than unpublished earlier patent applications may be taken into account. It was not permissible under the old law to ‘mosaic’ together a number of different publications, reconstructing the invention by taking a piece from one and another piece from another, unless for example one document directly referred to the other. The practice is that documents can be combined together in considering obviousness if a man skilled in the art would naturally consider them in association; thus it may be enough if they simply relate to the same technical field. The jurisprudence of the EPO is permissible to combine documents in assessing inventive step only if it would have been obvious for the skilled person to do so at the time of filing.

The concept of Patent Addition was not there found in EPO, any how earlier in UK Patent Act, it was there in 1977 for the compliance of EPO they repeated this concept.

3.4.4 Industrial Application

The third basic requirement of the EPC is that the invention should be capable of industrial application. Industrial application is broadly defined, and includes making or using the invention in any kind of industry, including agriculture. Methods of medical treatment or diagnosis performed on the human or animal bodies are defined as being incapable of industrial application, although substances invented for use in such methods

are patentable. This concept of 'industrial applicability' of an invention replaces the old and rather vague concept of 'manner of manufacture.'

3.4.5 Specific Exceptions:

The EPC make certain specific exceptions to patentability, which apply whether or not the invention is capable of industrial application. Artistic works and aesthetic creations are not patentable, and are generally not industrially applicable either; but scientific theories and mathematical methods, the presentation of information, business methods, and computer programs are also un-patentable, although they may very well be applied in industry. The practice of the EPO, based on decisions of the Board of Appeal, requires that for an invention to be patentable, it must be technical in nature. This is a very sensible approach 'technical' is interpreted broadly, but the criterion prevents the patenting in Europe of absurd 'inventions' such as that of a method of playing a tennis stroke, for which a patent was granted in the USA.\(^\text{26}\) However, it must be said that there seems to be no actual basis in the EPC for this requirement. Indeed, the word 'technical' appears in the EPC only in the context of the qualifications of members of the Board of Appeal.

Animal and plant varieties are not patentable in countries adhering to the EPC, although in the USA plants may be protected either by normal utility patents or by special plant patents for plant varieties. In EU countries like United Kingdom and certain other countries new plant varieties although not patentable can be protected by plant breeder’s rights granted under the UPOV convention. A major problem is presented by the fact that neither the EPO nor any other authorities gives a definition of what constitutes a 'variety'. Transgenic plants and animals are in principle patentable only if they do not constitute a variety. an application could be refused if the use of the invention would be contrary to law or morality, and also wider than that in the EPC, but uses the French term 'ordere public' instead of 'law'. At least the British wording makes it absolutely clear

\(^{26}\) USP 5,993,336.
that the provision relates only to publication or exploitation of the invention, and has nothing to do with any allegedly immoral behaviour of the applicant.

The EPC specifically states that an invention does not necessarily fall under this exclusion ‘merely because it is prohibited by law or regulation in some or all of the Contracting States’. If the use of an invention is illegal it is not necessarily unpatentable; a fortiori if its use is completely legal there seems no basis on which this exclusion from patentability could apply. The best view is that expressed in the Guidelines for examination in the EPO, which state that an invention should be excluded from patentability on this ground only if it was something which the public at large would consider abhorrent, for example an improved letter bomb. Nevertheless, article 53(a) is being used with some success by persons opposed to the patenting of animals, plants, genes, cells, and other biotechnological inventions, on the vague ground that this is immoral. But something is not necessarily contrary to morality just because one vocal group dislikes it.

A patent application could be refused because it claimed as an invention anything obviously contrary to well-established natural laws, for example a perpetual motion machine,” the EPC contains such a provision. Indeed, there is really no reason for one, since there is no explicit requirement that an invention actually works, and no one is likely to be much inconvenienced by the existence of a patent of something totally impractical. It is a fact that both in the UK and in the USA you may patent a perpetual motion machine so long as you give it an innocuous name. However, patent office examiners do not like to be made to look stupid, and if like Joe Newman you title your application ‘energy Generation System Having Higher Energy Output that Input’, you are asking for trouble. In the USA the Patent Office, used the power which it still has to require the inventor to produce a model ‘to exhibit advantageously’ his invention.”

27 S.10(1)(a), PA 1977
28 35 USC 114.
Newman did so, and produced a device which no one could prove did not work, but even though he appealed to the CAFC.  

3.5 INDIA  
3.5.1 Novelty  

The concept of novelty in intellectual property jurisprudence lay’s down that only what is new at the time of the filing of the application for a patent is patentable. Patent eligible subject matter is granted a patent if the subject matter is novel, non-obvious and is capable of industrial application. Of these requirements, novelty’s of core value. This is further emphasized by the definition of ‘invention’ as set forth in the Indian Patent Act. The Act lay’s down that invention consists of only a new product. The patent Amendment Act of 2005 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 filing of the application with the complete specification.

It has been laid down by Their Lordships of the Privy Council that “Invention is finding out something which has not been found out by other people. There are many instances in various branches of science of independent investigators making the same discovery. That does not prevent the one who first applies and gets a patent from having a good patent, for a patent represents a quid pro quo. The quid to the patentee is the monopoly; the quo is that he presents to the public the knowledge, which they have not got. That knowledge the other inventor has kept sealed in his own breast, and he therefore cannot complain that his rival got the patent. And if this is the case when a person can show that he actually made the discovery surely that is a much stronger case than the present, when the objector does not say that he did discover, but only that if he had

29 Newman V. Quigg 11 USPQ 2nd 1340 (Fed. Cir. 1989).  
30 Indian Patent Act, 1970, sec 2(j) reads “Invention” means a new product or process involving an inventive step and capable of industrial application”.  
31 Indian Patent Act, 1970, sec 2(1); Patents (Amendment) Act 2005, sec 2(g).
experimented he would have discovered. The real invention often may be and is just the last element of the combination. 52

In Raj Parkash V. Mangat Ram, 53 it was held that “invention, as is well known, is to find out something or discover something not found or discovered by anyone before... It is not necessary that the invention should be anything complicated. The essential thing is that the inventor was the first one to adopt it. The principle, therefore, is that every simple invention that is claimed, so long as it is something which is novel and new, it would be an invention...” A new invention may consist of a new combination of all integers so as to produce a new or important result or may consist of altogether new integers.

Patent system denies the issue of a patent to inventions that were disclosed prior to the time a patent application was filed at the Patent office. One of the conditions laid down by the United Kingdom Patent Act, 1977, is that a patent may be granted only for an invention, which is new. 54 The patent Act, 1977 was enacted to bring the law of UK into conformity with the corresponding provisions of the European Patent Convention. 55 In USA the concept of novelty is laid down in Title 35 of United States Code Sec 102. Novelty and anticipation are determined by reference to the language of the claim of the patent application. The grounds for opposition of a patent grant are almost the same as the tests for revocation of a patent once granted. Under section 64 of the Patents Act, a patent shall be revoked “where it is not novel”. 56 The Patents Amendment Act of 2005

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52 Pope Appliance Corp. V. Spanish River Pulp and Paper Mills Ltd., AIR 1929 PC 38.
53 AIR 1978 Del. 1.
54 United Kingdom Patents Act, 1977, Section 2 reads “(1) An invention shall be taken to be new if it does not form part of the state of the art.
(2) the state of the art in the case of an invention shall be taken to comprise all matters (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or oral description, by use or in any other way.”
55 Article 54 of European Patent Convention.
56 Indian Patent Act, 1970 sec 64 reads: “Subject to the provisions contained in this Act a patent, whether granted before or after the commencement of this Act, may, be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the Patent by the High Court or any of the following grounds, that is to say—
(a) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in India.
state that after an application for patent has been published and before the grant of a patent, the grant of patent may be opposed on the ground of novelty.37

3.5.2 Inventive step

Anticipation is a two step analysis. The first step involves construction of the claims of the patent at issue. In the second step, the claims are compared to the prior art. A claim will be anticipated, and therefore invalid, if every limitation is described in one prior art reference and the prior art is enabled such that one of ordinary skill in the art could practice the invention.

To be an anticipating reference, an item must disclose each and every element of the claimed invention. The test is to determine the elements of the claimed invention with that of the reference in issue. To anticipate a claim for a patent, a single prior source must contain all its essential elements. An invention said to be anticipated, only if another invention already known or used is identical in substance. A prior art reference must disclose all the elements of the claimed invention or their equivalents functioning in essentially the same way. Anticipation occurs only when some single prior article, patent or publication contain within its four corners every element of the claim in question. A patent is not anticipated when its elements are distributed among several prior publications and devices. Anticipation cannot be shown by combining more than one reference to show the elements of the claimed invention.

If the prior art reference does not expressly set forth a particular element of the

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37 Patents (Amendment) Act, 2005, sec 23.
claim, that reference may still anticipate if that element is inherent in its disclosure. To establish inherency, the extrinsic evidence must make it clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be recognized by persons of ordinary skill.

The Indian Patent Act refers to prior art as that which was published before the claim in any claim of a completed specification in

1. any specification filed for obtaining a patent in India or after 1st day of January, 1912.

2. in India or elsewhere and also in any other documents.

The only exception is where the applicant proves that the matter published was obtained from him and was published without his consent and that he had applied for the patent as soon as reasonably practicable after knowing about the publication. But this exception will not be available where the invention has been commercially worked in India otherwise than for the purpose of reasonable trial. The Act lays down that working of the invention for the purpose of reasonable trial can be considered as not anticipating the invention. The extent of publication required to constitute a ground for opposition was discussed in various decisions.

In Press Metal Corp. V. Nosher Sorabji, the invention was in relation to

38 Patents Act, 1970, section 29(2) reads: "Subject as hereinafter provided, an invention claimed in a complete specification shall not be deemed to have been anticipated by reason only that the invention was published before the priority date of the relevant claim of the specification, if the patentee or the applicant for the patent proves-

(a) that the matter published from him, or (where he is not himself the true and first inventor) from any person from whom he derives title, and was published without his consent or the consent of any such person, and

(b) where the patentee or the applicant for the patent or any person from whom he derives title learned of the publication before the date of the application for the patent, or in the case of a conversion application, before the date of the application for protection in a convention country, that the application or the application in the convention country, as the case may be, was made as soon as reasonably practicable thereafter.

Provided that this sub-section shall not apply if the invention was before the priority date of the claim commercially worked in India, otherwise than for the purpose of reasonable trial, either by the patentee or the applicant for the patent or any person from whom he derives title or by any other person with the consent of the patentee or the applicant for the patent or any person from whom he derives title."  
39 AIR 1983 Bom 144.
improvement in or relating to mufflers or exhaust silencers for internal combustion engines. The petitioners argued that the Controller was in error in rejecting the opposition that the invention as claimed by the inventor in the complete specification has been published before priority date of claim and that the invention was publicly known or used in India before the date. The controller overruled the objection of prior publication in “Motor Automotive Encyclopedia on the ground that no detail regarding the size of the perforations, which was one of the characterizing features of the applicant’s invention, was given in the books. The petitioners also opposed the grant of patent on the ground that the publication of the invention can be seen in the letters sent by Premier Automobiles Ltd, to the representatives of the inventor. The inventor has given 5 different mufflers to Premier Automobiles Ltd, for testing. The argument of the inventor was that none of the different silencers shown in the motor manuals could give any idea to any person to manufacture the applicant’s muffler. Having regard to the evidence adduced, the Court found that the claim made by the inventor is no more than a workshop improvement and the objection that the invention, as is claimed in the claim of the complete specification as, published before the priority date sustained.

Ram Narain V. Ambassador Industries, New Delhi, was a case in which the court found that the plaintiff had not specified the essentials required in a claim. The plaintiff in the patent-in-suit sought interim injunction to restrain the defendant from adopting the method and process for manufacturing, selling or offering for sale air coolers. The defendant claimed prior art. It was held that the plaintiff had not claimed, that the design proposed by him was an Improvement on any previously existing coolers, he had also not stated the advantages sought to be achieved by his invention. The plaintiff contended that the claim made by him read as a whole does disclose a improvement over the already existing coolers. The court concluded that the novelty/invention has to be succinctly stated in the claim. The applicant must describe the advantages sought to be achieved by his invention in the claim.

In Kay Laboratories, Bombay V. Hindustan Lever Ltd the invention was titled as a new method for making a plant growth nutrient/stimulant. The opponent alleged that it
was in fact discovered in 1977 at Michigan University and the results were published prior to the priority date of claims, and also the compound used in the invention was known much prior to 1977 and its reference was found in various books and literature, all available in India. The court held that prior publication was established and the application was rejected of anticipation.

Anticipation is judged by considering how a person skilled in the art would construe a prior publication. The issue was decided in Krishore Mahadeo Pole, G.M Walchand Nagar Industries Ltd V. Therax Pvt Ltd. The invention was entitled “a process for recovery of potassium sulphate from waste liquids such as distillery spirit wash”. The opponents relied on prior publication and prior public knowledge. It was held that the opponents failed to indicate all the steps of the invention was held to have a further improvement of incineration technology and was considered as novel.

In Indian Vacumm Brake Co.Ltd V. E.S.Luard, the petitioners were the holders of “Hardy Patent” and were importing from the factory in England and selling in British India vacuum brakes having certain specific features. The designs were published in and known publicly in British India since 1910. The respondent obtained a patent relating to the pistons of vacuum brake cylinders identical with the one of the petitioner. On detailed evidence, the court came to the conclusion that both in the working principle and general character of construction, the petitioner’s design and the respondent’s patent are founded on Hardy’s patent. It was also shown that the patented invention of the respondent was in use on Indian Railways long prior to the grant to the respondent.

Reckitt & Colman of India Ltd V. Godrej Hi Care Ltd, was an opposition to the grant of a patent to the application of M/s Reckitt & Colman of India Ltd, for their invention, “A mosquito/insect repellent device”. The opponents challenged the application on the ground of anticipation by prior claiming, prior public knowledge or public use and obviousness. The opponents relied on photographs of cordless ‘Good Night’ and also on

40 AIR 1926 Cal 152.
41 2001 PTC 637 (P.O).

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patent documents. The applicants opposed the patent document cited by the opponents that none of the patent documents were identical to the applicant's alleged invention. The applicants also submitted that the protection of designs to the mosquito repellent applies only to the feature of shape and configuration, pattern or ornament as applied to the art.

The tribunal after detailed scrutiny of the cited prior art found that the cited documents on patents and designs cannot establish anticipation by prior publication by combining the integers of the mosquito repellent from the cited patent and design article as produced by the alleged invention. The tribunal also found that the prior public knowledge or use cannot be applied as the citations of the designs and the US patent documents will not stop the prior users from doing what they were doing before.

A person cannot patent what was known or used by others in the country. "All ideas in general circulation be dedicated to the common good unless they are protected by a valid patent." The requirement for novelty differs from country to country. The USA Patent Act considers use and knowledge with the country alone as anticipating an invention. The Indian Patent Act provides that publication on or after the priority date of the applicant's claim 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 is a ground for opposition of patent. The UK patent Act has reflected the difference in the position between the USA and Indian Law. The UK Act lays down that the state of art can be said to contain everything that has been made available to the public whether in the UK or elsewhere. The Indian Act states that public knowledge and use can be a ground of opposition only if it was known or used in India. In the case of an invention related to a process, importation of the product made by the process to India is also considered as knowledge and used in India.

42 35 USC sec 102(a).
In *Surendra Lal Mahendra V. Jain Glazers*\(^45\) case the alleged invention is a laminating apparatus for producing a laminate by wet process as distinguished from dry process, plaintiff being already grantee of patents in respect of an invention for laminating apparatus but by dry process. The defendants denied the claim of the plaintiff contending that the patent was already known, published and used in India as well as throughout the world prior to the application in this case. In particular they averred that Morane Maxibond laminating machines were being imported into India from England. The court on a Juxtaposition of the plaintiff’s invention and the Morane Maxibond invention came to the conclusion that the plaintiff had not added a scintilla of invention to produce the same.

*Cadila Pharmaceuticals V. Insta Care Laboratories Ltd.*,\(^46\) the applicant produced an antibiotic combined with a dose of lactobacilli marketed under name LMX and patented it. Respondent, a pharmaceutical company started manufacturing similar combination drug. Same process was used in both. It was held that the process of making combination drugs of a chemical material and a micro organism was a well-accepted process and isolation of one of the ingredients by giving it a coating is also accepted. Hence the process had developed prior to the use by the appellants. Since the patent was for the process and not for the combination and as the process was known to pharmaceutical world for decades, the invention was found to be not novel.

“A man may make experiments in his own closet; if he never communicates these experiments to world, and lays them by, an another person has made the same experiments, and being satisfied, takes a patent, it would be no answer to say that another person had made the same experiments. There may be several rivals starting at the same time; the first who comes and takes a patent, it not being generally known to the public that man has a right to clothe himself with the authority of the patent, and enjoys the benefit of it”.

\(^{45}\) 1981 PTC 112.

\(^{46}\) 2001 PTC 472.
The Indian Patents Act states that a patent shall be revoked if the invention as claimed in a complete specification was secretly used in India otherwise that for the purpose of reasonable trial or experiment or by use by the government or by any other person who had obtained the knowledge with the consent of the applicant for the patent.47

The Patent Act provides certain exclusions in relation to information made publicly available through publication or use when deciding whether an invention is novel. They are:

1. any matter published without the consent of the patentee or his nominated person is to be disregarded so long as and the patentee had on learning of the publication made the application as soon as was reasonably practicable.48 But this exclusion cannot be applied where the invention was before the priority date of the claim commercially worked in India otherwise than for the purpose of reasonable trial either by the patentee or the applicant for the patent.

2. Communication to the government or to any person authorized by the government to investigate the invention or its merits.49

3. Publication of an invention at a recognized exhibition; description of the invention in a paper by the true inventor before a learned society and publication in the transactions of such society.50

49 Patent Act, Sec 30 reads "An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only of the communication of the invention to the government or to any person, authorized by the government to investigate the invention or its merits, or of anything done, in consequence of such a communication, for the purpose of the investigation".
50 Patent Act, 1970 Sec 31 reads "An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only of

(a) the display of the invention, with the consent of the true and first inventor or a person deriving title from him at an industrial or other exhibition to which the provisions of deriving title from him at an industrial or other exhibition to which the provisions of this section have been extended by the central Government by notification in the Official Gazette, or the use thereof with his consent for the purpose of such an exhibition, in the place where it is held; or

(b) the publication of any description of the invention in consequence of the display or use of the invention at any such exhibition, as aforesaid; or

(c) the use of the invention, after it has been displayed or use at any such exhibition as aforesaid, and during the period of the exhibition, by any person without the consent of the true and first inventor or a person deriving title from him; or
4. Public working of the invention for the purpose of reasonable trial having regard to the nature of the invention.\(^5\)

5. Publication of any matter described in the provisional specification after the date of filing of the specification.\(^6\)

The philosophy behind the concept of novelty is not only that patent should not grant the same monopoly twice but also that it is against the public interest to grant for a subject matter that has already been publicly disclosed.

3.5.3 Utility

An invention must be useful and capable of industrial application in order to be patented. There must be some demonstrable utility or specific benefit from an invention. The invention must have some practical utility in the form of immediate benefit to the public. As regards the conditions of industrial applicability, no special considerations should apply to certain specific type of inventions. The requirement of industrial applicability shall be satisfied not at the time of filing of patent application but at the time

\(^{(d)}\) the description of the invention in a paper read by the true and first inventor before a learned society or published with his consent in the transactions of such a society, if the application for the patent is made by the true and first inventor or a person deriving title from him not later than six months after the opening of the exhibition or the reading or publication of the paper, as the case may be.

5 Patent Act, 1970 Sec 32 reads “An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only that at any time within one year before the priority date of the relevant claim of the specification, the invention was publicly worked in India by the patentee or applicant for the patent or any person from whom he derives title, or by any other person with the consent of the patentee or applicant for the patent or any person from whom he derives title, if the working was effected for the purpose of reasonable trial only and... it was reasonably necessary, having regard to the nature of the invention, that the working for the purpose should be effected in public.”

6 Patent Act, 1970 Sec 33(1) reads, “Where a complete specification is filed or proceeded with the purpose of an application which was accompanied by a provisional specification or where a complete specification filed along with an application is treated by virtue of a direction under sub-section (3) of section 9 as a provisional specification, then notwithstanding anything contained in this Act, the Controller shall not refuse to grant the patent, and the patent shall not be revoked or invalidated, by reason only that any matter described in the provisional specification or in the specification treated as aforesaid as a provisional specification was used in India or published in India or elsewhere at any time after the date of the filing of that specification.

(2) Where a complete specification is filed in pursuance of a convention application, then, notwithstanding anything contained in this Act, the controller shall not refuse to grant the patent, and the patent shall not be revoked or invalidated, by reason only that any matter disclosed in any application for protection in a convention country upon which the convention application is founded was used in India or published in India or elsewhere at any time after the date of that applicant for protection.”

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of grant of the patent. It implies that at the time of filing the patent application if the invention has no practical utility or industrial application, nevertheless patent shall be granted, if the inventor could establish the utility before the date of the grant of patent.