CHAPTER 5

UTILITY

To be patentable, an invention has to be useful.[179] Utility or Usefulness of an invention is the second requirement for patentability. An invention is patentable only if it has some beneficial use for the society. Existence of usefulness in an invention determines its fate. If an invention is useful to the society, it is eligible for the patent domain else it enters the public domain. This Chapter elucidates the contours of the utility requirement in USA, Europe and India and analyzes its role in defining the size of patent and public domains.

USA

Section 101 of the United States Code provides that an invention has to be useful in order to get patent protection[180]. Courts and USPTO have been struggling to define the standards required to satisfy usefulness requirement. Case law and Utility guidelines of the US Patent Office have been attempting to coin the appropriate tests for usefulness that would suit all inventions. While the concept of usefulness has been in existence since the 1790 patent act, the first interpretation of the term "useful" was provided by Justice Story in Lowell v. Davis, in which he stated that an invention should not be frivolous or injurious to the well being, good policy, or sound morals of society[181]. Jurisprudence relating to utility requirement remained static for a long time after Justice Story's illumination of usefulness requirement until the US Supreme Court decision of Brenner v. Manson, which dealt with utility comprehensively[182].

Brenner V. Manson involved a chemical compound, which was an intermediate for a steroid compound having anti-tumor properties[183]. It was argued that the

[179] Usefulness, Utility and Industrial Applicability have been used interchangeably in this chapter.
[180] 35 USC Sec. 101 (2005).
[181] Lowell v. Lewis, 15 F.Cas. 1018, 1019 (No. 8568) (C.C.D.Mass.1817).
[182] Brenner v. Manson, 383 U.S. 519 (Mar 21, 1966).
[183] Id.

compound was useful for scientific research and that the intermediate, after conversion to the final product was chemically similar to or homologue of a compound having tumour inhibiting characteristics[184]. The court held that the existence of a homologue having tumor inhibiting affect in mice would not extend utility to the compound due to unpredictability of the field[185]. Furthermore, the court also held that the fact that process gives rise to the compound and that the compound is the subject of serious ongoing scientific research doesn't attribute patent utility to the compound[186]. If research is being conducted, utility can exist only after its completion. The Court went on to state that utility could be established only if specific benefit exists in currently available form[187]. It also stated that a patent is not a hunting license, not a reward for the search, but compensation for its successful conclusion[188].

In another case, 'In re Kirk', while dealing with utility of certain steroid compounds, the court held that a compound would not satisfy the utility requirement if experimentation were required to verify its utility[189]. The court stated that assertion of a general use that is yet to be ascertained would not make an invention useful under the patent law[190]. The court also stated that a compound would not be useful, if its use is to produce compounds of unknown use. Insubstantial, superficial nature of vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher' would not lend utility to the compound. Furthermore, the court stated that practical utility of the compound, or compounds, produced from a chemical 'intermediate,' the "starting material' in such a process, is an essential element in establishing patentability of that intermediate[191]. If a process for producing a product of only conjectural use is not itself 'useful', it cannot be

[184] Id. at 141.
[185] Id.
[186] Id.
[187] Id. at 142.
[188] Id.
[189] In re Kirk, 376 F.2d 936 (Cust. & Pat.App. 1967).
[190] Id. at 942.
[191] Id. at 945.

said that the starting materials for such a process-- i.e., the presently claimed intermediates-- are 'useful'[192].

'In re Krimmel', a case decided before Kirk and Brenner the Court of Customs and Patent Appeals, held that utility of a compound in the treatment of eyes of rabbit can be used to satisfy utility of the same compound in humans[193]. In another case, Nelson v. Bohler, the court held the use of a compound to influence blood pressure of rats in vivo and its ability to relax smooth muscle cells of gerbils in vitro to satisfy the usefulness requirement for humans[194]. These decisions enunciated that specific usefulness in mammals would satisfy the usefulness requirement for humans. Furthermore, In Cross v. Iizuka, the court held that the demonstration of biological activity of prevention of clumping of platelets through In vitro activity was considered to satisfy usefulness requirement thus reaffirming that In vitro activity would be enough to prove utility[195].

Later, In 'In re Brana', a case dealing with claims relating to antitumor compounds, the court held that claim specification satisfied statutory utility requirement by showing that compound was more effective in treating lymphocytic leukemia in mice than other known compounds[196]. As the antitumor compounds have a specific use directed toward a disease, the court held them to be useful[197]. The fact that celllines used in models were derived from mice did not destroy the utility of the compounds[198]. This case enunciates the applicability of tests done in animals to prove utility requirement. So, it can be said that the data generated from In vivo and In vitro tests is accepted for satisfying the utility requirement.

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[192] Id.
[193] Application of Krimmel, 292 F.2d 948 (Cust. & Pat.App. 1961).
[194] 626 F.2d 853 (C.C.P.A. 1980).
[195] 753 F.2d 1040 (Fed. Cir. 1985).
[196] In re Brana, 51 F.3d 1560 (C.A.Fed.,1995).
[197] Id.
[198] Id.

In 2005, the Federal Circuit decided 'In re Fisher', a case involving ESTs[199]. This can be considered to be the only case decided by Federal Circuit relating to gene-based inventions that delved comprehensively into the utility requirement. The case relates to a patent application claiming "expressed sequence tags" for identifying nucleic acid sequences in maize genes[200]. The claimed invention relates to five purified nucleic acid sequences that encode proteins and protein fragments in maize plants[201].

The application discloses the following uses for the five claimed ESTs:

(1) Serving as a molecular marker for mapping the entire maize genome, which consists of ten chromosomes that collectively encompass roughly 50,000 genes;

(2) Measuring the level of mRNA in a tissue sample via microarray technology to provide information about gene expression;

(3) Providing a source for primers for use in the polymerase chain reaction ("PCR") process to enable rapid and inexpensive duplication of specific genes;

(4) Identifying the presence or absence of a polymorphism;

(5) Isolating promoters via chromosome walking;

(6) Controlling protein expression; and

(7) Locating genetic molecules of other plants and organisms[202].

Despite claiming so many uses, the Federal Circuit held that the claimed invention had no utility. It started the analysis by citing Brenner v. Manson, which requires a specific utility in currently available form and which has been interpreted by the lower courts to mean specific and substantial utility[203]. As per decisions of various courts, 'substantial" utility' has been interpreted to mean significant and presently available benefit to the public and specific

[199] In re Fisher, 421 F.3d 1365 (C.A.Fed.,2005).
[200] Id.
[201] Id.
[202] Id. at 1371
[203] Id.

utility has been interpreted to mean an utility which is not so vague as to be meaningless and which has well defined and particular benefit to the public.

Considering the aforementioned principle, the court held that the utility requirement is not satisfied based on the following rationale:

a. As per Brenner, an invention, which results in an entity, which has no known functions, is considered to be not useful. As genes encoded by the claimed ESTs have no known functions, they are considered to be not useful[204].
b. Claimed ESTs are not useful as they act as no more than research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes. The overall goal of such experimentation is presumably to understand the maize genome: the functions of the underlying genes, the identity of the encoded proteins, the role those proteins play during anthesis, whether polymorphisms exist, the identity of promoters that trigger protein expression, whether protein expression may be controlled, etc[205]. These uses cited for the claimed ESTs are, in words of the Supreme Court in Brenner, mere "objects of use-testing," to which objects upon which scientific research could be performed with no assurance that anything useful will be discovered in the end and therefore have no utility under the patent law.
c. As the patent applicant has not presented either a single polymorphism or a single promoter, assuming at least one of each has been actually identified by using the claimed ESTs, he has failed to establish specific utility and all uses he has shown are uses that exist in all ESTs generally[206]. Asserted uses of Claimed ESTs are plainly not "specific" as any gene in the maize genome has the potential to perform any one of

[204] Id. 1372
[205] Id.
[206] Id.

the alleged uses. That is, any EST transcribed from any gene in the maize genome may be a molecular marker or a source for primers. Likewise, any EST transcribed from any gene in the maize genome may be used to measure the level of mRNA in a tissue sample, identify the presence or absence of a polymorphism, isolate promoters, control protein expression, or locate genetic molecules of other plants and organisms. As nothing about the patent applicant's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the patent application or indeed from any EST derived from any organism, they lack specific utility[207].

d. The patent applicant has failed to disclose in the specification that any of the claimed ESTs were used as a molecular marker on a map of the maize genome, that claimed ESTs were used or, for that matter, could be used to control or provide information about gene expression, that one of the claimed ESTs translates into a portion of one of those proteins and that claimed ESTs were used to locate genetic molecules in other plants and organisms and are therefore, not useful by virtue of having failed to satisfy the specific and substantial utility requirement.

As the patent applicant failed to prove that it's claimed ESTs can be successfully used in the seven ways disclosed in the application, the Federal Circuit decided that the claimed invention lacked utility under section 101. It further went on to say that granting of a patent over the ESTs would amount to granting a hunting license[208]. Though commercial use can be sufficient to prove utility, the court stated that it has not been proved in the case at bar because there is no proof of commercialization in libraries or agriculture. The court brushed aside policy arguments raised by the government and amici about the possible implications of granting patents to ESTs with unknown functions by

[207] Id.
[208] Id. 1375.

stating that such considerations are to be resolved by Congress and not by courts.

To summarize, as per judicial interpretation, an invention should have specific and substantial utility in order to satisfy the utility requirement in USA. The utility should be directed to a particular disease or aspect and general utility will not be sufficient. Usefulness for research and experimental purposes will not be sufficient to satisfy the utility requirement. Invitro and Invivo test data can be sufficient to prove utility and usefulness in animal models will be sufficient to satisfy utility requirement in humans. To reject utility asserted by an inventor, the USPTO has to be satisfied that a person with ordinary skill would doubt the utility of an invention.

USPTO's Guidelines

The decisions of the courts have largely been confusing and ambiguous, giving rise to lot of uncertainty in applying the utility requirement to genes and gene based inventions. Due to confusion created by various decisions of courts, the Commissioner of Patents held public hearings and issued 1995 Guidelines to clarify the USPTO's position on Utility.

A. 1995 Utility Guidelines

The Guidelines have been promulgated to assist Office personnel in the review of applications for compliance with the utility requirements of Sections 101 and 112 of Title 35 of the United States Code[209]. The 1995 Utility Guidelines "set forth a lower standard of proof of utility than that previously required by the USPTO for biotechnology inventions." Disclosure or assertion of a utility by the patent applicant, which would be considered specific and credible by one of

[209] Guidelines for Examination of Applications for Compliance with the Utility Requirement (1995) at http://www.uspto.gov/web/offices/pac/dapp/mpep_examguide.html visited on January 1st, 2006.

ordinary skill in the art, was henceforth considered to be sufficient to satisfy the utility requirement. Asserted specific utility has been defined by the Guidelines as a practical utility, which defines a "real world" context of use[210]. Utilities, which require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use, are considered to be not "specific utilities"[211]. Credible refers to the reliability of the assertion of utility based on the logic and facts offered by applicant to support the assertion of utility[212]. Thus the guidelines placed the burden on USPTO to prove lack of utility of an invention.

As per the 1995 Guidelines possession of actual sequence of the gene and its relevance to a disease or for research was considered to satisfy the utility requirement. In light of this reasoning ESTs could be granted patents based on their utility as probes[213].

B. 2001 Utility Guidelines

In December 1999, the USPTO issued the Revised Interim Utility Guidelines Training Materials to patent examiners and made them available to the public. The final version of the 1999 Utility Guidelines was promulgated on January 5, 2001[214]. The USPTO incorporated these guidelines into the Manual of Patent Examining Procedure. The guidelines were intended as a response to the huge volume of patent applications from the biotechnology industry for previously unknown DNA sequences that had no known biological function[215]. The 2001

[210] Definition, Chapter III Asserted Specific Utility, Guidelines for Examination of Applications for Compliance with the Utility Requirement (1995).
[211] Id.
[212] Definition, Chapter IV. Credible Utility Guidelines for Examination of Applications for Compliance with the Utility Requirement (1995).
[213] Mary Breen Smith An End To Gene Patents? The Human Genome Project Versus The United States Patent And Trademark Office's 1999 Utility Guidelines, 73 U. Colo. L. Rev. 747 at 767 (Spring 2002).
[214] Utility Examination Guidelines, 66 Fed.Reg. 1092 (Jan. 5, 2001).
[215] Julian David FormanAlbany Law Journal of Science and Technology A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications, 12 Alb. L.J. Sci. & Tech. 647 at 656 (2002).

guidelines require an invention to have "specific, substantial, and credible utility" in order to meet the requirements of 35 U.S.C. § 101. Credibility of utility is judged from the perspective of someone who is skilled in the relevant art, with the applicable question being whether that person would appreciate why the invention is useful. The guidelines do not clearly define the terms "specific" and "substantial"; instead they merely posit that the "requirement excludes 'throw-away', 'insubstantial', or 'non-specific utilities'.

The Guidelines suggest that the invention must have a real world use. The amount of additional research required to yield an immediate benefit is one factor toward the determination of whether an invention has real world use. "Throw-away" utilities, such as the use as ballast or "the use of a complex invention as a landfill," are insufficient to meet this requirement. Under the Guidelines, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target[216]. Similarly, a diagnostic utility would be considered a specific utility only if a specific disease or condition is likewise disclosed[217]. Under this standard, generalized utilities would be grounds for rejection under section 101.

The Training Materials explained the utility of genes and genetically modified animals with the help of examples[218]. Among them, examples 9 and 10 discuss about DNA fragments and Example 11 deals with claims over transgenic mice. The examples elucidate the utility criteria for receiving patent protection over gene related inventions.

Example 9[219] - This example discusses a 4332 nucleotides long sequence, which has been obtained from a cDNA library of an epithelial cell. Here the

[216] Revised Interim Utility Guidelines Training Materials, 1999 at http://www.uspto.gov/web/offices/pac/utility/utilityguide.pdf visited on January 1st, 2006.
[217] Id.
[218] Id. at 50
[219] Id. at 50

assumption is that the sequence is a fragment of a full-length gene, thus is a part of a coding region of a gene. So these fragments can be used as probes for identifying certain genes and making those genes by rDNA methods, which would enable one to study the functioning of those genes in the cell. The claimed invention in this example claims a cDNA fragment consisting of 4332 nucleotides.

The DNA fragment would not satisfy the utility requirement under section 101 because the claimed invention is not supported by specific and substantial utility or a well-established utility. The claimed cDNA compound is not supported by a specific asserted utility because the disclosed use of the nucleic acid is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence being claimed. Further, the claimed cDNA compound is not supported by a substantial utility because the specification states only that the cDNA compounds are useful as probes for assisting in the isolation of full-length cDNAs or genes, which would be used to make protein. Once the protein is obtained, the protein would be used in conducting research to functionally characterize the protein. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility.

In this case none of the proteins that are to be produced as final products resulting from processes involving the claimed cDNA have asserted or identified specific and substantial utilities. The research contemplated by applicants to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of the protein itself or the mechanisms in which the protein is involved does not define a "real world" context of use. Therefore, the claimed invention does not satisfy the utility requirement because it lacks specific, substantial and credible use under the patent law.

Example 10[220]- This example discusses certain Open Reading Frames (ORF), which has been identified from a cDNA library human kidney epithelial cells. This fragment shows homology to a particular DNA ligase enzyme, which helps in DNA repair. Also this ORF has been found to code for another ligase, thus showing the conservation of sequences in a particular gene family. Hence the identified fragment can be used for producing DNA ligase.

The invention claimed in this case is patentable as it has specific, substantial and credible use. The ORF has the specific utility of encoding a DNA ligase. Further, DNA ligases have a well-established use in the molecular biology art based on this class of protein's ability to ligate DNA. Since the ORF encodes for a DNA ligase, recognized by the artisan to have a specific, substantial and credible utility based on its enzymatic activity, the utility requirement is satisfied.

Example 11[221] - The invention described in this example is that of transgenic mice with genes responsible foe poly cystic kidney disease. Here, 8000 nucleotides long cDNA fragments were isolated from a cDNA library of Kidney cells from a patient with Polycystic Kidney (PCK) Disease. These fragments were used to make transgenic mice which could be used for studying the genetic basis of PCK disease which is a hereditary disease, whose chromosomal loci has not been identified. The genes were inserted into the mice but absence or presence of any particular protein coded by these genes could not be identified with the disease condition. The genetically modified mouse is not patentable as it lacks specific and substantial use.

The guidelines read with the case law determine the criteria for satisfying the utility requirement in USA. In order to be patentable an invention has to have

[220] Id. at 53
[221] id. at 55

specific, substantial and credible use. General, Insubstantial or throwaway uses are not acceptable. The credibility of an invention is determined from the point of view of a person with ordinary skill in the art. To receive patents over gene sequences or genetically modified animals or gene therapies, particular use has to be shown and generic uses will not be accepted.

EUROPE

In Europe and India, utility is referred to as Industrial Applicability. Article 52(1) of the European Patent Convention provides that European patents shall be granted for any inventions, that are susceptible of industrial application, and Article 57 provides that an invention will be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture[222]. So, in order to satisfy the requirement of Industrial Applicability in Europe, an invention should be capable of being manufactured or used in an industry. The Biotech Directive provides that sequences or partial sequences of genes have to be subject to the same criteria of patentability just like all other areas of technology[223]. It further provides that industrial application of a sequence or partial sequence must be disclosed in the patent application[224]. Recital 23 states that a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention[225]. However, if the function of a sequence or partial sequence of a gene to produce a protein or part of a protein and the function

[222] Article 52(1), Patentable inventions and Article 57, Industrial application, European Patent Convention of 5 October 1973, text as amended by the act revising EPC of 17 December 1991 and by decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996 and 10 December 1998.

[223] Recital 22, Directive 98/44/Ec Of The European Parliament And Of The Council of 6 July 1998 on the legal protection of biotechnological inventions, L 213/13 EN Official Journal of the European Communities 30.7.98.

[224] See supra note, Article 5.3 and Rule 23e(3) of Implementing Regulations To The Convention On The Grant Of European Patent of 5 October 1973 as last amended by Decision of the Administrative Council of the European Patent Organisation of 9 December 2004 .

[225] See Supra note, Recital 23.

such protein or part of a protein performs is specified then the sequence is considered to be Industrially Applicable[226].

As mentioned in Chapter 4, the European Patent Office considers public order and morality while determining patentability of an invention. Article 53 of the European Patent Convention provides that a European patent will not be granted in respect of inventions the publication or exploitation of which would be contrary to "ordre public" or morality[227]. Some scholars argue that determination of 'Industrial Applicability' includes morality analysis if the invention is a product of genetic engineering[228]. Support for their argument is derived from the Oncomouse decision of the Technical Board of Appeals[229]. Though the question of Industrial Applicability was never at issue in the "Oncomouse' case, the issue of the use, or industrial applicability, of the invention was addressed under the guise of answering questions relating to morality[230].

The Board in Oncomouse case stated that the public benefit to be gained from allowing the patent outweighed any possible suffering to the animal[231]. The Board equated the issue of morality with the public benefit to be obtained from the use of the invention[232]. Based on this scholars argue that the decision rendered by the Technical Board of Appeal suggests that as far as European patent law is concerned there must not only be a use shown for the invention but also that the use must then be shown to have some public benefit[233]. However, the European Patent Office has not connected the Industrial

[226] See Supra note, Recital 24.
[227] Article 53(a), European Patent Convention, 1973.
[228] Margaret Llewelyn, Industrial Applicability/Utility And Genetic Engineering: Current Practices In Europe And The United States, E.I.P.R. 1994, 16(11), 473-480 at 477
[229] Id.
[230] Id.
[231] Id.
[232] Id. at 478.
[233] Id.

Applicability requirement to morality or public benefit analysis and those are still treated as two separate enquiries[234].

The Industrial Application requirement for gene related inventions was elucidated by the Opposition Board of the European Patent Office in a case relating to a polynucleotide. Icos Corporation got a European Patent for a purified and isolated polynucleotide encoding the V28 seven transmembrane ("7TM") receptor. The patent was opposed on the ground of lack of industrial applicability along with other grounds and the Opposition Division revoked the patent[235]. The use of the invention as per the specification was the identification of additional seven transmembrane receptors (also known as G protein-coupled receptors that participate in immunological processes[236]. As per the specification, such a purified and isolated polynucleotide would: "for example, provide for the large scale production of the 7TM proteins, allow for the identification of cells naturally producing them, and permit the preparation/identification of antibody substances and/or other novel binding substances (including natural ligands, agonists and antagonists) which are specifically reactive with a particular 7TM receptor (or group of receptors) and which have the capacity to modulate the biological activities of the receptors[237].

The Opposition Board held that the invention could not be industrially applicable because the potential uses of the invention disclosed in the specification were based on insufficient disclosure of a proposed function of the V28 protein as a receptor[238]. The potential uses disclosed in the patent application were considered by the Board speculative. Furthermore, despite the isolation of a V28 cDNA clone from peripheral blood mononuclear

[234] Id.
[235] Rob J. Aerts, The Industrial Applicability And Utility Requirements For The Patenting Of Genomic Inventions: A Comparison Between European And Us Law, E.I.P.R. 2004, 26(8), 349-360. citingICOS Corporation/Novel V28 seven transmembrane receptor, , pp.293-308.O.J. EPO 6/2002.
[236] Id.
[237] Id. at 354
[238] Id.

cells and the expression of the V28 gene, among other things, in immune response relevant tissues, the involvement of the V28 protein in immunological processes was not considered as Industrial Application[239].

The case elucidates that speculative and tentative uses will not satisfy the Industrial Applicability requirement and that industrial applicability in gene related inventions has to be backed with conclusive experimental and scientific data.

To sum up, to satisfy 'Industrial Applicability' requirement in Europe, a gene based invention should be capable of being made and used in any Industry. A gene sequence with unknown or undisclosed functions will not satisfy the requirement. However, if the function of a sequence or partial sequence of a gene to produce a protein or part of a protein and the function such protein or part of a protein performs is specified then the sequence is considered to be Industrially Applicable. Having said that speculative or tentative uses of genes or gene related inventions will not be accepted. Experimental data may be required by the patent office to support the usefulness claim. Moral issues may be considered by the EPO under a different provision, while dealing with genetically modified animals.

Comparative Studies on Industrial Applicability

The USPTO, EPO and JPO have compared their practices with regard to biotech inventions in a series of studies with hypothetical examples[240]. The studies elucidate the interpretation of Industrial Applicability by different patent offices.

[239] Id.
[240] Trilateral Project 24.1, Comparative Study on Biotechnology Patent Practices Comparative Study Report at http://www.european-patent-office.org/tws/sr-3-bio.htm visited on January 3rd, 2006.

One of the hypothetical deals with the specification that discloses a cDNA library, which has been constructed from mRNA extracted from an important organ (example, brain)[241]. The specification further discloses that the cDNA library includes several DNA fragments detected specifically in an important organ/cell (example, cancer cell)[242]. The USPTO points out that the determination of the presence of Industrial Applicability requires additional facts in this example[243]. On the other hand, the EPO reveals that the industrial applicability of the cDNA library is acknowledged because such a cDNA library can be used in industry for the isolation and cloning of organ specific cDNAs coding for organ specific proteins[244]. It appears from the analysis that EPO's Industrial Applicability criteria are less stringent than that of USPTO.

The comparative study concludes that all nucleic acid molecule-related inventions, including full-length cDNAs and SNPs, without indication of function or specific, substantial and credible utility, do not satisfy industrial applicability requirement[245]. However, isolated and purified nucleic acid molecule-related inventions, including full-length cDNAs and SNPs, of which function or specific, substantial and credible utility is disclosed satisfy the requirement of industrial applicability[246].

In order to comply with the utility requirement in USA, an invention relating to a DNA sequence must be supported by a specific, substantial, and credible

[241] Id.
[242] Id.
[243] id.
[244] Id.
[245] Trilateral Technical Meeting in June, 2000, Trilateral Project B3b, Comparative study on biotechnology patent practices at http://www.european-patent-office.org/tws/sr-3-b3b-ad.htm visited on January 3rd, 2006.
[246] Id.

utility[247].The USPTO does not require any experimental evidence to demonstrate its function or utility. The burden of proof for establishing lack of utility is on the examiner. The examiner has to establish a prima facie case before the burden is shifted to the applicant. On the other hand, the EPO requires that the function performed by a claimed sequence and the protein it encodes are certain to the degree that a specific utility for the sequence becomes apparent beyond the realm of speculation[248]. If the alleged function of a claimed nucleic acid molecule is not credible beyond mere speculation the EPO will require experimental evidence demonstrating the function.

INDIA

As mentioned in Chapter 1, an invention is patentable in India if it is capable of being industrially applicable[249]. An invention is said to be capable of industrial application if it is capable of being used in an industry[250]. The provision is similar to the requirement under the European Patent Convention. Due to dearth of legislative history or case law relating to Industrial Applicability in India, the interpretation of the provision is based on the interpretation of the patent office stated in the Manual of Patent Practice and Procedure.

The Manual of Patent Practice provides that Industrial application of an invention is determined by confirming if the invention:

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

[247] Trilateral Project B3b, Mutual understanding in search and examination, Comparative study on biotechnology patent practices at http://www.european-patent-office.org/tws/sr-3-b3b_bio_search.htm visited on January 3rd, 2006.
[248] Id.
[249] Section 2(j) Indian Patent Act, 1970 as amended in 2005.
[250] Section 2(ac) Indian Patent Act, 1970 as amended in 2005.

iii. Can be reproduced with the same characteristics as many times as necessary[251].

As gene sequences and related inventions can be made and used in an industry and can be reproduced as many times as required, they would satisfy the Industrial Applicability requirement in India. The 'manufacture' and 'reproducibility' provisions are quite straightforward but it would be interesting to see how the Indian Patent Office and the courts would interpret the 'use' criteria. The guidelines for examining biotechnology inventions in the Manual of Patent Practice provide that gene sequences and DNA sequences whose functions are not disclosed do not satisfy the Industrial Applicability requirement[252]. So, just like in USA and Europe, functions of a gene should be known in order to receive patent protection in India. Furthermore, the Patent Act provides that new uses of a known invention are not patentable[253]. So, discovery of a new function for a known gene would not get patent protection in India.

Utility and Patent or Public Domain

Utility or 'Industrial Applicability' plays a very important role in defining the eligibility for patent domain and entry of a gene based invention into the public domain. The US provisions relating to utility of gene based inventions are more stringent when compared to European or Indian patent laws. This has been elucidated in the example cited in the trilateral comparative studies performed by USPTO, EPO and JPO, which has been cited under the portion on comparative study above. While US requires specific, substantial and credible utility, it would be enough if the invention can be made and used in an industry in Europe and India. While a DNA sequence, that has only research uses might not be patentable in USA, it might not have any problem in getting a patent in

[251] Page 13, Para 2.4, Chapter II, Manual of Patent Practice and Procedures 2005.
[252] 7.0 Biotechnology Inventions, Annexure - I,, Manual of Patent Practice and Procedure, 2005.
[253] Section 3(d), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.

Europe or India as long as the use in the industry is known and is not speculative. So, it appears that entry into the patent domain is tougher in USA when compared to Europe and India. So, gene sequences or related inventions whose functions are primarily for research might most probably enter into the public domain in USA, while they have better chances of entering into the patent domain in Europe and India. Therefore, utility requirement based public domain is larger in USA than in Europe and India.