

Clear and Complete Disclosure in Biotechnology Patent Applications – A Comparison of the Laws in the USA, Europe and India

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Introduction

The international patent regimes that allow for biotechnological patenting have come under considerable criticism concerning the ethical propriety of such patent protection. It is undeniable that advances in biotechnology have significantly enhanced the potency of the agricultural and pharmaceutical sectors.¹ Synonymous with these developments have been inventiveness and human endeavour. As a result the conflicting issues of sharing bio resources vis-à-vis the rendering of protection to the inventors of biotechnological matter assume paramount importance.² It is in this context that the debate on disclosure in biotechnology patents assumes relevance.

The anomaly in patenting biotechnological products arises because patent law was intended to satisfy the requirements of industrial technology. The advent of biotechnology necessitated that patent laws to be suitably modified to match the needs of science and technology.³ The traditional notions of adequate disclosure at the time of applying for a patent had to be altered to cater itself to biotechnological innovation.

International patent law is moving toward harmonization, especially since the adoption of TRIPS. The procedure for filing for a patent is therefore very similar in most jurisdictions. In Indian law, s10 of the Patents Act 1970 deals with the contents of a patent specification. s10(1) provides that the applicant shall describe the invention and begin the specification with a title. s10(2) and (3) state that the applicant shall furnish the Controller with drawings, models or samples to illustrate the invention, while s10(4) mandates that the applicant must include in the specification what is known as the “Best Mode” requirement (i.e. explaining the best method of performing the invention), the written description of the invention, and the claims, which are intended to delimit the exact scope of the monopoly claimed by the applicant.⁴

The purpose of this article is to achieve a comparative analysis of the requirements of disclosure for biotechnology patent applications, including enablement, Best Mode and

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¹ Y.G. Shim, “Intellectual Property Protection of Biotechnology and Sustainable Development in International Law”, 29 *N.C. J. Int'l L. & Com. Reg.* 157. The author notes that there are apprehensions as to the balancing of the interests seeking to profit out of biotechnology and the developing world. Moreover the exploitation of bio resources and the spread of genetically engineered technology in the environment require to be closely monitored.

² President George Bush Sr. of the United States (1989 to 1993) has pointed out that the US has objections to the Convention on Biological Diversity (CBD). The CBD provides for access of bio resources and intellectual property transfers of bio resources. Articles 15, 16 and 19, CBD impose obligations on Member States to provide access to, and transfer the benefits of biotechnology and bio resources to the developing countries. See: A. Streltzer, “U.S. Biotechnology Intellectual Property Rights as an Obstacle to UNCED Convention on Biological Diversity: It Just Doesn't Matter”, 6 *Transnat'l Law.* 271.

³ E. Verkey, “The Law of Patents”, (2005), p. 275.

⁴ D.P. Mittal, “Indian Patents Law and Procedure”, (2002), p. 88.

written description in different jurisdictions. Part I of this paper examines the philosophical and legal issues brought up by the need for disclosure in patent applications. The concepts of enablement, Best Mode and written description are introduced. Part II critically examines the biotechnology patenting regime in the US, focusing particularly on recent developments with regard to the abolition of Best Mode. Part III discusses the European patents regime by analyzing the Patents Act 1977 of the UK and the European Patent Convention. Part IV discusses Indian law encompassing the Patents Act 1970, recent controversies concerning the Protection of Plant Varieties and Farmer's Rights Act 2001, as well as biodiversity and traditional knowledge. Finally Part V concludes the article by providing recommendations on disclosure requirements for biotechnology, discussing *inter alia* TRIPS, the Budapest Treaty and culling out the most appropriate aspects of the law from the discussed jurisdictions.

I Adequate Disclosure

1.1 Biotechnology Patents – Scope and Rationale

Biotechnology can be defined as the creation of valuable products and processes for therapeutic, agricultural or industrial purposes by making use of living organisms⁵ Biotechnological products can be subject to various intellectual property regimes – trade secrets, patents and copyrights.⁶ Of these, patents are the most common, and are typically held as assets by biotechnology companies.⁷ They entitle the holder to produce, make use of and trade with the biotechnology product over a limited period of time, and is in the nature of a proprietary right.⁸

The foremost justification behind granting patent protection to biotechnological products is that such protection potentially encourages the high risk and heavy investment involved in biotechnology research and development.⁹ This, it is argued, will assist in combating endemic diseases and hunger, enhancing cultivation and furthering other benefits of genetic engineering. The trade-off that the inventor makes is disclosure of the product or process which is sought to be patented. The advantage of disclosure lies in the fact that it benefits both the patentee and society. The patentee is encouraged to disclose the invention in exchange for the patent protection that allows him scope for commercial exploitation. In addition, society benefits from the disclosure of an invention, since it adds to the general store of knowledge in society, and may stimulate further research in the technological art.¹⁰

1.2 Different Types of Disclosure

The patent specification in every patent application must disclose the invention clearly and completely enough for it to be performed by a person skilled in the art.¹¹ In English law this

⁵ R.K. Siede & F.A. Smith, "Intellectual Property Protection and Biotechnology", 67 – *JUN N.Y. St. B. J.* 52.

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ D.I. Bainbridge, "Intellectual Property", (2002), p. 373.

¹⁰ D.E. Komb, "Patent and Trade Secret Protection in University-Industry Research in Biotechnology", 24 *Harv. J. on Legis.* 191 at 210.

¹¹ W. Cornish, "Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights", (1999), p. 231.

requirement is contained in s14 of the Patents Act 1977. In Europe, Art. 83 of the European Patent Convention mirrors this provision. Analogous provisions in the USA and India are Article 112 of the Patents Act (USA) and s10 of the Patents Act 1970.

Disclosure requirements have subtle distinctions in different jurisdictions. The “How to Make” and “How to Use” disclosure requirements constitute “enablement.” In addition to this there is the Best Mode disclosure, the written description and the deposit requirement for micro organisms.

1.2.1 Enablement

The patent laws of the United States, Europe and India are substantially similar on the enablement requirement.¹² Art. 83 of the European Patent Convention provides the classical definition of enablement. It states that, “The European patent application must disclose the invention in a manner that is sufficiently clear and complete for it to be carried out by a person skilled in the art.”

A ‘person skilled in the art’, as defined by the UK court in 1876, is an “*ordinary workman, using that amount of skill of intelligence which is fairly to be expected from him, not a careless man, but a careful man, though not possessing that great scientific knowledge or power of invention which would enable by himself, unaided, to supplement a defective description or correct an erroneous description.*”¹³ In the US, the test is applied to a person of ordinary skill while in Europe, as per r27, a person skilled in the art must be able to reproduce the invention by applying his common general knowledge. Enablement disclosure in the patent specification should thus be intelligible to such class of persons.

There are two components to the enablement requirement– (1) How to Make and (2) How to Use. In determining the adequacy of this, disclosure requires consideration of the invention itself, as well as the state and development of prior art.¹⁴

The “How to Make” component of enablement therefore ensures that a person skilled in the art, applying ordinary skill and knowledge, can reproduce the invention on the basis of the application.

The enablement claim has to be specific and not unduly broad. In *Amgen Inc. v. Chugai Pharmaceutical Co.*¹⁵ DNA sequences coding for modified proteins having the same function, namely erythropoietin (EPO) which is a therapeutic substance having medicinal value in treating blood disorders, was sought to be patented. The disclosure covered certain products of recombinant DNA technology used to produce EPO, but did not cover the product EPO itself, since there were alternate methods to produce EPO without using recombinant DNA technology. It was held that the claim was invalid for lack of adequate disclosure as to how to make other DNA species within the broad genus of EPO. The impact of this decision is that the enablement disclosure must be specific, and not unduly broad. Broad claims can however be valid if they correspond to the disclosure of the invention.¹⁶

The second criteria that the enabling disclosure must fulfil is the “How to Use” component. The general rule is that there must be utility for every claim made, and such utility,

¹² *Supra* note 5 at 249.

¹³ *Plimpton v. Malcolmson*, (1876) 3 Ch D 531, Cited from: *Supra* note 5 at p. 251

¹⁴ *A.B. Dick v. Barnett*, 288 Fed. 799 (2nd Cir. 1923).

¹⁵ 927 F2d 1200 (Fed. Cir. 1994).

¹⁶ *Supra* note 15 at 258.

especially for biotechnological and pharmaceutical patents must always be expressly stated and can never be inferred.¹⁷ A utility to support a claim for a DNA sequence must be 'specific, substantial and credible.'¹⁸

In the American case of *Fiers v. Revel*¹⁹, Revel had filed for a patent for a DNA coded biotechnological product in Israel and sought to rely on that claim to establish priority over its American competitors. Revel claimed that it had disclosed clearly and adequately how to isolate DNA coding from J-IF (human fibroblast beta-interferon), a protein that had the therapeutic value of promoting viral resistance in human tissue and relied on the affidavits of two scientists who vouched for the fact that it was possible for a person skilled in the art to arrive at that solution without undue experimentation. However, another party, Fiers, had disclosed the complete nucleotide sequence of a DNA coding for J-IF. The Circuit Court held that Revel's disclosure was insufficient since what was required was not just an explanation of how DNA can be isolated from J-IF, but a description of the DNA itself. Further the Court held that a Japanese inventor, Sugano, had established priority because it had adequately disclosed a detailed method for obtaining the DNA coding for J-IF. Thus the legal position, as was re-enunciated in *In Re Gardner, Roe and Willey*²⁰, is that the specification must clearly state how to use the invention.

In Indian law, the "How to Use" requirement is enshrined in S. 10(4)(a) of the Patents Act 1970 wherein it is stated that the specification shall describe the operation or use of the invention and the method by which it is to be performed.

The requirement of enablement is also made compulsory by Article 29 of the TRIPS Agreement.²¹

1.2.2 Best Mode Requirement

The Best Mode requirement, which has evoked tremendous debate in the US lately and does not find a place in the European Patent Convention, means that the best method of carrying out the invention known to the inventor at the time of filing for the patent should be disclosed in the patent application, for each aspect of the invention.²²

The Best Mode requirement was enacted in 1870 and it forms a key consideration provided by the inventor in exchange for his patent rights. The philosophical justification behind the Best Mode requirement is that society would benefit from the knowledge of the inventor. If the Best Mode requirement were absent then the natural course of behaviour for inventors would be to disclose the inferior methods of fleshing out the invention while keeping the superior method for themselves.²³ In addition, the Best Mode requirement not only tells society how to make and use the invention as contemplated by the inventor, but also gives other inventors and companies a fair chance to compete after the period of the patent

¹⁷ *Ibid* at 328.

¹⁸ *Id.*

¹⁹ 984 F. 2d 1164 (Fed. Cir. 1993).

²⁰ 427 F. 2d 786 (CCPA 1970).

²¹ Article 29 (1), TRIPS Agreement states, "Members shall require that an application for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art..."

²² *Supra* note 15 at 329.

²³ D.L. Carlson *et al.*, "Patent Linchpin for the 21st Century – Best Mode Revisited", 87 *J. Pat. & Trademark Off. Soc'y* 89 at 92. The authors argue that the Best Mode requirement serves the dual purpose of giving an incentive to innovate as well as promoting private funding in research.

expires.²⁴

While disclosure is often referred to as an objective requirement, there is no disputing the fact that the Best Mode requirement is a subjective one, since it necessarily requires disclosure of the best method contemplated by the inventor. In practice, the Best Mode requirement may often be difficult to establish since failure of compliance must be proved by clear and conclusive evidence.²⁵

The Best Mode requirement is criticized severely because it is a disclosure requirement that is said to be too onerous upon the inventor. Although it is contained in Article 112 of the Patents Act, it is proposed to be removed in the US by the Patents Reform Act 2005. Those sceptical of Best Mode argue that it is actually a disincentive to innovate, leads to greater litigation and induces the inventor to forego a patent and obtain a trade secret instead.²⁶ In the US, the National Research Council of the National Academies (NRCNA) recommended abolition of Best Mode on two grounds – first, that it produces a negative result on a cost benefit analysis and second, that it is an impediment to international harmonization,²⁷ considering that Europe for example has no Best Mode requirement.

The TRIPS allows for states to incorporate Best Mode in Article 29. Under Indian law, it is contained in s10(4)(b) of the Patents Act 1970.²⁸

1.2.3 Written Description

Written descriptions are another disclosure requirement *sine qua non* to the grant of a patent. In simple terms, the written description requirement mandates that the specification describes and explains the invention claimed.

The import of the phrase “written description” was succinctly explained in *University of Rochester v. G.D. Searle & Co., Inc., Slip Op.*,²⁹ where it was observed that the “inventor must be able to describe the item to be patented with such clarity that the reader is assured that the inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection.”³⁰

The purpose of the written description is to allow persons skilled in the art to get a fair understanding of the invention and also serves to ensure that the patent applicant was actually responsible for the invention himself.³¹ It is imperative that the written description is complete – in *University of California v. Ei Lilly*³² it was held that the written description was not sufficient since the description of DNA of insulin in one species did not constitute a written description for all species.

The problem that arises with respect to written descriptions and biotechnological inventions is that it is virtually impossible to ambiguously describe a microorganism by written

²⁴ *Id.*

²⁵ *Railroad Dynamics Inc. v. A. Stucki Co.*, 469 US 871 (1984).

²⁶ *Supra* note 25 at 95.

²⁷ *Supra* note 25 at 102.

²⁸ S. 10(4)(b) states, “Every complete specification shall state the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection...”

²⁹ 00-CV-6161L, p. 1 (W.D.N.Y. March 5, 2003).

³⁰ M.N. Manak, “The Law of Written Description in Pharmaceutical and Biotechnology Patents”, 23 *Biotechnology L. Rep.* 30 at 32.

³¹ *Ibid* at 34.

³² 43 USPQ 2d 1398 (Fed Cir. 1997)

description.³³ To circumvent this problem, the Budapest Treaty was enacted. The Budapest Treaty allows the deposit of a strain/sample of the claimed microorganism. This ensures a sample is also available to the public.

There exists no doubt about the fact that the applicant must be fair, honest and open in his disclosure.³⁴ However whether or not there exists a duty of good faith is not clear.³⁵ It is pertinent to observe that all these three requirements – enablement, Best Mode and written description are conceptually and practically distinct. But together they comprise the substance of adequate disclosure comprehensively.

The next chapter critiques the disclosure requirements for biotechnology patents in US law.

II. USA and The Law of Disclosure in Biotechnology Patents

2.1 Enablement in the USA

The enablement requirements in the USA and Europe are largely similar. In addition to Article 112 of the Patents Act, the best way to understand the law pertaining to enabling disclosure would be through case studies. In *Genetech Inc. v. Novo Nordisk*³⁶ a specification that was filed in 1979 for the purpose of protecting a protein of hGH amino acids was struck down. The specification contained only a generic statement of the possibility of cleavable fusion expression along with the DNA sequence, but it did not describe in any detail how to make hGH using cleavable fusion expression. The Court rejected the patentee's argument that the disclosure was sufficient to enable a person skilled in the art to be able to provide all the missing information. The Court held that the specification must supply the novel aspects of the invention and reasonable details must be provided to enable members of the public to carry out the invention.

The standard laid down by the American courts for biotechnology enablement is high and strict. Another example of this is *Enzo Biochem Inc. v. Calgene Inc.*³⁷. The Federal Circuit invalidated two related patents concerning “antisense technologies”. The claims made were broad. They stated that the invention was applicable with respect to any organism containing genetic material, but taught only the application of “antisense technology” in regulating three genes. The broadness of the claim coupled with the fact that “antisense technology” was very unpredictable and required a detailed amount of explanation. In addition, if undue experimentation is required by a person skilled in the art to arrive at the invention, the disclosure is not adequate. These factors were sufficient to render the patent invalid. The Court employed the “Wands factors” in arriving at its conclusion.³⁸

³³ *Supra* note 15 at 248.

³⁴ *Supra* note 12 at 235.

³⁵ *Id.*

³⁶ 108 F 3d 1361 (Fed. Cir. 1997).

³⁷ 188 F 3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999).

³⁸ In this case, the Court referred to 8 factors, known collectively as the “Wands factors.” The Wands factors are (1) the quantity of experimentation necessary. (2) The amount of direction or guidance presented. (3) The presence or absence of working examples. (4) The nature of the invention. (5) The state of the prior art. (6) The relative skill of those in the art. (7) The predictability or unpredictability of the art. (8) The breadth of the claims. These are the factors to be considered in determining the validity of a claim based on adequate disclosure. See: D. Chisum, “Chisum on Patents”, Vol. 3, (2000) at p. 26.

The enablement requirement is a question of law.³⁹ The Court, in determining the validity of a specification, will consider various factors (i.e. Wands factors). If one individual Wands factor is not satisfied, that does not by itself render the patent application invalid. What needs to be considered is whether the disclosures in the application are enabling as per the Patents Act. It is sufficient as long as the application in totality contains the necessary enabling disclosure.⁴⁰

It is desirable that biotechnology patents in particular avoid allowing broad claims. The reason for this is that biotechnology as a science is unpredictable⁴¹. Therefore it is important to limit what an inventor claims to exercise patent rights over, for broad claims may encompass areas that the invention is incapable of providing and enabling disclosure for.⁴²

There has been some inconsistency over the extent of restrictiveness of the enabling disclosure. In *In Re Wright*⁴³ the Federal Circuit allowed only the narrowest claims to a vaccine genetically engineered to protect against retroviruses.⁴⁴ *Festo Corp. v. Skoketsu Co.*⁴⁵ further narrowed the scope of claims by stating that elements that seek to narrow down the claims, for which the inventor cannot establish an explanation, are subject to prosecution history estoppels. The effect of this is to eliminate the doctrine of equivalents⁴⁶ and tremendously narrow down the scope of biotechnology patents.

Thus whether the doctrine of equivalents should be rendered nugatory in such a manner is a debatable question. One could argue that high disclosure requirements and their narrow interpretation impede the incentive to innovate, but on the flip side, for biotechnological products and processes that often have therapeutic and medicinal value, the high enablement requirement could also be seen to be desirable.

³⁹ A.S.Y. Lim, A.S. Christie, "Reach-Through Patent Claims in Biotechnology: An Analysis of the Examination Practices of the United States, European and Japanese Patent Offices", *I.P.Q.* 2005, 3, 236-266 at p. 247.

⁴⁰ *Id.*

⁴¹ A.E. Cantor, "Using the Written Description and Enablement Requirements to Limit Biotechnology Patents", 14 *Harv. J.L. & Tech.* 267 at 285.

⁴² A primary example of this is when claims are very general, covering an entire genus or species. In *Vacek's* case, the specification listed two specific species of *Bacillus* that could be used as a source of the protein as well as nine genera of cyanobacteria that could be used as hosts. The claims were not limited to only the species or genus disclosed in the application. The Court rejected the claims for want of enablement, but upheld the two specific claims made in the specification. See *Vacek*, 947 F. 2d 488 (Fed. Cir. 1991). *Supra* note 43 at 289.

⁴³ 999 F. 2d 1557 (Fed. Cir.) 1993. See: K.S. Canady, "The Wright Enabling Disclosure for Biotechnology Patents", 4 *Fed. Circuit B.J.* 243.

⁴⁴ "Dr. Stephen E. Wright used recombinant DNA technology to develop a vaccine against an RNA virus that causes tumors in chickens. Wright applied for a patent on his strategy for genetically engineering vaccines against RNA viruses. His patent application included claims covering the specific vaccine he had developed, vaccines against other avian tumor viruses, and vaccines against pathogenic RNA viruses in general, which include the AIDS and leukemia viruses. The patent examiner rejected, for lack of enablement, all of Wright's claims except those limited to the single chicken tumor virus Wright described in his patent application." Cited From: *Supra* note 45.

⁴⁵ 234 F. 3d 558, 56 USPQ 1865 (Fed. Cir. 2000).

⁴⁶ "The doctrine allows products and processes that do not literally infringe the claims of a patent to be found to infringe if they are sufficiently similar to the claimed product or process." Cited From: S.R. Arriola, "Biotechnology Patents After Festo: Rethinking the Heightened Enablement and Written Description Requirements", 11 *Fed. Circuit B.J.* 919.

2.2 Utility

A biotechnology product/process to be patentable in the US must have utility. Article 101 of the Patents Act states that an invention must be useful. There must be one specific, credible and substantial utility of the invention, either evidenced in the specification or otherwise well established.⁴⁷ A substantial utility has been defined as a “real world” use.⁴⁸ The judicial interpretation of the utility requirement in the US has been strict with the Supreme Court negating a patent in the case of *Brenner v. Manson*⁴⁹ because the steroid compound, though possessing a possible tumour inhibiting effect in mice, had not been shown to be of any use in humans.

For biotechnological inventions in particular, two possible views of utility could be taken. One view supports the idea that evidence of utility for a specific compound can be dispensed with since the evidence over the entire genus of compounds described was not necessary.⁵⁰ The second, and more acceptable view was taken in *In Re Hozumi*⁵¹ that utility for solid tumours was not established by showing utility for an entire genus of tumours. The decision was in the context of a biotechnological product sought to be patented for chemotherapy. Given the importance of medical benefits, as well as the unpredictability of cancer cure, speculative statements are not to be permitted⁵² and the utility requirement is to be construed strictly.

2.3 Best Mode Requirement

The Best Mode Requirement has been the source of much animated debate in the US, with the Patent Reform Act 2005 seeking to delete this requirement from Article 112 of the Patents Act. Without the Best Mode requirement, the patentee will get the benefit of his monopoly, but at the same time, the public will be deprived of the knowledge as to what the best method of using the patent is, a result that some argue is antithetical to the US Constitution.⁵³ In addition, it may allow inventors to file additional improvements that they may have been aware of earlier and extend the duration of the patent.⁵⁴

The Best Mode requirement is generally considered to be subjective since it is meant to encapsulate what the inventor contemplated was the best method of performing the invention. In *Young Dental Manufacturing Inc. v. Q3 Special Products Inc.*⁵⁵ it was held that in order to ascertain compliance with Best Mode two factual inquiries need to be made – first, the subjective component, that tests whether at the time of filing the patent application, the inventor knew of a better method of making the invention and second, the objective element, in determining whether what was disclosed as the Best Mode can be practiced by those persons having ordinary skills in the art. These two requirements need to

⁴⁷ *Supra* note 41 at 249.

⁴⁸ *Id.*

⁴⁹ 383 U.S. 519, 86 S. Ct. 1033 (1965).

⁵⁰ L. Westerlund, “Biotechnology Patents – Equivalency and Exclusion under European and US Patent Law”, (2002), p. 95.

⁵¹ PTO Comr, 11-02-1985, 226 USPTQ, Cited From: *Id.*

⁵² *Supra* note 52.

⁵³ “Elimination of the Best Mode Requirement”,

http://www.piausa.org/patent_reform_issues/elimination_of_the_best_mode/ (Last Visited: 16th November 2005)

⁵⁴ *Id.*

⁵⁵ 112 F. 3d 1137 (Fed. Cir. 1997).

be satisfied in a Best Mode disclosure.⁵⁶

There is divergence of legal opinion as to whether the actual intent of the inventor is relevant in determining a Best Mode violation. It was held in *Glaxo Industries v. Novopharm*⁵⁷ that the intent of the inventor should not be taken into account, for this was not necessitated by the wording of Article 112 of the Patents Act. This appears to be a logically sound view.

Decisional law on Best Mode reveals the ambit of its operation. In *Evans Medical Inc. v. American Cyanamide*⁵⁸, the defendants argued that the plaintiffs had known of a better method in that they had not disclosed the best antibody for the patented process. The Court rejected this contention on the ground that though there might have existed better methods, the plaintiff chose that particular antibody for the purification process. As to the objective part of the Best Mode disclosure, the plaintiffs argued that their disclosure was sufficient for a person skilled in the art to perform the patented process. The Court held that though the descriptions were vague, and suspiciously so, there was insufficient evidence to warrant ruling that there had been a Best Mode violation.

In *United States Gypsum Co. v. National Gypsum Co.*⁵⁹ the Circuit Court ruled that since the purpose of Best Mode was public welfare, and to prevent the inventor from concealing his invention from the public, the time to examine whether the objective element of the Best Mode disclosure had been satisfied or not, is the date when the patent is issued and not the date of application.

It is often argued that a Best Mode challenge is of a very subjective nature and dependent on the personal philosophies of judges, and their inclination to weigh one relevant factor over another.⁶⁰ For this reason, it is believed that Best Mode leads to confusion and added litigation. Over and above this, abolishing the Best Mode requirement also would lead to international harmonization,⁶¹ since the European patent regime is Best Mode free. These two have been the most significant motivating factors behind the proposed revamp by way of the Patents Reform Act of 2005.

2.4 Written Description and Deposit

The oft-quoted decision that explains the concept of written description is *University of California v. Ei Lilly*⁶² where the University had isolated and sequenced the gene only for rat insulin, and the patent claimed genes for all mammalian insulin, including humans. The description was sufficient for the person skilled in the art to be able to isolate the human insulin gene, but the patent was held not to have satisfied the written description requirement, since the patentee never obtained the human insulin gene, nor did he describe it.

⁵⁶ See also: *Chemcast Corp. v. Arco Industries Corp.*, 913 F. 2d. 923 (Fed. Cir. 1990).

⁵⁷ 52 F. 3d 1043 (Fed. Cir. 1995).

⁵⁸ 52 USPQ 2d. 1455 (Fed. Cir. 1999).

⁵⁹ 74 F. 3d 1209 (Fed. Cir. 1996).

⁶⁰ T.S. James, "Implications of the Best Mode Requirement on Patents Involving Biotechnology", 2 *Hous. Bus. & Tax. L.J.* 96 at 142.

⁶¹ P. Grier, "Bill in Congress to Overhaul Patent Law Seeks to Quell Suits Support Seen to Make U.S. System More Consistent with Others", *The National Law Journal*, <http://www.law.com/jsp/article.jsp?id=1124109330603> (Last Visited: 16th November 2005)

⁶² 43 USPQ 2d 1398 (Fed. Cir. 1997).

*Enzo Biochem Inc. v. Gen-Probe Inc.*⁶³ held that the claims directed to nucleic acid probes that were described only by their function of selective hybridization did not satisfy the written description requirement. Later on it was held that a deposit of a sample was sufficient to meet the requirement for those sequences that were deposited.⁶⁴

These two cases illustrate the working of the written description requirement – how it is pivotal for a drafter of a patent specification to be very precise and specific, and how because of the difficulty of describing biotechnological processes, the law has evolved to accept deposits as a valid substitution for a written description since it serves the purpose of sharing information with the public.

In the next chapter, it would be suitable to examine how these disclosure requirements operate in Europe and the UK.

III. Disclosure in Europe and the UK

3.1 Enablement

Art. 83 of the European Patent Convention is the provision concerning enablement. Art. 83 states that an invention must be disclosed clearly and completely enough to be carried out by a person skilled in the art. R. 27 of the Implementing Regulations to the Convention on the grant of patents requires that the content of the specification must contain adequate technical information to enable a person skilled in the art to be able to perform it.⁶⁵

It assumes significance that for certain biotechnological inventions, disclosure has to be judged on a case-to-case basis since products or processes may contain inherent peculiarities. For example, the disclosure of nucleotides and amino acids has the additional requirement of listing of sequences.⁶⁶

In addition, it is a feature of European patent law that not every feature needs to be disclosed in the specification, since the claim relies on the skilled person's additional knowledge.⁶⁷ Herein there lies a distinction between the EPC and the US law. Under the EPC, only the "essential" features of the claim are scrutinized for adequate disclosure. In the US, this distinction between essential and non-essential features does not exist, and the claim is thus checked for disclosure more strictly.

Under UK law, lack of sufficiency is considered a ground of invalidity under s72 of the Patents Act 1977. The question of adequate disclosure in the UK was answered in the landmark decision of *Biogen Inc. v. Medeva Plc.*⁶⁸ Two antigens to the Hepatitis B virus, HBeAG and HBsAG were produced by Biogen using recombinant DNA technology. Although the specification enabled the production of both core and surface antigens, Biogen accepted that they would be entitled to the patent only if they were entitled to the priority date since there had been publication of a better method six months later. The House of Lords ruled against Biogen, since the claims covered every way of achieving a result while showing only one way of doing so.

⁶³ 62 USPQ 2d 1289 (Fed. Cir. 2002).

⁶⁴ J. Behringer *et al.*, "Amgen v. Hoechst Marion Roussel: The Written Description Standard in Biotechnology Patents", 22 *Biotechnology L. Rep.* 476.

⁶⁵ *Supra* note 41 at 248.

⁶⁶ R. 27a, Implementation Regulations, Cited From: *Supra* note 52 at 64.

⁶⁷ *Ibid* at 65.

⁶⁸ [1977] RPC 1.

The House of Lords dealt extensively with the question of adequacy of disclosure.⁶⁹ It increased the rigour of the enablement requirement by rejecting previous case law,⁷⁰ which held that a disclosure would be enabling if the specification allowed the skilled person to make one embodiment of the invention. It was held that if the patentee has invented a class of products then they would have to be sufficiently disclosed. The disclosure must enable “the whole width of the claimed invention to be performed.”⁷¹

Thus from a comparative point of view, it is clear that the American standard of enablement is stricter than the European standard. A case that amply elucidates this is the *Harvard Onco-Mouse T Application*.⁷² The claimed invention referred to all non-human mammalian animals, whereas the invention described in the specification could only be performed on mice.⁷³ It was assailed on the ground of being too broad, but the Board took the view that the application should not be refused on the ground that it contained an extrapolation from mice. The logic used was that unsuitability of unspecified variants is irrelevant, as long as the suitable variants were explained sufficient.⁷⁴

The stringent American standard has received much criticism, which is what has forced them to abolish the Best Mode requirement. The European patent laws are generally accepted to be a more pragmatic response to the interests of industry and commerce.⁷⁵

3.2 Utility, Best Mode and Written Description

The requirement of “utility” in the US again is stringent, and it has to be shown that a biotechnological invention is useful to humans. This standard is also lower in Europe and evidenced by Art. 57 EPC. The requirement in Europe is that an invention must be of “susceptible industrial application.”⁷⁶ Since this criterion is satisfied where the invention meets with any application in industry or agriculture, the threshold is much lower than that of utility in the US.

The Best Mode requirement has not been incorporated into the EPC. European patent laws require the inventor to show workability, which means that he need not have to disclose the most optimum manner of performing the invention.⁷⁷

The written description requirements in Europe are not substantially different in the US. In Europe, greater emphasis is given to the technical aspects of the description. The meaning of the invention should be clear from the words of the claim alone to a person skilled in the art, using terminology that has technical meaning in the concerned art.⁷⁸

⁶⁹ M. Spence, “Patents and Biotechnology”, 113 LQR 368 at 373.

⁷⁰ *Molyncke A.B. v. Proctor & Gamble Ltd.*, [1992] FSR 549 and *Chiron*, [1996] RPC 535.

⁷¹ W.R. Cornish, “Cases & Materials on Intellectual Property”, (1996), p. 101.

⁷² [1991] E.P.O.R. 525.

⁷³ *Supra* note 73 at 74.

⁷⁴ *Id.* Also, it must be noted that like the Patents Act, 1977, the EPC also does not have broad claims as a ground for disqualification. The lack of sufficient disclosure must be violative of the requirements of Art. 83

⁷⁵ T. Prime, “European Intellectual Property Law”, (2000), p. 174.

⁷⁶ Art. 57 states, “An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.” The term “industry” is also understood very broadly.

⁷⁷ *Supra* note 52 at 93.

⁷⁸ *Supra* note 41.

IV. The Indian Law on Disclosure

4.1 The Patents Act 1970

S10 of the Patents Act 1970 contains the Indian law of clear and complete disclosure. S10(4)(a) embodies the enablement and written description requirements, while S10(4)(b) states that the applicant shall disclose the Best Mode of performing the invention.

4.2 Traditional Knowledge and Biotechnology Patenting – Disclosure Requirements

India has a wealth of traditional knowledge(TK). TK refers to genetic resources or bio-active components that are invented and used for a variety of purposes, often by indigenous peoples. Biotechnological patent applications are increasingly beginning to be based on TK. It is imperative that the disclosure requirements be adapted to counter this problem of exploitation of TK.

The patenting of biotechnology having a TK component throws up a range of legal issues. First, Art. 8(j) of the Convention on Biological Diversity (CBD) mandates that prior informed consent (PIC) of the community will be taken before the TK is utilized in any manner whatsoever. Therefore, PIC from holders of TK must be insisted upon, before a biotechnological patent based on TK is granted.⁷⁹

A logical extension of concealing the TK component in a patent application would be that the enablement requirement would be violated. However, s10(4)(d)(B) and (D) of the Patents Act 1970 provide safeguards. The source, geographical origin and technical information regarding the patent have to be provided. Even so, there is no provision in the Patents Act that mandates that PIC is insisted upon before a product using TK is patented. This is a major flaw in the law that needs rectification.⁸⁰

4.3 Plant Varieties

Art. 27 of TRIPS allows for patenting of microorganisms and allows states to establish a *sui generis* patenting system to protect plant varieties.⁸¹ Pursuant to this the Protection of Plant Varieties and Farmer's Rights Act 2001 (PPVFR Act) was enacted. The PPVFR Act has been castigated for being anti-farmers for it allows scope for thieves of TK and plant varieties to obtain patent protection.⁸² S18 of the Act contains a disclosure requirement, description of its novelty, utility, geographical origin and a declaration that the plant variety has been obtained by lawful means. This provides farmers and traditional peoples with little leverage power when it comes to negotiating their TK and plant varieties.

⁷⁹ N.S. Gopalakrishnan, "TRIPS and Protection of Traditional Knowledge of Genetic Resources: New Challenges to the Patent System", [2005] 27 *EIPR* 11 at 15.

⁸⁰ Technically, S. 6 of the Biological Diversity Act, 2002 provides for PIC from the National Biodiversity Authority before grant of patent. But this can cover only that traditional knowledge whose existence the National Biodiversity Authority is aware of. Moreover, it is desirable that a precaution like this be included in the Patent Act itself.

⁸¹ D. Gervais, "The TRIPS Agreement – Drafting, History and Analysis", (2003), p. 217.

⁸² R. Dhawan, "License to Rob", *Down to Earth*, (September 15, 2001).

V. Conclusion and Recommendations

After an analysis of the disclosure requirements for patents in biotechnology in different jurisdictions, I have advanced the following observations and recommendations to make with the view to bringing about legal reform. These recommendations cull out the most suitable aspects of the law from different jurisdictions and may be applied in the legal system of both developing as well as developed countries.

First, a fundamental distinction requires to be made between a biotechnology patent used for pharmaceutical/medicinal/therapeutic purposes, and those inventions intended to be used for other purposes. The strictness of disclosure should be much higher for pharma/medicinal biotechnological inventions, and the claims should consequently be interpreted much more strictly.⁸³

Second, for medicines and pharmaceuticals, the watertight enablement requirement as is found in the US should be implemented. The reason for this is that the inventor should not be allowed to patent any result that is beyond the scope of his claim, for it may infringe on other related inventions.

Third, for medicinal/pharmaceutical biotechnological patents, the Best Mode requirement should be brought back. In cases of drugs and therapies benefiting human beings, it is in society's interest to be aware of the Best Mode of making those drugs. That should be the consideration exacted by the state in exchange for a patent monopoly.

Fourth, the Best Mode test is considered to be a subjective test. It is that method of disclosure that was the best in the contemplation of the inventor at the time of filing a specification. Evidentially, subjective intent is difficult to prove. Therefore an inventor may often conceal the Best Mode of production to himself. I recommend that the Best Mode standard should be made an objective standard. If a better method of making use of the invention is found, then the burden of proof should be shifted to the inventor to show that he did not know of it. Since technological advances take place and better modes of invention may genuinely be discovered after the specification is filed, the burden of proof should be placed on the inventor for one year after the issue of the patent.

Fifth, in determining adequate disclosure, there have been judicial decisions that have stated that the intent of the inventor is not to be taken into account when determining clear and complete disclosure. A good faith requirement must be imported into the patent application process. The applicant should be put under a duty of good faith to disclose what is required by the statute, in a specification.

Sixth, for industrial applications (non-medical/non-therapeutic) of a biotechnology patent, the law should harmonize toward the inventor and commerce friendly model laid down by the EPC. The "workability requirement" is ideal for industrial application patents since they do not have to conform to the higher standard for Best Mode then. This assures more protection to the inventor and retains the incentive to innovate in his favour.

Seventh, as compared to the US requirement of "utility", the European requirement of being susceptible of industrial application allows greater scope for patentability. Likewise, the deposit of sample provisions as facilitated by the Budapest Treaty may be allowed to supplement the written description requirement, as biotechnological products and processes are difficult to describe.

⁸³ This is also because biotechnology is inherently unpredictable, and therefore claims should be restricted to whatever is certain.

Finally, Indian law needs to change immediately and become more protective of traditional knowledge (TK). S10(4)(d) of the Patents Act 1970 does provide some basic protection against TK piracy, but the express undertaking of Prior Informed Consent (PIC), in accordance with Art. 8(j) of the CBD, from the holders of the TK, has to be a *sine qua non* to a patent being granted. The patenting of biotechnology that comprises unlawfully procured TK has to be countered. When TK is used in an invention, the enablement and written description must disclose accurately and elaborately, all the details pertaining to TK.

Introducing these recommendations would certainly lead to a more harmonized global patent regime that is both industry friendly as well as serving the needs of the developing world and society.