CHAPTER 8

WRITTEN DESCRIPTION AND ENABLEMENT

As mentioned in the first chapter, the patent system is based on the 'quid pro quo' between the public and the inventor. An inventor discloses an invention to the public and takes exclusive rights over it for a limited period of time. The patent law mandates disclosure of the invention to the public for grant of patent rights. The specification filter under the patent law ensures that the inventor discloses the invention to the public in the form of a written disclosure teaches the public to make and use the invention through enablement and defines the metes and bounds of the invention through the claims. Some countries also require the best mode of carrying out the invention. The invention will be granted a patent only if the inventor satisfies the disclosure requirements under the specification filter. The evolution of gene-based inventions has been posing challenges to the written description and enablement standards under the patent law. Considering the difficulties in making written descriptions for biological inventions, different countries have entered into a treaty for enabling deposit of biological materials to supplement their description[751]. Most countries have modified their filters and set higher standards of enablement for genetic inventions.

USA

Section 112 of the Patent Act provides that the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[752] It further states that the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant

[751] Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure done at Budapest on April 28, 1977,and amended on September 26, 1980.
[752] 35 U.S.C. Section 112

regards as his invention.[753] The Courts and USPTO have set different standards of written description and enablement requirements for genetic inventions when compared with other inventions due to lack of certainty in the field and their unique nature.

Written Description

The purpose of the written description requirement is to evidence the filing date as the prima facie date of invention by showing that the applicant was in full possession of the claimed subject matter on the filing date of the patent application.[754] Though there was initially confusion among the courts about existence of a separate written description requirement other than enablement requirement, the federal circuit ended this confusion in Vas-Cath v. Mahurkar, by stating that section 112 of the Patent Act requires a written description of the invention, which is separate and distinct from the enablement requirement.[755] Due to unpredictability of the art, the Federal circuit has been applying a heightened standard for written description requirement of gene based inventions. The following cases elucidate the standard of written description required for genetic inventions.

A. **Amgen v. Chugai**

The case related to an infringement of a patent over DNA sequences encoding Erythropoietin (EPO).[756] The defendant claimed invalidity of the patent based on failure to satisfy the written description requirement among other grounds.[757] The federal circuit held that the patent applicant failed to satisfy the written description requirement because the disclosure in the patent application does not support the claims.[758] As the patent holder gave details for preparing only a few EPO analogs, which are insufficient to support claims in

[753] Id.
[754] Lockwood v. American Airlines, Inc., 107 F.3d 1565 (Fed. Cir. 1997).
[755] Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991).
[756] Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200 (C.A.Fed. (Mass.),1991).
[757] Id.
[758] Id. at 1213.

the patent over all EPO gene analogs, the court held that the patent failed to satisfy the written description requirement.[759] It went on to state that generic claims to genetic sequences can be valid where they are of a scope appropriate to the invention disclosed by an applicant.[760]

This case laid down that claims in a patent application have to be adequately supported by the written description. Stating a few gene analogs would not support a claim over all gene analogs of a protein.

B. Fiers v. Revel

The case relates to patent applications for DNA coding for human fibroblast beta-interferon[761]. In a three way interference, one of the applicants relied on his foreign patent application to satisfy the written description requirement.[762]

The court started its analysis by observing that an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it and that the description of the DNA itself is required.[763] The court stated that the patent application at issue does not demonstrate that the disclosed method actually leads to the DNA, and thus that he had possession of the invention, since it only discloses a clone that might be used to obtain mRNA coding for <<beta>>-IF. [764]It further observed that a bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description and that it does not indicate that the patent applicant was in possession of the DNA. [765]It also pointed out that claiming all DNA's that achieve a result without defining what

[759] Id.
[760] Id.
[761] Fiers v. Revel, 984 F.2d 1164 (C.A.Fed.,1993)
[762] Id.
[763] Id. at 1170.
[764] Id. at 1171.
[765] Id.

means will do so is not in compliance with the description requirement and that it is an attempt to preempt the future before it has arrived. [766]

In the light of its reasoning, the court held that earlier filed foreign patent application which merely disclosed clone that might be used to obtain mRNA coding for human fibroblast beta-interferon did not contain adequate written description of DNA coding for beta-interferon because the patent application did not demonstrate that disclosed method actually led to DNA, and did not disclose that applicant had possession of the invention[767]. The court finally pointed out that written description in patent application for DNA coding for specific protein requires precise definition of DNA, such as by structure, formula, chemical name, or physical properties. It also pointed out that written description of DNA requires same degree of specificity as conception of DNA, and bare reference to DNA with reference to potential method for isolating it will not suffice. [768]

This case laid down that adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The disclosure of the actual sequence itself is required to satisfy the written description requirement. It also laid down that a written description of a DNA sequence coding for specific protein requires precise definition of DNA, such as by structure, formula, chemical name, or physical properties.

C. Regents of the University of California v. Eli Lilly & Co.

The patents in the case related to recombinant plasmids and microorganisms that produce human insulin, a protein involved in the regulation of sugar metabolism.[769] In an infringement suit by the patent holder, the defendant

[766] Id.
[767] Id.
[768] Id.
[769] Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, (C.A.Fed. (Ind.),1997).

claimed for patent invalidity based on inadequacy of written description among other grounds.[770]

The court started its analysis by stating that statutory written description requirement can be fulfilled only if patent specification describes the invention in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.[771] It further pointed out that adequate written description of DNA that is subject of patent requires precise definition, such as by structure, formula, chemical name, or physical properties and not mere wish or plan for obtaining claimed chemical invention. [772]It also pointed out that adequate written description of a DNA requires not just mere statement that it is part of invention and reference to potential method for isolating it but also description of DNA itself. [773]

Based on the above stated principles, the court held that the claim of the patent directed to recombinant prokaryotic microorganism modified to encode human insulin was invalid, because patent specification did not fulfill statutory written description requirement.[774]. Although specification provided adequate written description of rat cDNA, the court stated that it provided only general method of producing human insulin cDNA and not written description of human insulin cDNA, which is required by the claims in the patent. The court observed that the written description does not give any information relating to structure or physical characteristics of cDNA coding for human insulin.[775] Though the amino acid sequence of human insulin A and B chains and a general method of producing human insulin cDNA was provided in the written description, the court stated that it is not sufficient as the amino acid sequences and general methods do not make the cDNA sequence obvious [776]

[770] Id.
[771] Id. at 1A568.
[772] Id. at 1568.
[773] Id.
[774] Id. at 1569
[775] Id.
[776] Id.

The court pointed out that claims of patent relating to recombinant DNA technology which generically recited cDNA encoding vertebrate insulin, claim which was directed generically to cDNA encoding mammalian insulin, and dependent claims which recited cDNA encoding vertebrate insulin were not adequately supported by written description because written description disclosed only particular species within scope of the aforementioned generic claims and does not cover the genus itself.[777] However, the court further stated that the description of genus of cDNAs referred to in patent may be achieved by means of recitation of representative number of cDNAs, defined by nucleotide sequence, falling within scope of genus or of recitation of structural features common to members of genus, which features constitute substantial portion of the genus[778].

This case laid down that disclosure of a rat cDNA along with amino acid sequences of human proteins and general methods of coding those proteins is not sufficient to support claims of human cDNA coding for those proteins. It further pointed out that description of DNA sequences by function without pointing out the structure or physical characteristics would not be sufficient to satisfy the written description requirement. It also laid down that disclosure of structure, etc of a few species in a genus would not be sufficient to support a claim of the entire genus unless substantial features of the genus and substantial common physical characteristics are described.

D. Enzo v. Gen-Probe

The patent at issue in the case related to nucleic acid probes that selectively hybridize to genetic material of bacteria that cause gonorrhea[779]. In an infringement suit filed by the patent holder, the defendant claimed patent invalidity based on insufficient written description.

---

[777] Id.
[778] Id.
[779] Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (C.A.Fed. (N.Y.),2002)

The court started its analysis by stating that regulatory guidelines governing internal practice of Patent and Trademark Office (PTO) for examining patent applications under statutory written description requirement, like the Manual of Patent Examining Procedure, are not binding on Court of Appeals, but may be given judicial notice to the extent they do not conflict with the statute.[780] The court further stated that as per the guidelines, the written description requirement would be met for all of the claims of the patent at issue if the functional characteristic of preferential binding to N. gonorrhea over N. meningitidis were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed. It applied the guidelines and enquired whether Enzo's deposits of the claimed nucleotide sequences of claims may constitute an adequate description of those sequences and whether the description requirement is met for all of the claims on the basis of the functional ability of the claimed nucleotide sequences to hybridize to strains of N. gonorrhea that are accessible by deposit.

In light of the history of biological deposits for patent purposes, the goals of the patent law, and the practical difficulties of describing unique biological materials in a written description, the court held that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement. [781]In this case, Enzo's deposits were incorporated by reference in the specification. [782]A person of skill in the art, reading the accession numbers in the patent specification, could obtain the claimed sequences from the ATCC depository by following the appropriate techniques to excise the nucleotide sequences from the deposited organisms containing those sequences.[783] the sequences are thus accessible from the disclosure in the specification and although the structures of those

[780] Id. at 965.
[781] Id. at 965.
[782] Id.
[783] Id. at 966.As

sequences, i.e., the exact nucleotide base pairs, were not expressly set forth in the specification and those structures may not have been reasonably obtainable, the court held that reference in the specification to deposits of nucleotide sequences described those sequences sufficiently to the public for purposes of meeting the written description requirement.[784]

Furthermore, the court stated that written description is a factual enquiry and remanded the case to the district court for determination of adequacy of written description by considering access to deposits as part of description. [785]It also stated that the district court should consider whether one of skill in the art would find the generically claimed sequences described on the basis of Enzo's disclosure of the hybridization function and an accessible structure, consistent with the PTO Guidelines.[786]

The Court pointed out that even if a patent claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. [787]It further pointed out that where the words of the patent claim alone do not convey an adequate description of the invention, regardless of whether the claim appears in the original specification and is thus supported by the specification as of the filing date, the patent statute's written description requirement is not necessarily met.[788] It further stated that mere fact that specification of patent, which was directed to nucleic acid probes that selectively hybridize to the genetic material of the bacteria that cause gonorrhea, indicated that patent holder possessed claimed invention by reducing to practice three nucleotide sequences within the scope of the patent claims and deposited them in public depository does not establish that patent met the statutory written description requirement.[789]

---

[784] Id.
[785] Id. at 967.
[786] Id.
[787] Id. at 967.
[788] Id.
[789] Id.

Apart from reiterating earlier decisions, this case laid down that deposit of genetic sequences may constitute adequate written description. It also laid down that written description is a fact based enquiry. It also stated that possession of a gene sequence is not enough to satisfy the written description requirement.

E. Amgen v. Hoechst

The case related to patents pertaining to recombinant DNA product similar to natural erythropoietin.[790] In an infringement suit one of the issues related to adequacy of disclosure.[791]

The court started its analysis by reiterating that the purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not.[792] It stated that the applicant for a patent is therefore required to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.[793] It further stated that satisfaction of this requirement is measured by the understanding of the ordinarily skilled artisan. [794]

The court agreed with the district court that a claim to a composition rather than a process does not require written description to describe technological developments in the way in which the claimed composition is made that may arise after the patent application is filed. See United States. [795]It further pointed out that the adequacy of written description is checked in the light of the claims and nothing external. [796]The court further stated that the specification's description of producing the claimed EPO in two species of vertebrate or mammalian cells adequately supports claims covering EPO made

[790] Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (C.A.Fed.) (Mass.),2003).
[791] Id.
[792] Id. at 1330.
[793] .Id.
[794] Id.
[795] Id.
[796] Id.

using the genus vertebrate or mammalian cells. As the claim does not talk about human DNA, the Eli Lilly decision does not apply here.[797] The court pointed out that the patentee need only describe the invention as claimed, and need not describe an unclaimed method of making the claimed product. The court observed that as Amgen's written description was generally worded as an invention relating generally to the manipulation of genetic materials and, more particularly, to recombinant procedures making possible the production of polypeptides similar to EPO and as the description made statements that its invention is uniquely characterized" by exogenous expression of DNA, the claims fall within the scope of the description.[798] Based on the aforementioned analysis, the court held that the written description was sufficient.

The case laid down that sufficiency of written description is seen from the point of view of a skilled artisan. It also laid down that the sufficiency of the description is verified at the time the invention was made in the light of the claims.

F. Capon v. Eshhar

The case related to interference with regard to chimeric receptor genes.[799] One of the questions before the court was adequacy of written description.

The court started its reasoning by pointing out that the descriptive text needed to meet the written description requirement varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.[800] It stated that the law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. [801]Since the law is applied to each invention in view of the state of relevant knowledge, the court observed that

[797] Id.
[798] Id.
[799] Capon v. Eshhar, 418 F.3d 1349 (C.A.Fed.,2005).
[800] Id. at 1360.
[801] Id.

its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.[802] It further pointed out that as each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.[803]

As the chimeric genes at issue are prepared from known DNA sequences of known function, the court stated that these sequences need not be analyzed and reported in the specification.[804] It further held that the specifications need not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes as they are well known in the prior art and form part of the current knowledge of science. [805]

With regard to support for generic claims, the court stated that the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.[806] It pointed out the holding in an earlier case, which stated that an amino acid sequence supports the entire genus of DNA sequences that can encode the amino acid sequence because the state of the art has developed such that it is a routine matter to convert one to the other. It further pointed out that existence of support for each claim in a patent has to be analyzed claim by claim. Prior art and knowledge of a person with ordinary skill can be supplemented to extract support for claims. It held that the board erred by analyzing all claims at a time based on generic principles governing adequacy. [807]

[802] Id.
[803] Id.
[804] Id.
[805] Id.
[806] Id.
[807] Id.

In summary, the court held that there is no per se rule requiring recitation in the specification of the nucleotide sequence of claimed DNA, when that sequence is already known in the field. It also held that each claim has to be analyzed individually in the light of specific examples and teachings in the specification and known science.

G. Falko-Gunter Falkner v. Inglis

The case related to an appeal from an interference proceeding over an invention related to a novel vaccine that was comprised of "vector virus" in poxvirus family.[808]

In accordance with prior case law, the court in this case held that:

(1) Examples are not necessary to support the adequacy of a written description

(2) The written description standard may be met even where actual reduction to practice of an invention is absent; and

(3) There is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure. [809]

The court stated that the absence of examples involving poxviruses in the patent applications does not render the written description inadequate because the knowledge is advanced enough that examples are not required.[810] It further stated that actual reduction to practice is not required to satisfy written description requirement if the conception is concrete enough for a

[808] Falko-Gunter Falkner v. Inglis, 448 F.3d 1357 (C.A.Fed.,2006).
[809] Id. at 1366.
[810] Id. at 1367.

person with ordinary skill to reduce it to practice.[811] Though the applicant did not specify the DNA sequence and the essential regions in his application, the court stated that it is not insufficient because there is no per se rule to disclose structure and sequence. [812]

The USPTO passed the revised guidelines for written description in 2001, which are largely in confirmity with case law. [813]Some examples (6 to 16) in the guidelines explain how gene based inventions such as genes, ESTs, antisense, ORFs, etc., would be considered for purposes of written description. The principles in the examples are largely in consonance with the case law and have been recognized by courts to be valid.

The principles relating to standards of written description for genetic inventions can be summarized as follows:

a. Claims in a patent application have to be adequately supported by the written description. Stating a few gene analogs would not support a claim over all gene analogs of a protein.

b. Adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

c. The disclosure of the actual sequence itself is required to satisfy the written description requirement.

d. A written description of a DNA sequence coding for specific protein requires precise definition of DNA, such as by structure, formula, chemical name, or physical properties.

---

[811] Id.
[812] Id.
[813] USPTO Guidelines and Training Materials on Written Description, Federal Register /Vol. 66, No. 4/Friday, January 5, 2001.

e. Description of DNA sequences by function without pointing out the structure or physical characteristics would not be sufficient to satisfy the written description requirement.

f. Disclosure of structure, etc of a few species in a genus would not be sufficient to support a claim of the entire genus unless substantial features of the genus and substantial common physical characteristics are described.

g. Disclosure of a rat cDNA along with amino acid sequences of human proteins and general methods of coding those proteins is not sufficient to support claims of human cDNA coding for those proteins.

h. Deposit of genetic sequences may constitute adequate written description.

i. Possession of a gene sequence is not enough to satisfy the written description requirement.

j. Sufficiency of written description is seen from the point of view of a skilled artisan.

k. Sufficiency of the description is verified at the time the invention was made in the light of the claims.

l. There is no per se rule requiring recitation in the specification of the nucleotide sequence of claimed DNA, when that sequence is already known in the field.

m. Each claim has to be analyzed individually in the light of specific examples and teachings in the specification and known science.

n. Examples are not necessary to support the adequacy of a written description

o. The written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and

The cases point out that the written description standards for genetic inventions have been treated differently when compared with other inventions. Initially the courts adopted heightened written description standards as seen in Amgen, Fiers and Enzo due to unpredictability in the art. However, as the field matured, the recent decisions, such as Capon, Ealko and so on have relaxed the requirements by considering the advancements in the art. As it stands today, the written description requirement is not as daunting as it was fifteen years ago. However, the requirement is still stringent when compared to other inventions.

Enablement

Section 112 of the patent act provides in part that the specification shall contain a written description of the manner and process of making and using the invention in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same[814]. A written description is considered to be enabling, if a person with ordinary skill in the art can make and use the invention based on it without undue experimentation[815].

In re Wands, the federal circuit enunciated the factors that may be considered for determining requirement of undue experimentation for carrying out the invention[816]. The factors to be considered are:

(1) the quantity of experimentation necessary to obtain the claimed invention based on the content of the disclosure;
(2) the existence *419 or lack of direction or guidance;

[814] 35 USC Section 112.
[815] In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).
[816] Id.

(3) the presence or absence of specific working examples compared to the breadth of the claimed invention;
(4) the nature of the invention;
(5) the state of the prior art;
(6) the ability of persons skilled in the art to reduce the invention to practice;
(7) the predictability of the art; and
(8) the breadth of the claims.

The enablement requirement assumed a higher standard for gene based inventions due to unpredictability of the art. The following case law elucidates the contours of enablement requirement for genetic inventions.

A. Amgen v. Chugai

The case related to a patent infringement suit over DNA sequences encoding Erythropoietin. The defendant claimed that the patent is invalid as it lacked enablement[817].

The court began its reasoning by stating that the fact that some experimentation is necessary does not constitute a lack of enablement unless undue experimentation is required[818]. It stated that the essential question is whether the scope of disclosure is broad enough to enable a person with ordinary skill to carry out the invention commensurate to the scope of claims[819].

The court observed that the patent holder (Amgen) has not enabled preparation of DNA sequences sufficient to support its all-encompassing claims[820]. Though it is well accepted that an invention can be enabled without

[817] Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200 (C.A.Fed. (Mass.),1991).
[818] Id. at 1313.
[819] Id.
[820] Id.

describing all species that a claim encompasses, the court observed that in the present case the patent holder disclosed very few analogs of the EPO gene and the method of making them, which would not be sufficient to cover the broad claims[821]. Though the disclosure might well justify a generic claim encompassing the specified and similar analogs, the court stated that it represents inadequate support for Amgen's desire to claim all EPO gene analogs[822].

As there may be many genetic sequences that code for EPO-type products and Amgen has disclosed how to make and use only a few of them, the court stated that it is not entitled to claim all of them[823]. The court observed that considering the structural complexity of the EPO gene, the manifold possibilities for change in its structure, with attendant uncertainty as to what utility will be possessed by the specified analogs, the court considered that more is needed concerning identifying the various analogs that are within the scope of the claim, methods for making them, and structural requirements for producing compounds with EPO-like activity[824]. As per the court, it is not sufficient, having made the gene and a handful of analogs whose activity has not been clearly ascertained, to claim all possible genetic sequences that have EPO-like activity[825].

This case elucidated that a disclosure will be enabling only if it is commensurate to the scope of the claim. Disclosure of a few analogs of a gene would not enable the making of all analogs because the field is unpredictable and undue experimentation is required.

B. In re Vaeck

[821] Id.
[822] Id.
[823] Id. at 1213.
[824] Id.
[825] Id.

In this case, the patent applicant claimed the expression of endotoxin proteins in all strains of cyanobacteria, as opposed to any particular genus or species of cyanobacteria[826]. The court rejected the claims to the extent that claims were too general to enable person skilled in art to make and use the claimed invention without undue experimentation[827].

As cyanobacteria were diverse and relatively poorly studied group of organisms, comprising some 150 different genera and as successful use of even one type in the manner specified in the invention being unpredictable, the court held that the invention was not enabled[828]. Because only one particular species of cyanobacteria was employed in the working examples of the patent specification, and only nine genera of cyanobacteria were mentioned in the entire document, considering the high unpredictability of the field, the court found that there was insufficient correlation between the narrow disclosure in the specification and the broad scope of the claims[829]. Although patent applicants are not required to disclose every species encompassed by their claims, even in unpredictable art, in order to satisfy enablement requirement for patentability, the court pointed out that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use invention as broadly as it is claimed. As the patent at applicant failed to give sufficient disclosure, the court held that the specification lacked disclosure[830].

This case laid down that generic claims in highly unpredictable fields have to be supported by specific examples and disclosure to teach the skilled persons in the art to make and use the invention.

[826] In re Vaeck, 947 F.2d 488 (C.A.Fed.,1991).
[827] Id. at 494.
[828] Id.
[829] Id.
[830] Id.

C. Enzo Biochem, Inc. v. Calgene, Inc.

In this case, patents relating to genetic antisense technology were challenged based on lack of enablement[831]. The court started its reasoning by observing that Wands factors for determining whether patent's disclosure would require undue experimentation are applicable in context of both ex parte prosecution and inter partes litigation, since enablement determination is made retrospectively in either context[832].

The court observed that genetic antisense technology, used to block expression of particular genes, was a highly unpredictable technology and therefore required lot of experimentation[833]. As the inventor failed to adapt claimed antisense technology from particular prokaryote disclosed in patent specification to other organisms, the court observed that the amount of experimentation required to adapt the technology in the patents was quite high and therefore, the disclosure to practise such claims was not enabling[834]. It found that specifications of patents claiming genetic antisense technology provided little guidance or direction as to practice of antisense in cells other than particular prokaryote disclosed in specifications, for enablement purposes, because teachings set forth in specifications provided no more than a plan or invitation for those of skill in the art to experiment with practicing antisense in eukaryotic cells and because teachings did not provide sufficient guidance or specificity as to how to execute that plan[835]. As per the court, the claims in the patents were much beyond the scope of the narrow specification[836]. The court went on to hold that the patents were not enabled

[831] Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362 (C.A.Fed. (Del.),1999).
[832] Id. at 1373.
[833] Id.
[834] Id. at 1374.
[835] Id.
[836] Id.

because persons skilled in the art i.e. a junior faculty members or post doctoral students, were able to practice invention relating to genetic antisense technology only by the exercise of substantial experimentation well beyond the broad concepts that appeared in the patent specifications[837].

This case laid down that necessity of undue experimentation to carry out the claims makes the disclosure nonenabling. It also laid down that the level of a person with ordinary skill in an unpredictable art would be higher. It reiterated that claims have to be adequately supported by the specification in an enabling manner.

D. Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.

The case related to a patent directed to method of modifying bacterial genetic structure in order to produce amino acids in increased quantities, which was challenged based on lack of enablement[838]. The court stated that the invention was enabling because all of the methods needed to practice the invention were well known to those skilled in the art and despite the diversity existing among bacteria, practitioners of this art were prepared to carry out the identification, isolation, recombination, and transformation steps required to practice the full scope of the claims[839]. As the disclosure was sufficient and the field well developed to practise the invention, the court stated that the patents were enabled. It further pointed out that deposit of related biological materials at the depository, which gave access to the public was sufficient to make the specification enabling[840].

E. Amgen v. Hoechst

[837] Id.
[838] Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co., 228 F.3d 1338 (C.A.Fed. (Del.),2000).
[839] Id.
[840] Id.

The case related to patents pertaining to recombinant DNA product similar to natural erythropoietin[841]. In an infringement filed by the patent holder, the defendant raised lack of enablement as one of the grounds for invalidating the patent[842].

The court held that the patent relating to use of various cultured vertebrate and mammalian cells to produce human erythropoietin satisfied enablement requirement because with the assistance of the specification, a skilled artisan would have been able to determine with routine experimentation which cultured vertebrate cells would produce human erythropoietin[843]. The court started its reasoning by pointing out that the specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without "undue experimentation[844]. As the patent holder disclosed at least one way of obtaining purified EPO from mammalian cells grown in culture, as EPO was shown to have therapeutic activity in mice and as a person with ordinary skill would infer that results from mice, monkey, etc, could be expected from other mammalian cells, the court concluded that the patent was enabled.

The case laid down that enablement of an invention can be inferred from the prior art if a person with ordinary skill in the art can carry out the invention with his knowledge.

F. Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.

In this case, the patent holder brought action against competitor relating to patent on use of Agrobacterium to insert bar gene into both dicotyledons and

[841] Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (C.A.Fed. (Mass.),2003).
[842] Id.
[843] Id. at 1338.
[844] Id. at 1334.

monocotyledons and the federal circuit upheld the claim of non-enablement by the competitor[845].

The court held that the patent was not enabled as of the date of its filing because it required undue experimentation and was not a pioneering patent. The court concluded that the patent at issue was not entitled to both a broad scope of coverage and a lower standard of enablement like a pioneering invention because the court stated that though monocots existed in 1987, they were difficult to produce and the patent at issue gave no instruction on the method of producing them and therefore was not an enabled invention[846]. The court found that the prior art on the date of filing including the 1986 work of Goldman and Graves and that of from did not enable one skilled in the art to stably transform corn cells without undue experimentation[847]. As the specification was incomplete and as it required undue experimentation by a person with ordinary skill in the art, the court held that the patent was invalid due to lack of enablement.

This case laid down that enablement is verified based on the state of the art and the skill of person with ordinary skill on the date of filing. A pioneering patent would get benefit of broad claims and low enablement hurdle only if it has an enabling disclosure.

G. In re Fisher

In a case relating to a patent covering expressed sequence tags for identifying nucleic acid sequences in maize genes, the court held that the patent lacked enablement[848]. The court stated that the patent application cannot be enabled because the claimed ESTs were not disclosed as having a specific and

[845] Plant Genetic Systems, N.V. v. DeKalb Genetics Corp., 315 F.3d 1335 (C.A.Fed. (Conn.),2003).
[846] Id. at 1343.
[847] Id. at 1344.
[848] In re Fisher, 421 F.3d 1365 (C.A.Fed.,2005).

substantial utility and as it is well established that the enablement requirement of Section 112 incorporates the utility requirement of Section 101. The court pointed out that if a patent application fails section 101, then it would also fail section 112.

H. Invitrogen Corp. v. Clontech Laboratories, Inc.

The case relates to patents that disclosed genetically modified enzyme, reverse transcriptase, involved in DNA replication[849]. It was argued by the defendant that the written description for the patents-in-suit describes how to implement the claimed invention by deletion mutation but fails to implement the claimed invention by point mutation and is therefore not enabling. The court pointed out that Section 112 requires the patent specification to enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation in order to extract meaningful disclosure of the invention and, by this disclosure, advance the technical arts. As the patent law requires enablement by any one mode, the court held that the disclosure of the deletion mutation is enough to satisfy the enablement requirement.

I. Falko-Gunter Falkner v. Inglis

In an appeal from an interference relating to a novel type of vaccine that was comprised of "vector virus" in poxvirus family, the court held that the patent application satisfied the enablement requirement[850]. The court held that the patent application provided detailed example of embodiment that comprised herpesvirus, rather than poxvirus, including identity of deleted essential sequences therein, was adequately enabled, where high level of skill existed in the art, differences between herpesviruses and poxviruses were well known, which would have aided person of ordinary skill in art in application of lessons

[849] Invitrogen Corp. v. Clontech Laboratories, Inc., 429 F.3d 1052 (C.A.Fed. (Md.),2005).
[850] Falko-Gunter Falkner v. Inglis, 448 F.3d 1357 (C.A.Fed.,2006).

of herpesvirus example in construction of poxvirus vaccines, and publications in professional journals had disclosed DNA sequence of poxvirus genome along with locations of essential regions[851]. The court in this case assumed a skilled artisan as having 5-10 years experience creating recombinant poxvirus, as being familiar with the poxvirus literature, the use of poxvirus as a vector for the expression of heterologous genes, and having the needed technical skill to practice the experimentation described in the scientific literature relating to recombinant virus, including poxvirus[852].

The court observed that there is extensive disclosure of the selection of an essential gene, its deletion or inactivation and the production of a mutated virus with said deleted or inactivated gene, albeit for herpesvirus. Moreover, because the differences between the herpesviruses and poxviruses were well known, the court pointed out that this would have aided the person of ordinary skill in the art in her application of the lessons of the herpesvirus example in the construction of poxvirus vaccines[853]. The court further observed that the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be 'undue' in this art[854]. Thus, the court found the patent applications to be enabling.

The principles relating to enablement of gene based inventions can be summarized as follows:

a. Generic claims in highly unpredictable fields such as genetic inventions have to be supported by specific examples and disclosure to teach the skilled persons in the art to make and use the invention.

[851] Id.
[852] Id.
[853] Id.
[854] Id.

b. A disclosure will be enabling only if it is commensurate to the scope of the claim. Disclosure of a few analogs of a gene would not enable the making of all analogs because the field is unpredictable and undue experimentation would be required.

c. Necessity of undue experimentation to carry out the claims makes the disclosure nonenabling.

d. Level of a person with ordinary skill in an unpredictable art like genetics would be higher.

e. Claims have to be adequately supported by the specification in an enabling manner.

f. Deposit of genetic materials in an authorized depository can help in satisfaction of the enablement requirement.

g. Enablement of an invention can be inferred from the prior art if a person with ordinary skill in the art can carry out the invention with his knowledge.

h. Enablement is verified based on the state of the art and the skill of person with ordinary skill on the date of filing.

i. A pioneering patent would get benefit of broad claims and low enablement hurdle only if it has an enabling disclosure.

j. Enablement requirement subsumes utility requirement.

The principles lay down a heightened enablement standard for genetic inventions due to unpredictability of the field. It is tough to satisfy the enablement requirement for genetic inventions when compared with other inventions.

EUROPE

Article 83 of the European Patent Convention provides that the European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art[855]. As per the article a patent applicant must sufficiently disclose the invention in such a way that a person by following such disclosure can carry out the invention without undue experimentation. The disclosure requirement with regard to genetic inventions has assumed a heightened standard when compared to other inventions due to lack of maturity in the field. The cases that follow elucidate the enablement requirement in relation to genetic inventions.

A. Pioneer case

The case concerned an invention relating to oilseed Brassica containing an improved fertility restorer gene for ogura cytoplasmatic male sterility. The patent application was challenged on the ground that it lacked enablement[856].

The applicant argued that the application was not an enabling disclosure because it did not disclose the combination of homozygosity of the restorer gene and low glucosinolate content in a single Brassica plant[857]. It was further

[855] Article 83, Convention On The Grant Of European Patents (European Patent Convention) of 5 October 1973 text as amended by the act revising Article 63 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, 10 December 1998 and 27 October 2005 and comprising the provisionally applicable provisions of the act revising the EPC of 29 November 2000.
[856] Pioneer/Oilseed Brassica, Technical Board of Appeal 3.3.4, [2004] E.P.O.R. 41.
[857] Id. at 421.

argued that as no seeds or molecular markers had been deposited in respect of the lines, the plant lines used in the invention were proprietary and not available to public[858]. The applicant alleged that the information in the patent application was unreliable, criticised the experimental work it detailed and relied upon the fact that only three of 700 crosses gave seeds with low glucosinolate levels[859]. The applicant finally submitted that a skilled man seeking to repeat the experiments described in the patent application faced an undue burden given that the three lines used were not shown to be homozygous for the restorer gene[860].

The Board started its reasoning by stating that (i) for the disclosure of an invention to be sufficiently clear and complete to satisfy Art.83 EPC the skilled person had to be able to achieve the desired result without undue burden on the basis of information provided in the patent application itself and common general knowledge[861] and (ii) the criteria for reproducibility of a technical teaching was the same in cases where disclosure of a prior art document was in issue; and (iii) a prior art document whose teaching was not enabling was not to be considered when assessing novelty. The Board further stated that examination as to sufficiency in a patent application or a prior art document had to be conducted in each case on its own merits, and depended on correlation of the facts with a number of general parameters, including:

(i) the amount of reliable technical details disclosed;

(ii) the time when the disclosure was made to the public;

(iii) the corresponding common general knowledge;

[858] Id.
[859] Id.
[860] Id.
[861] Id. at 422.

(iv) the character of the technical field; and

(v) the average amount of effort necessary to put into practice a certain written disclosure in that technical field[862]. The Board observed that the break in the link between restorer genes and high glucosinolate levels by meiotic crossing over in a plant breeding programme as disclosed in the patent application was a fortuitous event. As per the Board dependence on fortuitous or chance events for reproducibility in the absence of evidence that their frequency was sufficiently high to guarantee success constituted an undue burden which prevented the disclosure of patent application from being enabling[863].

This case laid down that a patent application would not be enabling if it requires undue experimentation to make and use the invention. It pointed out that fortuitous or chance events for reproducibility in the absence of evidence that their frequency was sufficiently high to guarantee success would constitute an undue burden making a patent application non-enabling.

B. R. v. MASSACHUSETTS INSTITUTE OF TECHNOLOGY

The patent application at issue was directed to a method for constructing polyhydroxybutyrate (PHB) or related biopolymers in a host comprising, as a first step, providing genes encoding the enzymes beta-ketothiolase, acetoacetyl-CoA reductase and polyhydroxybutyrate synthetase[864]. The application was rejected for lack of sufficiency of disclosure by the Examining

[862] Id.
[863] Id.
[864] R. v. MASSACHUSETTS INSTITUTE OF TECHNOLOGY/Biopolymers, Technical Board of Appeal 3.3.4, [2003] E.P.O.R. 16.

Division on the ground that the gene encoding PHB synthetase, which was an essential feature of the claimed method, was not disclosed[865].

On appeal, the Board started its reasoning by stating that assessment of the sufficiency of a disclosure depends on the correlation of the facts of the case to certain general parameters such as, for example, the character of the technical field; the average amount of effort necessary to put into practice a certain written disclosure in that technical field; the time when the disclosure was presented to the public and the corresponding general knowledge and the amount of reliable technical details disclosed in a document[866]. The Board dismissed the appeal by stating that the incompleteness of some of the cross-references in the description was a preliminary hurdle for the skilled person, which served to increase the amount of effort necessary to put into practice the protocol outlined in the text for obtaining the PHB synthetase gene. The Even if each individual step per se in an overall complex plan can be considered as feasible with a certain amount of trial and error, the Board observed that the total amount of experimental effort necessary to successfully advance step by step towards the final goal may still be regarded as undue for the skilled person[867]. It further observed that the Baumberg statement supporting sufficiency of disclosure was clearly opinionative and not founded on the experience of repeating the experimental protocol suggested[868]. Therefore, as the enabling of the invention required undue experimentation, the Board held that the application lacked enablement[869].

The Board laid down in this case that assessment of the sufficiency of a disclosure depends on the correlation of the facts of the case to certain general parameters such as the character of the technical field; the average amount of effort necessary to put into practice a certain written disclosure in

[865] Id.
[866] Id. at 142.
[867] Id.
[868] Id.
[869] Id.

that technical field; the time when the disclosure was presented to the public and the corresponding general knowledge and the amount of reliable technical details disclosed in a document. In gene based inventions, the Board observed that requirement of trial and error to carry out the invention would make the disclosure non-enabling as the field is fraught with ambiguities.

C. WEYERSHAEUSER Case

The patent in the case to microbiologically produced reticulated cellulose[870]. The Opposition Division rejected opposition based on the grounds of lack of novelty, inventive step and sufficient disclosure and maintained the patent in an amended form[871].

The Board started its reasoning by stating that the patent claim covered not only Acetobacter derived from the deposited strains but also Acetobacter micro-organisms from a different genetic background which had the stated characteristics in common with the deposited strains[872]. It stated the rule relating to enablement, which was that sufficient disclosure required information to be provided by the specification to enable a person skilled in the art to isolate without undue burden stable cellulose high-producing Acetobacter micro-organisms from a different genetic background, as well as those derived from the deposited strains[873]. Although there was no undue burden on a person skilled in the art in relation to the isolation of the relevant micro-organisms derived from the deposited strains, the board stated that there was an undue burden in respect of the isolation of the relevant micro-organisms from a different genetic background because such isolation depended on chance for reproducibility[874]. As per the Board, Reliance on chance was unsatisfactory unless there was evidence that the probability of the

[870] Eyershaeuser/Cellulose, Technical Board of Appeal 3.3.4, [2001] E.P.O.R. 35.
[871] Id.
[872] Id.
[873] Id.
[874] Id.

chance events occurring was sufficiently high to guarantee success. Based on its reasoning, the Board revoked the patent due to lack of enablement[875].

The Board laid down in this case that disclosure of chance for reproducability, which requires undue experimentation would not be sufficient to satisfy the enablement requirement.

D. Mycogen case

The patent at issue was directed to a method for genetically modifying a plant cell by transferring into it a combination T-DNA/plant promoter gene such that expression of the protein encoded by the plant structural gene was detectable in the plant cell. The patent was opposed by 11 opponents on the ground of sufficiency of disclosure among other grounds[876]. The opponents objected to the patent on the grounds of lack of sufficiency of disclosure because the claims were not limited to the expression of phaseolin but the expression in any plant cell of any plant structural gene under the control of any plant promoter[877]. The Opposition Division held that the patent satisfied the enablement requirement and opponents appealed[878].

On appeal, the Board stated that the experimental evidence and technical details in the description were not sufficient for the skilled person to reliably achieve without undue burden the technical effect of expression in any plant cell of any plant structural gene under the control of any plant promoter as claimed in the patent other than for the expression of phaseolin or its variant forms[879].As per the Board, the limitation in the patent to the method for the expression of phaseolin and its variant forms overcame the sufficiency

[875] Id.
[876] MYCOGEN/Modifying Plant Cells(Oppositions by Unilever, Centerns, Sandoz, Monsanto & Max Planck Institute), Technical Board of Appeal 3.3.4, [1998] E.P.O.R. 114.
[877] Id.
[878] Id. at 114.
[879] Id.

objections. The Board pointed out that the generalisation in respect of phaseolin and its variant forms was justified because the technical circumstances for the expression of variants of the phaseolin gene and promoter were so similar to those of phaseolin[880].

The Board in this case laid down that the enabling disclosure has to be commensurate to the claims in the patent. A person with ordinary skill in the art is not in a position to carry out all claims based on the disclosure; else the disclosure would lack enablement.

E. R v. Genentech

The case related to sufficiency of disclosure in a patent concerning amino acid sequence and DNA sequences of interferon-gamma[881], The Board started its reasoning by acknowledging that at the time of priority the average amount of time and effort needed to produce, clone and express a gene was high[882]. However, it pointed out that the DNA-sequence, coding for interferon-gamma was fully disclosed in the priority application, which makes it possible for a person with ordinary skill in the art to reproduce the invention.

Though the reproducibility of the whole process of expressing the gene to produce the desired interferon-gamma was still a difficult, complex and time-consuming task in 1981, the Board was nevertheless convinced that the provision of the DNA-sequence in 1981 enabled those skilled in the art to reproduce the invention. The Board stated that knowledge of the DNA-sequence opened up other routes for cloning and expressing the gene than that proposed in the priority application. It stated that it was convinced that based on the knowledge of the DNA-sequence, provided in the priority application,

[880] Id.
[881] R. v. GENENTECH/HIF-Gamma, Technical Board of Appeal 3.3.2, [2003] E.P.O.R. 12.
[882] Id.

use of the invention was possible, as were methods of using it to develop further inventions.

The Board was thus convinced that the application provides a reliable technical teaching which placed those skilled in the art in a position to reproduce the production, cloning and expression of interferon-gamma, possibly in a time consuming and cumbersome way, but, in the given circumstances, without undue burden of experimentation and without needing inventive skill. Though the option of depositing a biological material was available, the Board pointed out that if the disclosure in the written description is enough to repeat the invention, deposit is not necessary.

The Board laid down in this case that a patent application relating to a gene would be enabling even if the experimentation required is burdensome as long as undue experimentation is not required. It further laid down that deposit of biological materials is not compulsory as long as an application can be enabled based on written description.

F. Harvard Case

The case related to a patent concerned with a method of manufacturing a protein by recombinant DNA technology, comprising fusing the heterologous gene to a bacterial gene coding for a portion of a bacterial extra-cellular or periplasmatic carrier protein by a recombinant step so that the fused protein is excreted through a membrane of the cell within which it is made[883]. The Opposition Division revoked the patent based on lack of sufficient disclosure and the patent holder appealed.

[883] Harvard/Fusion Proteins(Oppositions by Hoechst;Unilever; Gist- Brocades), Technical Board of Appeal 3.3.2, [1992] E.P.O.R. 320.

The Board started its decision by pointing out that there are gaps in the written description of the patent, which cannot be filled by a person with ordinary skill in the art[884]. According to the Board if the skilled persons had worked exactly according to the rather vague information provided in the working example, within a reasonable amount of time and investigation, they would not be able to come up with the invention[885].

In particular in 1978, the Board pointed out that cleaving the penicillinase gene with the Taq restriction enzyme would have produced seven fragments and at that time it would have been extremely difficult to handle the problem[886]. Further, as per the Board, the control over the enzymes nibbling back the DNA was not yet well developed and it would have been very cumbersome to stop the reaction mixture exactly at that point where it was necessary to form a perfect fusion. Thus, the Board stated that the proposal in the working example of the patent would not have enabled a skilled person to carry out the process of the claim when working exactly along the wording of the part of the description, without undue burden. Although the penicillinase gene in the plasmid pBR322 was known, restriction enzymes had been on the market and exonucleases were known which nibble back the DNA once cut with a restriction enzyme, the Board, however, pointed out that replacing the restriction enzyme Taq, which apparently is unsuitable for carrying out the invention, by a more suitable restriction enzyme, namely Pvul, as used by the patent applicants in their experiment in their supplemental statement, was not a variant available for the skilled person within common general knowledge[887]. The Board clearly stated that although the restriction enzyme Pvul was available as such, the skilled person would not have used it because the known and published restriction map of the plasmid pBR322 did not show the site for

[884] Id. at 323.
[885] Id.
[886] Id.
[887] Id. at 324.

this restriction enzyme[888]. The Board therefore pointed out that one cannot, reasonably assume that the skilled person would have used the mentioned restriction enzyme[889].

Furthermore, the Board opined that the skilled person in the field of genetic engineering in 1978 is not to be defined as a Nobel Prize laureate, even if a number of scientists working in this field at that time were actually awarded the Nobel Prize. Rather, it is understood that the skilled person was to be seen as a graduate scientist or a team of scientists of that skill, working in laboratories which developed from molecular genetics to genetic engineering techniques, at that time[890]. It cited decision T292/85, in which the Board had concluded that it is not necessary for a sufficient disclosure of a claimed process that each and every variant can be carried out as long as there are variants available within common general knowledge. As per the Board, in the present case neither was it within common general knowledge to find variants suitable to carry out the method proposed in the working example nor was it likely that a skilled person would have been successful in reproducing the method of the patent Claim when working exactly according to the wording of example. Based on its reasoning the Board concluded that the invention failed to satisfy the enablement requirement.

The Board laid down in this case that if there is inadequate knowledge concerning an enzyme to justify it being regarded as a variant by the skilled person within the compass of his common general knowledge at the time of filing, the invention would not be enabling. The Board also laid down that the skilled person in the field of genetic engineering in 1978 was not to be defined as a Nobel Prize laureate. And the skilled person was to be regarded instead as the graduate scientist, or team of scientists, working in relevant laboratories.

---

[888] Id.
[889] Id.
[890] Id.

G. Biogen Case

The patent in suit was broadly concerned with providing an improved route through recombinant DNA technology to certain types of interferons, and had been revoked by the Opposition Division on the ground of insufficiency among other grounds. In the case, it was strongly urged by various respondents that the patent was invalid and should be revoked on the basis that the claims defined the invention too broadly, because the description of the invention in terms of how to carry it out was much more limited in scope[891].

The Board started its reasoning by stating that an invention is sufficiently disclosed if at least one way is clearly indicated enabling the person skilled in the art to carry out the invention[892]. It further pointed out that in appropriate cases even specifically described examples need not be exactly repeatable and that variations in the starting materials are acceptable as long as the claimed process reliably leads to the desired product[893]. The Board further stated that variations in the construction within a class of genetic precursors, such as recombinant DNA molecules claimed by a combination of structural limitations and functional tests, are immaterial to the sufficiency of the disclosure provided the skilled person could reliably obtain some members of the class without necessarily knowing in advance which member would thereby be made available[894]. As the field is fraught with unpredictability, the Board pointed out that the general method of carrying out the invention with variant starting materials would be patentable as long as the result can be achieved even in a slightly different form. It further pointed out that description of materials

[891] Biogen/Recombinant Dna(Oppositions by Hoffmann la Roche; Upjohn; Boehringer Ingelheim Zentrale; Bender; Cetus; Hoechst; Boehringer Mannheim, Technical Board of Appeal 3.3.2, [1990] E.P.O.R. 190.
[892] Id. at 201.
[893] Id.
[894] Id.

based on structure is not necessary as long as they can be identified by the function[895].

The Board pointed out that the process relating to the claim, as described in the patent was reproducible in the sense that the skilled person would not obtain a useful precursor, which hybridises and leads to polypeptides of the IFN-<<alpha>> type, and which was therefore a member of the claimed class[896]. The Board stated that the requirement that the skilled person should have instructions in the patent how to obtain any one claimed member in the class at will would be inappropriate and go too far in the field of genetic recombinants, and their broad classes[897]. The Board pointed out the need for a partial reliance on functional characteristics in situations such as in the present case, in view of the special circumstances which prevail in the field of genetics[898].

The Board held that deposition of biological materials would be very useful in satisfying the disclosure requirements, if the deposition establishes sources for structural standards for comparison, and starting points for modifications[899]. It pointed out that it is a characteristic of the present case that the patentee had supported the description with a substantial number of deposited organisms which provide a great practical choice to outsiders exploring the invention further[900].

It stated that the reference to DNA molecules incorporated in deposited microorganisms could well be the definition of an available source that is, starting material, from which the desired plasmid or even part thereof may be obtainable. Thus, the Board observed the deposition is an available starting

[895] Id. at 204.
[896] Id.
[897] Id.
[898] Id. at 203.
[899] Id.
[900] Id.

point and can be interpreted as a basis of an implied product-by-process definition for the end-product in question since the latter can be reliably obtained by commonly known steps of isolation or be used in situ operatively for cloning etc. The Board concluded that there is a detailed description of the actual reduction to practice of the invention, and a great number of depositions which could provide a variety of immediate short cuts for the public to carry out the invention without having to go through the cumbersome route from natural sources, thus making the disclosure enabling[901].

The Board in this case laid down that every single variant in the claim need not be disclosed or claimed. Deposits can supplement the disclosure as starting materials. It also laid down that the requirement that the skilled person should have instructions in the patent how to obtain any one claimed member in the class at will would be inappropriate and go too far in the field of genetic recombinants, and their broad classes[902]. The Board also laid down that disclosure can rely on functional characteristics in case of genetic inventions. This decision gives lot of flexibility to patent disclosures relating to genetic inventions.

H. Genentech Case

The patent application in the case was directed to a recombinant plasmid comprising of heterologous DNA encoding a desired functional heterologous polypeptide or intermediate[903]. The application had been rejected by the Examining Division for failure to fulfill the requirements of (sufficiency of disclosure); and (support for the claims[904].

[901] Id. at 204.
[902] Id.
[903] GENENTECH I/Polypeptide Expression, Technical Board of Appeal 3.3.2, [1989] E.P.O.R. 1.
[904] Id.

The Board in this case stated that the use of functional phraseology was established and was proper in cases where such features cannot otherwise be defined more precisely without restricting the scope of the invention and that the principle could be applied to biotechnology inventions. It went on to state that an invention is sufficiently disclosed if at least one way is clearly indicated enabling the skilled person to carry out the invention and pointed out that Non-availability of some particular variants of a functionally defined component feature of the invention is consequentially immaterial to sufficiency as long as there are suitable variants known to the skilled person through the disclosure or common general knowledge which provide the same effect for the invention. The Board further stated that the disclosure need not include specific instructions as to how all possible component variants within the functional definition should be obtained. It pointed out that the key test for biological processes of general applicability, so far as sufficiency was concerned, was whether or not the process as such was reproducible.

The principles relating to sufficiency of disclosure in Europe relating to genetic inventions can be summarized as follows:

a. A patent application would not be enabling if it requires undue experimentation to make and use the invention.

b. Fortuitous or chance events for reproducibility in the absence of evidence that their frequency was sufficiently high to guarantee success would constitute an undue burden making a patent application non-enabling.

c. Assessment of the sufficiency of a disclosure depends on the correlation of the facts of the case to certain general parameters such as the character of the technical field; the average amount of effort necessary to put into practice a certain written disclosure in that technical field; the time when the disclosure

was presented to the public and the corresponding general knowledge and the amount of reliable technical details disclosed in a document.

d. In gene based inventions, requirement of trial and error to carry out the invention would make the disclosure non-enabling as the field is fraught with ambiguities.

e. Disclosure of chance for reproducability, which requires undue experimentation, would not be sufficient to satisfy the enablement requirement in gene based inventions.

f. The enabling disclosure in genetic inventions has to be commensurate to the claims in the patent. If a person with ordinary skill in the art should be in a position to carry out all claims based on the disclosure, the disclosure would lack enablement.

g. A patent application relating to a gene would be enabling even if the experimentation required is burdensome as long as undue experimentation is not required.

h. Deposit of biological materials is not compulsory as long as an application can be enabled based on written description.

i. If there is inadequate knowledge concerning an enzyme to justify it being regarded as a variant by the skilled person within the compass of his common general knowledge at the time of filing, the invention would not be enabling.

j. Every single variant in a genetic claim need not be disclosed or claimed.

k. Deposits can supplement the disclosure as starting materials.

l. The requirement that the skilled person should have instructions in the patent how to obtain any one claimed member in the class at will would be inappropriate and go too far in the field of genetic recombinants, and their broad classes.

m. Disclosure can rely on functional characteristics in case of genetic inventions.

n. It is enough if one method of carrying out a genetic invention is disclosed.

The disclosure requirement in Europe as it can be seen from the cases has evolved since the late 1980S and early 1990s. While the science was reasonably new, the enablement requirement was quite easy and relaxed as seen in Genentech and Biogen cases. The latest cases show that the enablement requirement has stronger as the field matured. Such a trend can be seen in cases such as Pioneer, R v. Massachussets and so on. The scope of permitted experimentation to enable an invention was very broad initially but now, it is very narrow.

INDIA

In India, provisions relating to specification are provided under section 10 of the Patent Act[905]. The section provides that every complete specification shall fully and particularly describe the invention and its operation or use and the method by which it is to be performed; Section 10(4) of Indian Patent Act 1970 as amended in 1999, 2002 and 2005. It further provides that the applicant should disclose the best mode of carrying out the invention[906]. If biological materials are described in the specification, the law provides for deposit of such biological materials at a recognized depository, which would be accessible

[905] Section 10 of Indian Patent Act 1970 as amended in 1999, 2002 and 2005.
[906] Id.

to the public from the date of filing. In case of inventions made out of traditional knowledge, the specification requires the applicant to submit the source of traditional knowledge[907]. The applicant should also mention the source of biological origin, if an invention is based on biological resources. The Manual explains that the complete specification (techno-legal document describing the invention) should disclose the invention completely so that a person skilled in the art can perform the invention[908].

The provisions are largely similar to those of other countries. However, the scope and extent of the provisions and their interpretation is not clear due to lack of legislative history and case law.

Patent/Public domain analysis

There are similarities in the written description and enablement requirements of gene based inventions in USA, Europe and India. All countries require a disclosure that would enable a person with ordinary skill in the art to carry out the invention without undue experimentation. There is no difference with regard to level of ordinary skill of the person among various countries. The enablement of an invention is considered on the date of filing based on the specification and not based on what is filed after the date. In USA and Europe, common general knowledge can be supplemented to make and use the invention.

Comparative study

[907] Id.
[908] 2.6 Sufficiency of Disclosure, MANUAL OF PATENT PRACTICE AND PROCEDURE, 2005.

Despite the similarities, there are some differences between enablement requirements of the three countries. The differences are elucidated in the case studies adopted from the trilateral project[909].

Case 1

(1) The claimed invention is

(a) a recombinant vector,

(b) a process for producing a recombinant vector,

(c) a transformant,

(d) a process for producing a transformant,

(e) a process for producing a recombinant protein X, or,

(f) a recombinant protein X.

Description of the invention contains a working example of cloning cDNA encoding protein X, but there are no working examples of the inventions themselves.

The USPTO stated that it is difficult for the USPTO to definitively determine enablement for the proposed working example and provide specific answers to the questions. However, if the description is reasonably adequate to allow one skilled in the art to produce the protein via use of the cDNA as indicated, USPTO observed that the description would be enabling.

The EPO pointed out that the invention would be enabled, if actual invention of the application by cloning of the cDNA is sufficiently disclosed in the patent application.

[909] Trilateral Project 24.1, Biotechnology Comparative Study on Biotehnology Patent Practices Comparative Study at http://www.trilateral.net/projects/biotechnology/patent_practices/ visited on 9th August, 2005.

It would be tough to predict the IPOs point of view as the law has not developed adequately.

Case 2

The claimed DNA is characterized by the term "hybridize" (ex. A DNA sequence hybridizing to the DNA sequence X and encoding a polypeptide having the biological activity x). The original cDNA sequence (the DNA sequence X) is disclosed in the description of the invention, while there is no working examples how to clone allelic mutants by way of hybridization, The claim contains not only natural-occurring but also artificial DNA,

According to the USPTO, the breadth of the claim in the example does include more DNA embodiments than allelic mutants, and the necessary analysis requires an assessment of the adequacy of the description in the specification as to the means of identification of "biological activity X".

EPO pointed out that the disclosure is enabling since it is within common general knowledge to clone other similar DNAs by way of hybridization or the hybridization technology was developed some 20 years ago and it has been used in the relevant field of technology since 1980 as a common method in order to obtain allelic mutants.

It would be tough to predict the IPOs point of view as the law has not developed adequately.

The case study elucidates that the US enablement requirement is stringent when compared to the European requirement. European patent law assumes a well developed and more certain field of genetic science when compared to USA. As seen in the above examples, USA requires more details to make the invention enabling when compared to that required by European patent law.

Furthermore, USA enquires the satisfaction of written description and enablement separately, while Europe and India consider them together. The written description relating to genetic inventions is not treated as stringently in India and Europe as it is in USA.

The trend in decisions of the courts in USA and Europe with regard to gene based inventions is also reverse. US Courts initially started with a very stringent written description and enablement requirement for gene based inventions and later on started relaxing the requirements when the field of genetics started maturing. On the other hand, the European Courts relaxed the enablement provisions to start with for gene based inventions and later on strengthened the requirement as the field matured. To give a simple example, US courts required the structure of the gene to be described precisely in order to pass through written description and enablement requirement and later on relaxed such requirement when structure became well-known among skilled persons in the art. On the other hand, European courts allowed genes and related inventions to be described by function when it was not possible to define the structure and at a later stage as the field matured required the structure to be disclosed for enablement purposes. Based on the patent law in both countries, it can be said that European enablement requirement is easy to satisfy when compared to that of USA.

Like other requirements, the written description and enablement requirements relating to gene based inventions also have varying scopes in different countries. They create patent and public domains of different sizes. USA has a stringent written description and enablement requirement when compared to Europe and creates a smaller patent domain and a larger public domain when compared to that of Europe. As a result more number of genetic patents would pass through this requirement in Europe when compared to USA. The scope of Indian enablement requirement has not been properly expounded due to dearth of legislative history and case law. So, the size of patent and public

domain created by the Indian requirement cannot be clearly ascertained. However, the filter shows a medium scope.