Patentability in the Post-Genomic Era

Raising the Bar on Biotechnological Inventions in Europe and the United States

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Abstract

Patents are of great importance to the biotechnology industry. The purpose of this thesis is to describe, discuss and contrast the patentability criteria for biotechnological inventions within the EPC system and in the United States. The thesis discusses what a new scientific era might mean for biotechnology patent law.

There is a consensus that US patent law has applied more liberal patentability standards than the EPO. However, the gap has diminished in recent years as both legal systems have raised the bar on biotechnological inventions.

The completion of the Human Genome Project is one of the reasons why the context for patenting biotechnological inventions has changed markedly. Functional genomics and the raised patentability standards will provide more narrow and robust patents on uses for genes and proteins.
Contents

Abbreviations..............................................................................................................4
1. Introduction.............................................................................................................5
  1.1 Purpose...............................................................................................................5
  1.2 Method and material..........................................................................................5
  1.3 Source criticism ...............................................................................................5
  1.4 Delimitations .....................................................................................................6
2. Background to Patents and Biotechnology.............................................................6
  2.1 Patents................................................................................................................6
  2.2 Biotechnology.....................................................................................................7
3. Patenting Biotechnological Inventions within the EPC System.............................8
  3.1 The general legal framework..............................................................................8
  3.2 EPC statutes concerning patentability..............................................................13
  3.3 EPO practice......................................................................................................24
  3.4 Case law on biotechnology ...............................................................................26
4. Patenting Biotechnological Inventions in the United States....................................33
  4.1 The general legal framework..............................................................................33
  4.2 Patentability criteria..........................................................................................35
5. EPC contrasted with US Law..................................................................................49
  5.1 Introduction........................................................................................................49
  5.2 Patentable subject matter................................................................................50
  5.3 Novelty...............................................................................................................52
  5.4 Inventive step/Nonobviousness.........................................................................53
  5.5 Industrial application/Utility.............................................................................54
  5.6 Concluding remarks..........................................................................................56
6. Patentability in the Post-Genomic Era........................................................................56
7. Conclusions............................................................................................................59
References..................................................................................................................59
# Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPAI</td>
<td>Board of Patent Appeals and Interferences</td>
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<td>CAFC</td>
<td>Court of Appeals for the Federal Circuit</td>
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<td>EBA</td>
<td>Enlarged Board of Appeal</td>
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<td>EC</td>
<td>European Community</td>
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<td>ECJ</td>
<td>European Court of Justice</td>
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<td>EIPR</td>
<td>European Intellectual Property Review</td>
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<td>EPC</td>
<td>European Patent Convention</td>
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<td>EPO</td>
<td>European Patent Office</td>
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<td>EU</td>
<td>European Union</td>
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<td>HGP</td>
<td>Human Genome Project</td>
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<tr>
<td>ISA</td>
<td>International Searching Authority</td>
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<td>NIR</td>
<td>Nordiskt Immateriellt Rättsskydd (Nordic Intellectual Property Law Review)</td>
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<td>OJ EPO</td>
<td>Official Journal of the European Patent Office</td>
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<td>PCT</td>
<td>Patent Cooperation Treaty</td>
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<td>PHOSITA</td>
<td>Person having ordinary skill in the art</td>
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<tr>
<td>TBA</td>
<td>Technical Board of Appeal</td>
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<tr>
<td>TRIPs</td>
<td>Trade-Related Aspects of Intellectual Property Rights</td>
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<tr>
<td>USPTO</td>
<td>United States Patent and Trademark Office</td>
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<tr>
<td>WIPO</td>
<td>World Intellectual Property Organization</td>
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<tr>
<td>WTO</td>
<td>World Trade Organization</td>
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1. Introduction

1.1 Purpose
The purpose of this thesis is to describe and discuss the patentability criteria for biotechnological inventions within the EPC system and in the United States, and in this connection contrast the application of EPC patent law with the US equivalent. The focus is on the development in recent years. In this context, the thesis also discusses if the differences in the number of granted biotechnology patents by the USPTO compared to the EPO is related to differences in the patentability standards applied. Finally, the thesis looks ahead and discusses what a new scientific era in biotechnology might mean for biotechnology patent law.

1.2 Method and material
The thesis is based on a traditional jurisprudential method, i.e. studying and analyzing the central sources of law such as statutes, judicial decisions, doctrine etcetera. In patent law, agency regulations and guidelines play an important role and are consequently also part of the material used. As complementary material, non-governmental reports and articles not published in law reviews are utilized.

1.3 Source criticism
Some of the references are written in the Swedish language. The reason for using them is that they add to the overall list of references and provide a useful background from the perspective of national patent law. When cited, they have been translated by the author to the best of his ability. A Swedish-speaking reader will of course have a better chance than others of following up on these references. On balance though, it was decided to keep them, since the typical reader of the thesis probably will be a Swedish citizen.

When studying and analyzing cases referred to, not only the judicial decisions in the original have been used, but also reliable secondary sources. This can be seen as a drawback, but the sheer number of relevant cases and the total number of pages made it an unreasonable task only to read the original texts. The secondary sources used are casebooks, agency summary reports and governmental preparatory works.
1.4 Delimitations

National European patent law is, by and large, not covered in the thesis. With reference to US patent law, only the federal level is discussed.

Provisions on patentable subject matter are only discussed insomuch that it is relevant for the aims of the thesis. Explicit exceptions to patentability are only briefly mentioned to describe the general framework.

Concerning US patent law only utility patents are discussed. So called design and plant patents are not covered in the thesis.

The reader is presupposed to have some basic understanding of patent law, since it is not possible within the framework of the thesis to cover and explain everything regarding patents that are outside of the scope of the thesis.

The reader does not have to be knowledgeable about biotechnology, but a certain general idea of how biotechnology works, is helpful.

In addition to the fundamental patentability criteria there is the requirement of disclosure of the invention, sometimes described as a patentability criterion, and sometimes not. This requirement is in some respects connected with industrial applicability/utility and will therefore, when relevant, be discussed in the same context as that criterion.

2. Background to Patents and Biotechnology

2.1 Patents

A patent is a legal title granting its holder, for a limited period of time, the right to prevent third parties from commercially exploiting an invention without authorization. In return for the protection, the holder of the patent has to disclose the details of the invention. This information is published in the patent document so that everyone can benefit from it.\(^1\) The disclosure of the invention in exchange for patent protection is called the "patent bargain" or securing a "quid pro quo"\(^2\) for society.

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\(^1\) See e.g. the EPO homepage: http://www.epo.org/patents/Grant-procedure/About-patents.html (visited 2009-10-15).

\(^2\) Latin, meaning "something for something".
The main parts of a patent application are the description of the invention, and the claims. The claims state what is sought protected. They define the invention and if a patent is granted, the scope of protection is limited by the claims.³

There are three types of patent protection, namely product patents, process patents and use patents. Product patents protect the object of the invention. Process patents protect the procedure through which a product is produced. Use patents protect a new use of an already known product. If a certain industrial application is not stated in the claims for a product patent, the subsequently granted patent will provide protection for all uses of the product, including those not mentioned in the description and unknown on the filing date of the application. This is called absolute product protection.⁴ It is however possible to apply for a patent for a new use of a patented product. The new use must be stated in the claims and the protection is consequently limited to this use.⁵

Patents are of great importance to the biotechnology industry. An editorial in Nature Biotechnology calls patents "the [intellectual property] bedrock on which biotech is built".⁶

2.2 Biotechnology

Biotechnology is not a new phenomenon. Dutta points out that "[s]ince ancient days people knew how to utilize microorganisms to ferment beverage and food, though they did not know what was responsible for those biological changes."⁷ In recent years though, the term biotechnology is being used to refer to novel techniques such as i. a. recombinant DNA (genetic engineering) and cell fusion. Recombinant DNA is the direct manipulation of genetic material of individual cells, which may be used to develop microorganisms that produce new products as well as useful organisms. Cell fusion is a technique to form a single hybrid cell with nuclei and cytoplasm from two different types of cells in order to combine the desirable characteristics of the two.⁸

The European Patent Convention (EPC) defines a biotechnological invention as "inventions which concern a product consisting of or containing biological material or a process by means of which

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⁴ Id., at 29-30.
⁵ Domeij, Bengt, Patenträtt - Svensk och internationell patenträtt, avtal om patent samt skyddet för växtsorter och företagshemligheter, Iustus Förlag AB, Uppsala 2007, at 52.
⁸ Id.
biological material is produced, processed or used. The term "biological material" means "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system."

3. Patenting Biotechnological Inventions within the EPC System

3.1 The general legal framework

3.1.1. Obtaining a patent in Europe

A patent is always valid in a certain country. There are consequently no such thing as an international patent. However, a patent can be obtained in several ways, and two of these have international elements. Firstly, a patent can be applied for at a national patent office, resulting in a national patent valid in the country of application. Secondly, an international patent application can be filed under the Patent Cooperation Treaty (PCT). In the PCT system, an International Searching Authority (ISA), which are authorized national patent offices or international organisations, does some of the work of the patent application process in order to avoid duplication at national patent offices. The ISA conducts a search, and sometimes a preliminary examination. This leads to a report which can be filed with the national patent offices of the applicant's choosing, or with the European Patent Office (EPO). The national patent offices and the EPO are not bound by the results of the international report, but the application processes are facilitated and costs reduced. Currently, 141 states are partners to the PCT. Thirdly, a European patent can be obtained through an application directed to the EPO under the European Patent Convention (EPC). This will now be outlined.

3.1.2 The European Patent Convention

The Convention on the Grant of European Patents, normally referred to as The European Patent Convention (EPC), was signed in Munich in 1973. It came into force in 1977. The EPC is administered by the European Patent Organisation, with headquarters in Munich. One of the bodies of the European Patent Organisation is the European Patent Office (EPO) which grants patents

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9 Rule 26(2) of the Implementing Regulations to the EPC.
10 Rule 26(3) of the Implementing Regulations to the EPC.
11 Domeij, at 15.
13 Id.
according to the convention. An important point to notice is that the EPC is an international convention which has no legal connection with the EU Treaty. The EU as such has no jurisdiction over the EPC. The EPO currently has 36 European member states, which i. a. means that they are contracting states to the EPC.

The EPC has been revised on a number of occasions. The latest version is the 13th edition, also called EPC 2000. Supplementing the EPC in itself are, i. a., the Rules of the Implementing Regulations (the Rules), which are considered an integral part of the EPC. In the case of a conflict between the EPC and the Rules however, the provisions of the EPC in itself prevails. Part of the EPC system are also the Guidelines for Examination in the European Patent Office (the Guidelines), which are frequently amended.

Patent applications directed to the EPO leads to so called "European patents" in one or several of the member states, depending on which countries the applicant has designated. The phrase "European" is somewhat of a misnomer, since what comes out of the process is really a bundle of independent national patents. The motive for the EPC is the same as for the PCT, i. e. a central examination for more than one country at once in order to facilitate and lower the costs for the applicants, but in this case taken further so as to also grant patents. At a national level there are no substantial differences between a national patent and a European patent granted by the EPO for that same country. According to the EPC, a granted European patent shall confer on its proprietor the same rights in the country for which it is granted as a national patent granted in that state confer.

In recent years, more and more inventors have chosen to apply to the EPO rather than to national patent offices.

EPO is organized in Examining Divisions, each with its technical speciality, which examines the patent applications. Opposition Divisions handle examinations of oppositions to European patents. Decisions of the Examining Divisions and the Opposition Divisions can be appealed to the Boards of Appeal, also specialized in different technologies. There are currently 26 Technical Boards of Appeal.

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19 Paterson, at 4-5.
20 Id., at 7.
21 EPC Art. 64(1).
22 Domeij, at 16.
Appeal (TBA). Two of these handle biotechnology.\textsuperscript{24} To ensure a uniform application of the EPC, or if important points of law arise, there is also an Enlarged Board of Appeal (EBA) to which the Boards of Appeal and the President of the EPO can refer questions.\textsuperscript{25} The parties before the EPO though, can not appeal the decisions of the Boards of Appeal. European patents can however be brought up before national courts concerning infringement and validity in the country at question.\textsuperscript{26}

The Boards of Appeal inform about their decisions through the Official Journal of the EPO.\textsuperscript{27} Not all cases are published. Those which are, generally carry a greater weight. A decision by a Board of Appeal is only binding in respect of the particular case decided, but is nevertheless normally followed by the Examining and Opposition Divisions.\textsuperscript{28} The EPC and the decisions of the EPO Boards of Appeal also have a dominating influence on the rulings of national patent courts.\textsuperscript{29} The Swedish Patent Law, as an example, is interpreted guided by the EPC and the EPO case law.\textsuperscript{30}

3.1.3 The Biotechnology Directive

The European Community Biotechnological Patent Directive (98/44/EC) came into force on July 30, 1998 after many years debate. The member states were given two years to amend their laws to comply with the Directive.\textsuperscript{31} However, that process was not completed until 2006.\textsuperscript{32} The Directive was also challenged before the European Court of Justice as i. a. contrary to basic human rights and dignity. The Court settled the matter in 2001, holding the Directive valid.\textsuperscript{33} There were several motives behind the Directive. One reason discussed in the literature is that Europe was lagging behind other economic powers, especially the United States. Unevenness in the member states' approach towards biotechnological inventions was also at odds with the European Commission's plans for completing the Internal Market.\textsuperscript{34} Other references point to the fact that a large number of patent applications for DNA sequences prompted reactions from governmental agencies.\textsuperscript{35} Another

\begin{flushright}
\textsuperscript{24} Min proficiency, Timo, När anses en bioteknisk uppfinning vara komplett och praktiskt användbar - del 2 - om senare utveckling kring kravet på "industrial application" och "utility" för gen- och proteinrelaterade uppfinningar i USA och Europa, NIR 4/2008, pp. 339 - 387, at 382.
\textsuperscript{26} Domeij, at 17.
\textsuperscript{27} EPO homepage, supra note 25.
\textsuperscript{28} Paterson, at 9.
\textsuperscript{29} Domeij, at 18.
\textsuperscript{30} Bernitz, at 137.
\textsuperscript{31} Tritton, at 197.
\textsuperscript{33} Id. The full reference to the case is: C-377/98 Kingdom of the Netherlands v Council of the European Union and the European Parliament [2002] FSR 36.
\textsuperscript{34} MacQueen, Hector, Waelde, Charlotte and Laurie Graeme, Contemporary Intellectual Property - Law and Policy, Oxford University Press, Oxford 2008, at 499.
\textsuperscript{35} Aerts, at 350.
\end{flushright}
reason is no doubt the ethical concerns surrounding biotechnology. The member states have implemented the Directive in different ways, some countries e. g. allowing absolute product protection on genes, and some not.

Even if the Directive only applies to the 27 member states of the EU, many of the articles of the Directive have been implemented into the EPC. A new chapter entitled "Biotechnological inventions" and containing new Rules was inserted into the Implementing Regulations. These new Rules correspond closely to the Directive. In Rule 26(1) EPC it is expressly stated that the relevant provisions of the EPC shall be applied and interpreted in accordance with the new chapter and that the Directive 98/44/EC shall be used as a supplementary means of interpretation. The reason for this amendment of the EPC was to ensure that the approach of the EPC to biotechnological inventions is the same as the Directive. A difference between the EPC and the Directive would be unacceptable since the contracting states of the EPC are required to align their national patent laws to comply with the EPC. On the other hand, according to MacQueen, some of the articles of the Directive were "a direct endorsement of the policy that had been rigorously pursued by the EPO".

The Directive's provisions on patentability are found in Chapter I. The relevant articles for this thesis will now be outlined and briefly commented. Article 1(1), first sentence, simply states that "[m]ember states shall protect biotechnological inventions under national patent law". This is a broad introductory provision, requiring national law to align with the Directive.

According to Article 3(1) "inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by which biological material is produced, processed or used." Article 3(2) states that "[b]iological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature." The corresponding provision in the EPC is Rule 27(a) of the Implementing Regulations.

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36 Tritton, at 197.
37 Paterson, at 407.
38 In EPC 2000 the provisions have been renumbered. Originally they were contained in Chapter VI, now in Chapter V, and the provisions are now numbered Rules 26 - 34.
39 Tritton, at 197.
40 MacQueen, at 499-500.
According to Article 5(1) "[t]he human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions." However, as stated in Article 5(2) "[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element." The corresponding provision in the EPC is found in Rule 29(1-2) of the Implementing Regulations. In Article 5(3) it is stated that "[t]he industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application." The corresponding Rule in the EPC Implementing Regulations is Rule 29(3) which has the same wording.

In Recital 24 of the directive, the provision in Article 5(3) is further elaborated regarding proteins. Here it is stated that to comply with the application criterion "it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs". In other words, the demand for the disclosure of a function of genes in the patent application is in some circumstances extended to the corresponding protein. The patenting of DNA sequences is also mentioned in Recital 23 of the directive. There it is stated that "a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention". Torremans comments on this by arguing that "the mere discovery of a gene sequence is not patentable, but locating a previously unknown gene, determining its function and making it accessible for further exploitation brings about the required application of knowledge." In other words Torremans emphasizes the solution of a technical problem as a key element in distinguishing between discoveries and inventions, i. e. between non-patentable and patentable subject matter. The question of discoveries versus inventions will be further discussed below.

Article 4 concerns the conditions for patentability of plants and animals. Article 6(1) discusses unpatentable subject matter on the grounds of ordre public and morality. This is developed in Article 6(2) which specifically mentions cloning of human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes and finally processes for modifying the genetic identity of animals which causes harm without substantial medical benefit, as unpatentable. The corresponding provision to Article 6(2) is
Rule 28 of the Implementing Regulations to the EPC. Articles 4 and 6 are outside of the scope of the thesis.

According to Torremans, the Directive clarifies the law, but did not really cover a lot of new ground. The law still lags behind while science presses on.\footnote{Torremans, at 91.}

3.1.4 TRIPs

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), signed 1994, is an international convention negotiated within the framework of the World Trade Organization (WTO). TRIPs was considered necessary in order to create a level playing field in international trade. Countries must offer a certain minimum standard of intellectual property protection. If they do not, or if the agreement is violated in other ways, trade sanctions may follow.\footnote{Domeij, at 21.}

According to TRIPS Article 27(1), "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." A footnote adds that the terms "inventive step" and "capable of industrial application" may be deemed synonymous with "nonobvious" and "useful" respectively.

TRIPs Article 27(1) is included in EPC article 52(1) with essentially the same wording. The United States is a signatory to the agreement.\footnote{See: http://www.state.gov/www/global/legal_affairs/tif_01e.pdf (homepage visited 2009-10-15).}

The European Court of Justice has declared the TRIPs agreement not to have direct effect within the EU. The ECJ, however, has emphasized that EU intellectual property law to the utmost possible extent shall be interpreted in the light of the TRIPs agreement's wording and purpose.\footnote{Bernitz, at 12-13.}

3.2. EPC statutes concerning patentability

3.2.1. Introduction

Article 52(1) of the EPC states what is to be regarded a patentable invention according to the convention. The article reads as follows:

"European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application."\footnote{EPC Art. 52(1).}
The scope and meaning of this provision is further elaborated in the rest of Part II, Chapter I of the EPC. Articles 52(2-3) and 53 contain provisions on exceptions to patentability. Articles 54, 56 and 57 deal with novelty, inventive step and industrial application respectively, the so called patentability criteria. The articles mentioned, and in some cases the corresponding EPC Rules, will be discussed below.

Paterson points to the fact that if the criteria invention, novelty, inventive step and industrial application are met, the wording of Article 52(1) EPC is mandatory; i.e. European patents "shall be granted" for such inventions, subject only to the exclusions and exceptions set out in the remainder of Article 52 EPC and in Article 53 EPC.47

3.2.2 The concept of invention

One of the conditions for granting a European patent is, according to EPC Article 52(1), that an "invention" is at hand. There is no explicit positive definition of the concept in the EPC.48 Instead, the concept is negatively defined, the EPC stating what is not to be regarded as inventions. Moreover, the concept of invention has been relatively concisely and coherently developed through case law. According to Westerlund, an invention in European patent law exists where it has technical character, technical effect and is reproducible. Technical character means that "it must be a solution to a technical problem by means of utilising natural substances and energy."49 This definition of the concept leaves out discoveries, which are also explicitly non-patentable under the EPC. Technical effect means that the technical problem which the invention concerns has been solved and that it is at least probable for a person skilled in the art that the alleged effect will be reached when the invention is exercised.50 The demand that the invention must be "reproducible" means that the alleged effect is to be reached with certainty when the invention is properly exercised repeatedly.51

3.2.3 Exceptions to patentability

Article 52(2) sets out what in particular shall not be regarded as inventions within the meaning of article 52(1). The non-exhaustive provision mentions discoveries, scientific theories, mathematical

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47 Paterson, at 404.
48 Tritton, at 111.
50 Bernitz, at 140.
51 Id.
methods, aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business, programs for computers and presentations of information.

Observations of conformities in nature, such as discoveries, scientific theories and mathematical methods are excluded from patentability. The regularities of nature can not be patented in its abstract form.\textsuperscript{52} According to EPC Article 52(3) however, the subject matter and activities mentioned in Article 52(2) are excluded only to the extent that a European patent application or patent relates to such subject matter or activities "as such". If a patent application concerns a useful product or process that builds upon one of nature's conformities, such a product or process might be patentable, since the patent application is not for a discovery as such, or in other words not only for a discovery.\textsuperscript{53} Torremans explains the effect of the words "as such": "[W]hile it is not possible to patent [...] a discovery on its own, it is quite appropriate to patent some process embodying the discovery, or a product in which the discovery has been transformed into a product of practical value."

Article 53 EPC states what inventions in particular that are not to be granted European patents. The article mentions inventions the commercial exploitation of which would be contrary to ordre public or morality, plant or animal varieties or essentially biological processes for the production of plants and animals, and finally methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.\textsuperscript{55} The provisions correspond to the Biotechnology Directive, Articles 4 and 6(1).

3.2.4 Novelty

The first patentability criterion is that an invention has to be new or, differently phrased, not anticipated. According to Article 54(1) EPC "[a]n invention shall be considered to be new if it does not form part of the state of the art."\textsuperscript{56} The concept "state of the art" is defined in Article 54(2) EPC: "The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application."\textsuperscript{57} Article 54(3) EPC states that other European patent applications filed before

\textsuperscript{52} Domeij, at 50.
\textsuperscript{53} Id.
\textsuperscript{54} Torremans, at 81-82.
\textsuperscript{55} EPC Article 53.
\textsuperscript{56} EPC Article 54(1).
\textsuperscript{57} EPC Article 54(2).
the date of filing of the application to be examined, but published on or after that date, shall also be considered as comprised in the state of the art.\textsuperscript{58}

If an undefined number of outsiders, even a single person, anywhere in the world, have been able to access information about the invention in a way that makes it possible for a person skilled in the art to exercise it, then the invention is considered to have been made available to the public.\textsuperscript{59} As can be seen in Article 54(2) it does not matter if the information is written, presented orally or accessed by analyzing e. g. a sold product. If somebody actually has analyzed the product or for instance read about the invention is also irrelevant. What matters is that outsiders theoretically have had the possibility to access the information.\textsuperscript{60} Where in the world the information is made available, or in what language, is of no relevance. Neither does it matter if the information comes from the applicant or from a third party.\textsuperscript{61} However, an inventor can share information about the invention with a defined group of people in return for a confidentiality agreement, without the novelty being lost.\textsuperscript{62}

For prior use to constitute anticipation, it is enough that another person, not under any obligation of confidence, can secure, from the thing or process, the knowledge necessary to make or perform the invention himself.\textsuperscript{63} The EPO Guidelines labels this principle "enabling disclosure". According to The Guidelines C-IV.6.2.: 

"Subject-matter can only be regarded as having been made available to the public, and therefore as comprised in the state of the art pursuant to Art. 54(1), if the information given to the skilled person is sufficient to enable him, at the relevant date [...] to practise the technical teaching which is the subject of the disclosure, taking into account also the general knowledge at that time in the field to be expected of him."

The corresponding guideline regarding subject-matter described in a document is outlined in The Guidelines C-IV.9.4. Regarding chemical and biotechnological substances, the EPO principle is that a prior document disclosing the structure of a chemical substance and the method for its manufacture will not anticipate a claim for the chemical product if the starting and intermediate products required to manufacture the chemical substance are not available from the document or general knowledge.\textsuperscript{64}
The EPO Enlarged Board of Appeal requires that a skilled person must have been able to discover the composition of a product, and reproduce it "without undue burden." A gene sequence e. g. could in principle be made public if deposited in a gene bank, provided it could not only be detected by probing tens of thousands of samples.

The word "public" in Article 52(4) does not, according to case law from the EPO, necessarily refer to the man in the street. A disclosure before a skilled person makes it "public" in the sense that the skilled person is able to understand the disclosure and is potentially able to distribute it further to other skilled members of the public.

Furthermore, to be novelty-destroying, the information made available to the public must describe the invention in its entirety. An invention only lacks novelty if it is more or less identical to an invention in a patent application or existing patent, in its entirety is described in the prior art or in its entirety exists on the market. This is called the "whole contents principle". There is no anticipation if several documents are read together ("mosaicing") and one does not positively cross-refer to the other. In this case however, the invention may possibly lack inventive step.

Mercer discusses biotechnological inventions relating to the criterion of novelty. In a hypothetical case, he analyzes several of the products common in biotechnology, e. g. cell lines, proteins, cDNA sequences, etcetera. Concerning the cell line his conclusion is that it is novel: "If the existence of a particular cell line is not suspected and it is then isolated, it may be novel. Until it was isolated, it was not available to the public." He argues in the same manner regarding the hypothetical protein: 

"[The protein] had never been made available to the public as an isolated material. This conclusion is not affected by the fact that [it] may have existed in human bodies for many millions of years. It is also unaffected by the fact that the function fulfilled by the protein had been known before. The knowledge that the function exists does not make available to the public the product which produces that function."

cDNA (complementary DNA) sequences are common products of biotechnology and consists of gene sequences removed of its non-coding parts, the so called introns. Regarding this, Mercer concludes that they are capable of meeting the criterion of novelty: "Until [...] produced, the cDNA

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65 Id.
66 Id., at 191-192.
69 Koktvedgaard, at 280-281.
70 Cornish, at 190.
71 SOU 2008:20, supra note 68.
73 Id.
had not existed, even in nature."74 In other words, the fact that cell lines, proteins, gene sequences, microorganisms etcetera have occurred in nature and therefore are not new in the sense that they are something that man has created, is not relevant for the assessment of novelty. It is the invention that must be new. The fact that the invention uses already known phenomena is of no significance for the novelty assessment.75 The enactment of these principles in Article 3(2) and 5(2) of the Biotechnology Directive and the corresponding EPC Rules 27(a) and 29(2) have already been discussed. Reference can also be made to the EPO Boards of Appeal case H2-Relaxin in which the Opposition Division held that a DNA fragment encoding a human protein, does not lack novelty by virtue of having always been present in the human body, and that the isolation and characterisation of a DNA fragment encoding a human protein does not represent a discovery.76

The principle that once a thing has been made public no one may have a patent for it, is in reality a ground rule with a number of exceptions.77 Selection patents, selecting a particular product in a known range of products, are e. g. permissible under certain circumstances. The fact that a sub-range of compounds has a technical effect which differentiates it from the wider class does not per se mean that it is novel and inventive. The applicant must show that all the substances claimed in the sub-class have an unexpected and beneficial quality.78

The EPO also treats as novel a claim to a known way of using a known thing where it is shown that this has a novel and nonobvious advantage. Subsequent decisions of the EPO though have stressed that there must be a new purpose and not merely a novel technical effect.79

The EPO Guidelines carefully stress that novelty and inventive step are different criteria: "Novelty exists if there is any difference between the invention and the known art. The question – 'is there inventive step?' – only arises if there is novelty."80 Inventive step will now be considered.

3.2.5 Inventive step

The second patentability criterion is inventive step. Article 56 EPC states that "[a]n invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art." The state of the art within the meaning of this article is the same

74 Id., at 483.
76 Koktvedgaard, at 255. See also the case: T 272/92, Relaxin/HOWARD FLOREY INSTITUTE, O.J.EPO 1995 s 388.
77 Cornish, at 193.
78 Tritton, at 95-96.
79 Cornish, at 196.
conception that operates in assessing novelty, except that European patent applications filed prior to the filing date of the patent application to be examined, but published on or after that date, shall not be considered as comprised in the state of the art.\textsuperscript{81} According to Article 56 EPC, 2nd sentence: "If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents shall not be considered in deciding whether there has been an inventive step." Inventive step is also referred to as nonobviousness. The US patent law uses this term.\textsuperscript{82}

The purpose of the requirement for an inventive step is to secure that patents are granted only for inventions which are innovative achievements. A comparatively simple modification of the state of the art can result in a patent application being considered novel. On the other hand, to be considered as involving an inventive step, there has to be a substantial difference between the invention and the state of the art. If this requirement is underplayed, banal developments of a certain invention can be granted patent protection and so called "royalty- stacking" can result, to the detriment of research.\textsuperscript{83}

The Swedish Committee on Patent Protection for Biotechnological Inventions points out that the assessment of inventive step is not an exact science. Every patent application is unique and a coherent standard for inventive step is above all created through case law.\textsuperscript{84} Tritton is of the same opinion, arguing that the issue of obviousness is much more case-dependant than the issue of novelty. However, the approach of the EPO can be ascertained from its Guidelines and from cases of the Boards of Appeal.\textsuperscript{85}

The examiner can arrive at a comparatively exact opinion about the state of the art when testing the novelty criterion. In contrast, as reference for the assessment of inventive step is used the fictitious "person skilled in the art". Obviousness is to be tested by making a hypothetical assessment. The EPO Guidelines C-IV.11.4 phrases it like this:

"[T]he question to consider, in relation to any claim defining the invention, is whether before the filing or priority date valid for that claim, having regard to the art known at the time, it would have been obvious to the person skilled in the art to arrive at something falling within the terms of the claim. If so, the claim is not allowable for lack of inventive step."\textsuperscript{86}

The term "obvious" is defined in The Guidelines as "that which does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something

\textsuperscript{81} Cornish, at 198.
\textsuperscript{82} MacQueen, at 444.
\textsuperscript{84} Id.
\textsuperscript{85} Tritton, at 99.
which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art.\textsuperscript{87}

The person skilled in the art is not an inventor. On the contrary, he or she is an ordinary practitioner and lacks inventive capacity. The EPO Guidelines C-IV.11.2., defines the concept in the following manner:

"The 'person skilled in the art' should be presumed to be an ordinary practitioner in a field of technology aware of what was common general knowledge in the art at the relevant date. He should also be presumed to have had access to everything in the 'state of the art', in particular the documents cited in the search report, and to have had at his disposal the normal means and capacity for routine work and experimentation. If the problem prompts the person skilled in the art to seek its solution in another technical field, the specialist in that field is the person qualified to solve the problem. The assessment of whether the solution involves an inventive step must therefore be based on that specialist's knowledge and ability [...]. There may be instances where it is more appropriate to think in terms of a group of persons, e.g. a research or production team, than a single person. This may apply, for example, in certain advanced technologies such as computers or telephone systems and in highly specialised processes such as the commercial production of integrated circuits or of complex chemical substances."\textsuperscript{88}

When assessing inventive step, the EPO uses the so called "technical problem-and-solution approach" and the "could-would approach". These are outlined under heading 3.3.2 below.

As outlined above, when assessing novelty, it is not possible to combine different pieces of prior art in order to say that something is not new. In contrast, this is permissible when testing inventive step so long as it is something that the person skilled in the particular art would have done.\textsuperscript{89}

The EPO has, in a couple of rulings, developed the concept of the "person skilled in the art". He or she is capable of making certain changes to the known art to improve it or adjust it for some purpose. It follows from this that there must be a certain distance from the known art to a patentable invention.\textsuperscript{90} Moreover, the person skilled in the art is not a risk taker and it is expected that he or she wants to finish the job within a reasonable time. For this reason, he or she would like a reasonable expectation of success when choosing between different solutions to a technical problem. Consequently, there is no inventive step if it is obvious that a person skilled in the art would have tested the solution for which a patent is sought with a reasonable expectation of solving the problem at hand in this manner.\textsuperscript{91} This is called "the obvious-to-try test" (see also 3.3.4 below). According to Cornish, "the fact that an idea escapes being anticipated only by the shortest remove will often jeopardise the chances of it being found inventive."\textsuperscript{92} The obvious-to-try test is appealing

\textsuperscript{87} Id.
\textsuperscript{88} Guidelines for Examination in the European Patent Office, C-IV.11.2.
\textsuperscript{89} MacQueen, at 445.
\textsuperscript{90} SOU 2008:20, The Committee on Patent Protection for Biotechnological Inventions, at 162.
\textsuperscript{91} Id., at 163.
\textsuperscript{92} Cornish, at 208.
to tribunals in many situations where pre-existing information falls only a little short of what is claimed to be inventive.\textsuperscript{93}

In T 149/93, the EPO Board of Appeal stated that a course of action could be considered obvious within the meaning of Article 56 EPC if the skilled person would have carried it out in expectation of some improvement or advantage. In other words, obviousness was not only at hand when the results were clearly predictable but also when there was a reasonable expectation of success.\textsuperscript{94}

In T 296/93, the Board of Appeal held that the fact that other persons or teams were working contemporaneously on the same project might suggest that it was obvious to try or that it was an interesting area to explore, but it did not necessarily imply that there was a "reasonable expectation of success". A reasonable expectation of success should not be confused with the understandable "hope to succeed". The skilled person has the ability to predict rationally, on the basis of the knowledge existing before a research project was started, the successful conclusion of the project within acceptable time limits. The more unexplored a technical field of research was, the more difficult it was to make predictions about its successful conclusion and, consequently, the lower the expectation of success.\textsuperscript{95}

Defining the concept of the skilled person as a group of researchers is, in effect, a way of raising the bar to patentability. On the other hand, stating that the expectation of success is lower in unexplored technical fields can in effect lower the bar.

Though the person skilled in the art is labeled "an ordinary practitioner", he can be thought of as an odd and unrealistic character. Indeed, according to the UK Lord Justice Jacob, he is "first and foremost, a nerd!"\textsuperscript{96} On the one hand he is aware of everything in the state of the art, i. e. he or she has an unlimited capacity to consume and grasp enormous amounts of technical literature. On the other hand, as MacQueen puts it, "he will not join the dots between different pieces of prior art unless it is obvious to do so."\textsuperscript{97}

\textsuperscript{93} Id., at 209.
\textsuperscript{95} Id., at 133.
\textsuperscript{96} MacQueen, at 446.
\textsuperscript{97} Id.
3.2.6 Industrial application

The third and last patentability criterion is industrial application. Article 57 EPC states that "[a]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture." The phrase "made or used" means that according to this article, at least at first glance, it is enough that an invention can be produced within an industry. The term "industry" is widely interpreted and to be understood as meaning activities carried out continuously, independently and for financial gain.

As has been outlined above under 3.1.3, article 57 EPC is however not the sole provision governing the criterion of industrial application for European patents regarding biotechnological inventions. The Biotechnology Directive and the corresponding Rules and Recitals of the Implementing Regulations to the EPC are also to be considered. Since they have been outlined and commented above they are not reiterated here, but their relation to Article 57 are discussed, as well as the EPO case law applying and interpreting them.

According to Aerts, "[t]he provision of [Rule 29(3)] distinguishes genomic inventions from other inventions, for which it is sufficient if the invention can be made or used to fulfil the requirement of industrial applicability under the EPC." Actually, this is not entirely true, since Rule 42(1)(f) of the Implementing Regulations to the EPC requires that the patent description for inventions in general indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable. The difference is that the industrial application of a sequence or partial sequence of a gene is never, pursuant to Rule 29(3), considered obvious, and must therefore always be disclosed in the patent application.

An important point to note is that the combined reading of Rule 42(1)(f) and Rule 29(3) leads to the conclusion that the industrial application does not have to be disclosed in the patent claims. It is enough to disclose the industrial application in the patent description. In other words, absolute product protection on genes and gene sequences is not precluded. Aerts also points to the fact that the requirement in Rule 29(3) does not apply to sequences or partial sequences of proteins. Nevertheless, the explicit demand that the industrial application must be disclosed in the patent application is unique to biotechnology.

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98 Minßen, part 2, at 343.
99 Tritton, at 110.
100 Aerts, at 351.
101 Minßen, part 2, at 344.
102 Domeij, at 51-52.
103 Aerts, at 351.
Whereas Article 5(3) of the Biotechnology Directive is binding on the 27 member states of the EU to which it is directed, and consequently on their respective national patent laws, Rule 29(3) EPC is subsidiary to Article 57 of the EPC. This is a consequence of Article 164(2) EPC stating that "[i]n case of a conflict between the provisions of this Convention and those of the Implementing Regulations, the provisions of this Convention shall prevail." This has in the past caused uncertainty, reflected in the EPO case law.  

The requirement of industrial application poses a practical barrier to a patentee deciding at what stage of the inventive process an application for a patent should be sought. If the invention is still at a theoretical stage, no matter how advanced it is, it will still be premature to make an application if the industrial applicability cannot be demonstrated.

Generally speaking, it would seem that the requirements of the Biotechnology Directive have increased the relative importance of the criterion industrial application in the overall examining procedure.

In addition to the basic patentability criteria, there is also the requirement of disclosure of the invention. EPC Article 83 provides that: "The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art." This is also called "enabling disclosure." According to Rule 42(1)(e), the patent description is to describe in detail at least one way of carrying out the invention claimed, using examples where appropriate and referring to the drawings, if any. Regarding biological material, Rule 31(1)(a) states that a sample can instead be deposited with a recognised depository institution no later than the filing date of the application and on the terms laid down in the so called Budapest Treaty. The case law of the EPO requires that a skilled person must be able to reproduce the invention "without undue burden." This is also reflected in the EPO Guidelines for examination. In this situation, the person skilled in the art is presupposed to have the same properties as in relation to novelty and inventive step. The description must also contain

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104 Minβen, part 2, at 345-346.
105 Torremans, at 77.
106 See e. g. the discussion in Minβen, part 2, at 373-374.
107 MacQueen, at 438.
108 Rule 42(1)(e) of the Implementing Regulations to the EPC.
109 Rule 31(1)(a) of the Implementing Regulations to the EPC.
112 SOU 2008:20, supra note 110.
sufficient information to allow the person skilled in the art to perform the invention over the whole area claimed.\textsuperscript{113}

3.3 EPO practice

3.3.1 Introduction

In their examination process, the EPO uses different methods, or "approaches". A general motive for applying is to promote objective estimates and fair dealing. Some of the methods have been briefly mentioned above. The most relevant approaches in relation to biotechnology patents are now to be outlined.

3.3.2 The technical problem-and-solution approach

This method is used when considering inventive step and is intended to eliminate the problem of hindsight, i.e. assessing inventive step by reference to the invention itself rather than from the prior art.\textsuperscript{114} Via this approach, the situation at the filing date is, to a certain extent, restored and the problem of hindsight can be avoided.\textsuperscript{115} The problem-and-solution approach was first established in the EPO case law.\textsuperscript{116} The method is described in the EPO Guidelines C-IV.11.7. as follows:

"In practice, in order to assess inventive step in an objective and predictable manner, the examiner should normally apply the so-called 'problem-and-solution approach'. In the problem-and-solution approach, there are three main stages: (i) determining the 'closest prior art', (ii) establishing the 'objective technical problem' to be solved, and (iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person."\textsuperscript{117}

The first stage in the method is to determine the closest prior art. This concept is not synonymous with prior art. Rather, "prior art" is a starting point to determine the "closest prior art". According to the Case law of the Boards of Appeal:

"[C]areful consideration must be given to the question whether, in the case concerned, the skilled person, taking into account all the available information on the technical context of the claimed invention, would have had good reason to take this prior art as the starting point for further development. […] [T]he closest prior art for assessing inventive step is normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common."

The second stage is to establish the objective technical problem to be solved. The examiner is to study the application, the closest prior art and the difference in terms of features between the

\textsuperscript{113} Id.
\textsuperscript{114} Tritton, at 100.
\textsuperscript{115} Domeij, at 86.
\textsuperscript{116} Id., at 85.
\textsuperscript{117} Guidelines for Examination in the European Patent Office, C-IV.11.7.
\textsuperscript{118} Case Law of the Boards of Appeal of the European Patent Office, at 121.
invention and the closest prior art and then formulate the technical problem. The problem must be a technical problem, it must be solved by the solution claimed and all the features in the claim should contribute to the solution.

In the third stage, the so called "could-would approach" is applied in certain cases. This is used in tandem with the problem-and-solution approach. The EPO considers:

(i) whether the skilled but un inventive person could have come up with the invention. This is in effect to consider the degree of cleverness of the invention.
(ii) whether the skilled but un inventive person would have come up with the invention. This is essentially to consider if the skilled person would have been motivated to improve the prior art in expectation of some improvement or advantage.

3.3.3 Technical advantage

Technical advantage is an indicator of inventive step, particularly in research intense areas. If an invention is shown to be of considerable technical value, and especially if it has a new and surprising technical advantage, the EPO examiner is instructed to be "hesitant" to object to the application on the grounds of lack of inventive step. This is so provided that it would not have been obvious for a skilled person to arrive at the invention, for example due to a lack of alternatives creating a "one-way street" situation, in which case the advantage is merely considered a bonus effect which does not indicate inventive step.

Domeij points out that he who objects to an invention with a considerable technical value on the grounds of lack of inventive step must be able to explain why someone else did not come up with the invention if it was possible for the uninventive person skilled in the art. Therefore, these types of inventions are normally patentable.

3.3.4 Obvious to try and no real expectation of success

If the inventor chose from a finite number of identified, predictable solutions, with a reasonable expectation of success, then it was "obvious to try", which is indicative of lack of inventive step. On the other hand, there might be a situation where prior art points to a particular research path, but such a path is seen as involving real difficulties and requiring complex technique. In other words, research in a certain direction is discouraged. In those circumstances, even if there is a "signpost" to

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120 Tritton, at 100-101.
121 Id., at 103.
122 Domeij, at 89.
124 Id.
125 Domeij, at 87.
the invention, the person skilled in the art is unlikely to try it as there is no real expectation of success.  

If the invention nevertheless is based on that path, that may support a finding of inventive step.

3.3.5 Secondary indications

Secondary indications have been developed in case law and may support inventive step, but are as a generality regarded as secondary compared to the technical considerations.

If there is a long period between the prior art and the invention, that is an indication of inventive step, especially if there are evidence of failed attempts to improve the state of the art. If an invention otherwise fulfils a long-felt need, this may also indicate inventive step. According to the EPO Guidelines, commercial success alone is not to be regarded as an indication of inventive step, but evidence of immediate commercial success when coupled with evidence of a long-felt need is relevant. However, the examiner must be convinced that the success derives from the technical features of the invention and not from other influences, e.g. marketing. Torremans, looking at European patent law from a UK perspective, is critical and calls this nonsense. He argues that all manner of factors go towards explaining the success of a new product. The view, expressed in UK case law, that obviousness is a technical question and not a commercial one, is to be preferred.

3.4 Case law on biotechnology

3.4.1. Case law on novelty

The Boards of Appeal case T 838/97, Translational inhibition/RESEARCH FOUNDATION, concerned a patent application for a nucleic acid construct with three segments: a promoter segment, a nucleic acid segment and a termination segment. The appellants objected to novelty on the grounds that the construct had been presented in a scientific publication before the filing date. The article mentioned the nucleic acid segment, but not the promoter and the termination segment. The TBA stated that a certain document can be novelty-destroying only if it contains a

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126 Tritton, at 109.
127 Paterson, at 560.
128 Domeij, at 89-90.
130 Id.
131 Id.
132 Torremans, at 73.
"clear and unmistakable disclosure for the skilled person of the subject matter of a claim in question." The board went on by saying that:

"[N]ovelty assessment is not based on a mere photographic comparison with a prior art document, but requires consideration of both the explicit and implicit disclosure of the document. However, there must be no doubt that the prior disclosure, as read by the skilled person, unambiguously corresponds in all its technical features to the subject-matter as claimed." According to the board this was not so in the case at hand.

The appellants in T 838/97 also objected to novelty on the grounds that the invention had been presented orally at a conference prior to the patent application. The conference was attended by about 100 of the most renowned experts in the relevant technical field. The TBA considered that the participants were bound by a confidentiality agreement and thus the invention was not part of the state of the art. The confidentiality restrictions which the participants were invited to accept upon registration could not be narrowly interpreted as being limited to e.g. printed references.

In the Boards of Appeal case T 576/91, Plasmid pTR2030/NORTH CAROLINA STATE UNIVERSITY, patent protection was sought for a plasmid. To be able to produce it, two sorts of so called "starting strains" from an outside laboratory were needed. The Examining Division refused a patent on the grounds i.a. that the plasmid and the method to synthesize it had been presented in a scientific journal prior to the filing date. There was also an ethical rule of the scientific community that specimens of published microorganisms must be made available to other researchers on request. The TBA stated that the ethical rule did not automatically mean that the invention was made available to the public. The receiving researcher is obliged to respect patent rights. The publication in the scientific journal did not contain an enabling disclosure. The publication would have enabled a skilled person to reproduce the plasmid provided the starting strains were available. However, one of the strains was not available to the public. Only the laboratory and the appellant had access to it, and the appellant was obliged not to make it available to third parties.

T 838/97 and T 576/91 develop the EPO principles on novelty. The assessment of novelty only considers information that directly and unambiguously discloses the invention. If there are any doubts about this, then a patent application cannot be rejected on the grounds of lack of novelty. The invention must furthermore be disclosed in its entirety by the information made available to the

134 T 838/97, Translational inhibition/RESEARCH FOUNDATION, at 12.
135 Id.
138 T 838/97, at 10.
140 Id., at 151.
public for it to be novelty-destroying. The invention must in all essentials be identical to an already known corresponding phenomenon for there to be lack of novelty. The holding regarding the oral presentation at the conference in T 838/97 underlines that an agreement ruling out availability to the public does not necessarily have to be a contract made in writing.

3.4.2. Case law on inventive step

In the TBA case T 923/92, t-PA/GENENTECH, the board had to decide whether the skilled person would have attempted, with a reasonable expectation of success, to produce cDNA coding for the human protein t-PA. The board stated that, although hoping to succeed, the skilled person would have known that the successful conclusion of the project depended not only on technical skill in putting into practice the sequence of precise steps of the theoretical experimental protocol, but to a large extent also on the ability to take the right decisions along the way whenever a difficult experimental situation so required. Under these circumstances, it could not be said that the skilled person with a reasonable expectation of success would have attempted to produce the cDNA.

A similar and more recent ruling from the Boards of Appeal is T 182/03, Phosphodiesterase/SMITHKLINE BEECHAM, concerning an invention involving an isolated nucleic acid molecule encoding an enzyme acting on the cellular signaling involved in several illnesses. The board stated that already described in the known art was another form of the enzyme. In said description however, it was stressed that using the known cDNA to search for a potential drug was difficult, since there were a large number of variants of the enzyme. In addition to this, the enzyme was present in many different forms of tissue. The person skilled in the art would not from prior art have been capable to determine the number of enzymes existing. Moreover, the cDNA in the patent application was different from the known art in that it only occurred in certain types of tissue, which made it suitable to search for a chemical substance to be used as a drug, something that the applicant had succeeded in. On these grounds, inventive step was considered present.

A relatively common situation when assessing inventive step in biotechnological inventions is that there are homologous gene sequences to the gene sequence in the patent application. A homologous gene sequence is a similar sequence occurring in other organisms. A human gene sequence might e. g. have a homologous sequence in a mouse or a rat.

141 Id., at 161.
142 T 838/97, at 8.
145 Id., at 165.
In T 150/03, Channel proteins/CHIBA UNIVERSITY, a protein complex occurring in humans and rat was already in the state of the art, as was cDNA from rat coding for the protein complex. The applicant sought a patent for the homologous gene sequence, but the TBA concluded that the skilled person would have had a strong incentive to look for the human homolog and that, considering the similarities between the rat and human protein complexes, he or she would have arrived with a reasonable expectation of success at the solution in the patent application. Therefore, the board concluded that the claim in question did not involve an inventive step.146

In the Boards of Appeal case T 280/00, Inhibin/GENENTECH, the patent application was for the human gene sequence of a hormone, inhibin. In prior art there were information about inhibin isolated from cattle and pig. Moreover, the cDNA coding for inhibin was known. The technical problem allegedly solved in the patent application was the method for producing the human gene sequence for inhibin. The board stated that the knowledge of the function of inhibin in cattle and pig made it an interesting substance from a medical perspective. The skilled person would for this reason be interested in finding the homologous human gene sequence encoding inhibin.147 However, there was no reason to believe that there would exist in humans the exact counterpart of porcine inhibin. Thus, in using the porcine inhibin encoding DNA to help isolate the human inhibin encoding DNA, the skilled person would have had some hope that he or she might succeed in isolating the human gene sequence. However, this hope did not amount to a reasonable expectation of success. For these reasons, inventive step was acknowledged.148

The cited cases T 150/03 and T 280/00 illustrate the importance of the "reasonable expectation of success" approach in relation to biotechnological inventions. They also illustrate that inventive step in applications on homologous gene sequences presupposes unexpected properties compared with the already known gene sequence.149

3.4.3. Case law on industrial application

The case law of the Boards of Appeal has clarified the current position of the EPO on the interpretation of Article 57 and the associated Implementing Regulations and relevant articles of the Biotechnology Directive.

146 Id.
147 Id., at 166-167.
148 T 280/00, at 19.
In the Opposition Division case V28 seven transmembrane receptor/ICOS, O.J.EPO 2002 p. 293, a patent on a purified and isolated gene encoding a protein was opposed on the grounds i. a. that the function of the protein was not sufficiently disclosed in the patent application. The case concerned articles 57 and 83 of the EPC. The patentee argued that according to Article 57 the requirements for industrial application of an invention are satisfied "if it can be made or used in any kind of industry". It was argued that the specification discloses how to make the V28 protein and also discloses uses of V28 protein mainly as a receptor involved in immunological processes. The Opposition Division stated that the protein in the patent application was only predicted to function as a receptor. The specification did not demonstrate that the V28 protein is a receptor. Instead, it disclosed several methods which could be used by the skilled person in order to verify the prediction that the V28 protein is indeed a receptor. However, the skilled person seeking to perform the claimed invention had to test millions of available candidate compounds. This undertaking constituted an undue burden for the skilled person. The Opposition Division held that "[a] DNA sequence encoding a protein without a credible function is not a patentable invention." The patent was revoked. The Opposition Division also stated that "the potential uses disclosed in the application are speculative, i. e. are not specific, substantial and credible and as such are not considered industrial applications." The formulation "specific, substantial and credible" is identical with the phrasing in the USPTO Utility Guidelines, adopted in 2001. For formal reasons, the EPO Board of Appeal never tried the ICOS case. Therefore a certain insecurity remained as to the legal status of Rule 29(3).

The Boards of Appeal case T 870/04, BDP1 Phosphatase/MAX-PLANCK concerned a patent for BDP1 Phosphatase, an enzyme catalyzing a process believed to be of importance in the emergence of colon cancer. The EPO Examining Division refused a patent on the grounds that the industrial application of the invention was not disclosed in the patent application. The decision was appealed to the TBA, but dismissed. The board stated that the requirement of Article 57 EPC that the invention "can be made or used" in at least one field of industrial activity emphasized that a "practical application" of the invention had to be disclosed. Merely because a substance could be produced in some ways did not necessarily mean that this requirement was fulfilled, unless there would be a specific use of the substance in a particular field of industry. The formulation "specific, substantial and credible" is identical with the phrasing in the USPTO Utility Guidelines, adopted in 2001. For formal reasons, the EPO Board of Appeal never tried the ICOS case. Therefore a certain insecurity remained as to the legal status of Rule 29(3).

151 V28 seven transmembrane receptor/ICOS, O.J.EPO 2002 p. 293, at 303.
152 Id., at 300.
153 Id., at 301.
154 Id., at 293.
155 Id., at 308.
156 Id., at 304.
157 Minfjen, part 2, at 346.
was also some profitable use for which the substance could be employed. The board also stated that in cases where a substance, naturally occurring in the human body, was identified, and possibly also structurally characterised and made available through some method, but either its function was not known or it was complex and incompletely understood, and no disease or condition had yet been identified as being attributable to an excess or deficiency of the substance, and no other practical use was suggested for the substance, then industrial applicability could not be acknowledged. The board observed that no doubt existed that a BDP1 polypeptide could be "made and used" as a further tool for exploring the cellular signal transduction pathways. The whole burden was however left to the reader to guess or find a way to exploit it in industry by carrying out work in search of some practical application geared to financial gain, without any confidence that any practical application existed. The board considered that no such suggestion could be derived from the application itself or from the prior art. The purpose of granting a patent was not to reserve an unexplored field of research for an applicant. Minßen emphasizes that the board in T 870/04 characterizes the polypeptide in question as a research object, not a research subject. This was a crucial factor for finding a lack of industrial application.

Some subsequent Boards of Appeal cases will be briefly summarized. T 1329/04, Factor-9/JOHNS HOPKINS reflected the establishment of a stricter case law and is considered important. The case established the "at least plausible test". At the filing date it must be at least made plausible by the disclosure in the application that its teaching solves the problem it purports to solve. Therefore, even if supplementary postpublished evidence may also be taken into consideration, it may not serve as the sole basis to establish that the application solves the technical problem. This means that already at the filing date it must be at least plausible to a person skilled in the art whether an invention is capable of fulfilling the patentability criteria. In T 604/04, PF4A receptors/GENENTECH, the board however demonstrated that it intended to apply a pragmatic and case-by-case interpretation to the "at least plausible test", as well as to the principles laid down in T 870/04. T 604/04 and T 338/00, Multimeric Receptors/SALK INSTITUTE, has shown that a protein can be regarded as industrially applicable even if the patent application can not refer to sufficient experimental data. In these cases the industrial application was derived from the patent description combined with the general knowledge in prior art.

160 Minßen, part 2, at 357.
161 Minßen, part 2, at 358-359.
163 Minßen, part 2, at 358.
164 Id., at 362-363.
165 Id., at 368.
T 898/05, Hematopoietic receptor/ZYMOGENETICS, developed the concept "practical industrial application" established in T 870/04. The board held that a claimed invention must have such a sound and concrete technical basis that the skilled person can recognise that its contribution to the art could lead to practical exploitation in industry, i.e. to a concrete benefit, which is immediately derivable directly from the patent description. It is necessary to disclose in definite technical terms the purpose of the invention and how it can be used in industrial practice to solve a given technical problem. The board also stated that the fact that a function is based on computer-assisted methods rather than on traditional wet-lab techniques does not mean that it has to be automatically disregarded or excluded from examination. Instead the value of the methods has to be examined on a case-by-case basis. Finally, the board held that the function of a protein can be seen at different levels, the molecular function, the cellular function and the biological function. The elucidation of one of these levels of function might be enough for a finding of industrial application.

In the relatively recent TBA cases T 641/05, GPCR-like receptor/PHARMACIA; T 1452/06, Serine Protease/BAYER and T 1165/06, IL-17 related polypeptide/SCHERING, the board has confirmed its pragmatic approach, while at the same time retaining high demands for computer-assisted homology studies. It can be concluded that the TBA now definitely has established that Rule 29(3) of the Implementing Regulations to the EPC must be strictly interpreted and is consistent with Article 57 EPC.

3.4.4. Case law in 2008 and 2009

The development of EPO case law regarding the patentability criteria seems, at the moment, to have taken a hiatus. In 2008 and in 2009 so far there have been no EBA cases and only two TBA cases decided on EPC articles 54, 56 and 57 deemed important enough for internal distribution, let alone publication in the Official Journal. A reason might simply be that no controversial cases have come before the boards. Nevertheless, a couple of TBA's decisions will be very briefly mentioned. Note that the cases in question are not necessarily commonplace. It is rather a question about the case law applied already being established.

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167 T 898/05, Hematopoietic receptor/ZYMOGENETICS, at 1-2.
168 Minjšen, part 2, at 370-373.
169 Id., at 374.
170 The two internally distributed cases, T 385/07 and T 390/07, include assessment of patentability criteria, but essentially address other provisions in the EPC.
In T 1154/07, Antibody fragments/UNILEVER, decided in May 2008, a patent for a method to
prepare a gene library was rejected for lack of inventive step. Replacing a pre-immunised source in
the method by a non-immunised source would have been obvious to try with a reasonable
expectation of success.\(^{171}\) In T 1540/07, Cytokine receptor/HUMAN GENOME SCIENCES,
decided in December 2008, the TBA again confirmed its case law on industrial application.
Referring to T 898/05, which established the demand for a disclosed "immediate concrete benefit",
a gene sequence coding for the protein cytokine was held industrially applicable based on
computer-assisted sequence homology studies.\(^{172}\) In T 861/08, Subtilisin changes
epitopes/NOVOZYMEs, decided in August 2009, inventive step was rejected for the
immunogenicity reducing protein subtilisin and a method of producing it, on the ground of an
inadequately disclosed causal link between the technical problem and the invention. The court also
referred to T 1329/04 and restated that postpublished evidence may be used only to support
information already derivable from the original application.\(^{173}\)

4. Patenting Biotechnological Inventions in the United States

4.1 The general legal framework

4.1.1 Foundation and judicial review

The foundation of the US patent law, and copyright law, is part of the Constitution. Article I,
Section 8, Clause 8 empowers Congress "[t]o promote the progress of science and useful arts, by
securing for limited times to authors and inventors the exclusive right to their respective writings
and discoveries."\(^ {174}\) The United States Supreme Court has understood this clause to be both a grant
of power and a limitation.\(^{175}\)

Patents are under the exclusive jurisdiction of the United States federal government.\(^{176}\) Licensing
and assignments of patents though, are governed by state contract and property law.\(^ {177}\) The current
statute of American patent law is the Patent Act of 1952, which is embodied in Title 35 of the
United States Code.\(^ {178}\)

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\(^{171}\) T 1154/07, Antibody fragments/UNILEVER, at 6-7.
\(^{172}\) T 1540/07, Cytokine receptor/HUMAN GENOME SCIENCES, at 15-16.
\(^{173}\) T 861/08, Subtilisin changes epitopes/NOVOZYMEs, at 11, 16-17.
\(^{174}\) US CONST. ART 1, § 8, CL. 8.
\(^{175}\) Halpern, Sheldon W., Nard, Craig Allen and Port, Kenneth L., Fundamentals of United States Intellectual Property
\(^{177}\) Id., at 112.
\(^{178}\) Halpern, at 196.
The United States Patent and Trademark Office (USPTO) issue patents in accordance to the Patent Act. Adverse decisions of examiners are, on written appeal of applicants, reviewed by the Board of Appeal and Interferences (BPAI), a body within the USPTO.\textsuperscript{179} The BPAI also decides interferences, a procedural mechanism to determine who the first inventor is.\textsuperscript{180} In contrast to the rest of the world, the USA practices a first-to-invent system, granting the patent to the first inventor who reduces the invention to practice. Other countries grant the patent to the inventor who first files a patent application.\textsuperscript{181}

Decisions by the BPAI can be appealed to the United States Court of Appeals for the Federal Circuit (CAFC).\textsuperscript{182} Patent applicants can, instead of bringing the case to the CAFC, seek remedy by civil action in the United States District Court for the District of Columbia.\textsuperscript{183} Decisions by the district court are appealed to the CAFC.\textsuperscript{184} Rulings by the CAFC in turn may be reviewed by the United States Supreme Court by writ of certiorari.\textsuperscript{185, 186}

4.1.2 Obtaining a patent in the United States

A patent valid for the United States can be sought via a patent application to the USPTO as discussed above. However, the United States is also a signatory to the Patent Cooperation Treaty (see 3.1.1 above).\textsuperscript{187} The PCT is incorporated into Title 35 of the United States Code.\textsuperscript{188} The USPTO acts as Receiving Office for international applications designating the United States.\textsuperscript{189} Patents granted in the United States are effective only within the United States and its territories and possessions.\textsuperscript{190}

Three types of patents are granted under the US Patent Act: utility patents, design patents and plant patents. Utility patents constitute over 99\% of all patents in the United States. Design patents concern the ornamental design of an article of manufacture, whereas plant patents are issued for

\begin{footnotes}
  \item[179] 35 U.S.C. §§ 6(b) and 134.
  \item[180] 35 U.S.C. § 6(b).
  \item[181] Domeij, at 24.
  \item[182] 35 U.S.C. § 141.
  \item[184] 28 U.S.C. § 1292 (c)(2).
  \item[185] 28 U.S.C. § 1254.
  \item[186] A writ of certiorari is a request that the Supreme Court order a lower court to send up the record of the case for review. The Court usually is not under any obligation to hear these cases, and it usually only does so if the case could have national significance, might harmonize conflicting decisions in the federal Circuit courts, and/or could have precedential value. See: http://www.uscourts.gov/outreach/topics/hamdan/procedures.html (homepage visited 2009-10-15).
  \item[190] Carlson, at 107.
\end{footnotes}
asexually reproduced plant varieties.\textsuperscript{191} Design and plant patents are outside of the the scope of the thesis and are not further discussed. Instead of patents, many industries in the United States opt for and rely on trade secret protection, especially for process-related inventions.\textsuperscript{192}

Governing the patent prosecution in the USPTO are, in addition to the Patent Act, Title 37 of the Code of Federal Regulations (CFR), also called the Consolidated Patent Rules, and the Manual of Patent Examining Procedure (MPEP).\textsuperscript{193}

4.2 Patentability criteria

4.2.1 Introduction and patentable subject matter

According to 35 U.S.C. § 101 "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." Patentable subject matter are in other words divided into four categories of inventions.

The term "machine" might speak for itself. A "composition of matter" is a substance resulting from known or new ingredients.\textsuperscript{194} A "manufacture" is anything human-made that is not a machine or composition of matter.\textsuperscript{195} Machines, manufactures and compositions of matter can be summarized under the title product claims. This is contrasted with process claims.\textsuperscript{196} 35 U.S.C. § 100(b) defines "process" as "process, art or method [including] a new use of a known process, machine, manufacture, composition of matter or material." In other words, a process may entail a new use for a known product.\textsuperscript{197}

Notwithstanding the fact that 35 U.S.C. § 101 includes the word "discovers", and the term "invention" for the purpose of the Patent Act according to 35 U.S.C. § 100(a) are defined as "invention or discovery", the courts have held that patent protection is not available for the laws of nature and natural phenomena.\textsuperscript{198} Products of nature, mathematical formulas, printed matter and objects offensive to public morality are also excluded subject matter.\textsuperscript{199}

\begin{thebibliography}{9}
\bibitem{191} Id.
\bibitem{192} Halpern, at 200.
\bibitem{194} Halpern, at 243.
\bibitem{195} Id.
\bibitem{196} Id., at 242.
\bibitem{197} Id., at 244.
\bibitem{198} Carlson, at 108.
\bibitem{199} Id.
\end{thebibliography}
According to Halpern, when discussing patentable subject matter in relation to biotechnology in the United States, one must begin with the Supreme Court case of Diamond v. Chakrabarty.\textsuperscript{200} The application was for a genetically modified micro-organism, an oil-eating bacterium, and the claims included a product claim for the bacterium itself.\textsuperscript{201} The USPTO rejected the product claim on the grounds that the bacterium was a product of nature, or alternatively a living thing and therefore outside of the purview of the US Patent Act.\textsuperscript{202} The Supreme Court ultimately overturned the USPTO examiner's rejection and held the bacterium patentable. Though the Court confirmed that patents are not available for products of nature per se, a patent may nevertheless be obtained once significant changes are made to that natural substance, such as purifying or isolating it from its source.\textsuperscript{203} The Court also stated that "the relevant distinction [is] not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."\textsuperscript{204} In Diamond v. Chakrabarty the Court also interprets the legislative history of the 1952 Patent Act as stating that patentable subject matter was intended to include "anything under the sun that is made by man."\textsuperscript{205} The precedential value of Diamond v. Chakrabarty has remained steady over the past three decades.\textsuperscript{206}

According to 35 U.S.C. § 101 an invention is to be "useful" to be granted a patent. In the American patent system, utility has a central role in the delimitation of patentable subject matter.\textsuperscript{207} This criterion can therefore be seen as an important element of the concept of invention pursuant to 35 U.S.C. § 101.\textsuperscript{208}

A recent case by the CAFC, In re Bilski, has caused concerns regarding patent eligibility for biotechnological inventions, especially for diagnostic methods, even though the case in itself is about a business method used in commodity trading.\textsuperscript{209} An article in Nature Biotechnology opines that the holding could have "serious implications for molecular diagnostic patents by narrowing

\textsuperscript{200} Diamond v. Chakrabarty, 447 U.S. 303 (1980).
\textsuperscript{202} Id., at 60.
\textsuperscript{203} Id., at 67.
\textsuperscript{204} Halpern, at 244.
\textsuperscript{205} Adelman, at 66.
\textsuperscript{206} Adelman, at 67.
\textsuperscript{207} Minñen, Timo, När anses en bioteknisk uppfinning vara komplett och praktiskt användbar - del 1 - om senare utveckling kring kravet på "industrial application" och "utility" för gen- och proteinrelaterade uppfningar i USA och Europa, NIR 3/2008, pp. 201 - 260, at 217.
\textsuperscript{208} Id., at 217-218.
\textsuperscript{209} In re Bilski, 545 F.3d 943 (Fed.Cir.2008).
what is patentable." According to Ballardini, Bilski represents "a massive shift in US patent policy, remarkably narrowing down the overall scope of process patents." The CAFC reconsidered and modified the standard for determining if a process is statutory subject matter.

The court adopted a "machine-or-transformation" test for determining patent eligibility under 35 U.S.C. § 101. According to this test, in order to be patentable, a process must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing. The CAFC indicated that the test should be used to determine whether any process claims are patentable in the United States, regardless of the nature of the technology. According to Adelman, the machine or transformation test is not new. Instead it recreates a situation of similar tests prevailing up until 1998. Before 1998, business methods were not eligible subject matter in the United States. The US Supreme Court granted certiorari on June 1, 2009 in the matter, now called Bilski v. Doll.

4.2.2 Novelty

As stated above, novelty is mentioned as a precondition for patent eligibility pursuant to 35 U.S.C. § 101. In more detail, the requirements for novelty are outlined in 35 U.S.C. § 102. The first to invent-system of the United States make for some differences compared to the EPC. According to 35 U.S.C. § 102, subsection (a) "[a] person shall be entitled to a patent unless [...] the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." As can be seen in Section 102, the knowledge or use must have occurred "in this country", whereas foreign patents and foreign printed publications may constitute prior art. This geographic limitation has been confirmed by the US Supreme Court.

Anticipatory prior art demands "identity of invention in a single prior art reference." US case law has provided that a patent claim is anticipated by prior art only if "each element of the claim at issue is found, either expressly or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice."

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213 Ballardini, at 368.
214 Simmons, at 245-246.
215 Adelman, at 119.
216 Carlson, at 108. In State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368 (Fed. Cir. 1998) the CAFC declared that business methods were not ineligible subject matter.
218 See Halpern, at 215-216.
219 Id., at 212.
The single prior art reference must have existed before the patent applicant's date of invention.\textsuperscript{220} The date of invention is the date when the inventor "reduces his invention to practice."\textsuperscript{221} This can consist either of "actual reduction to practice", when an invention is being shown to be suitable for its intended purpose, or "constructive" ditto, when a patent application is filed, regardless if anything is actually built, provided that the disclosure requirements of 35 U.S.C. § 112 (see below) are satisfied. In the absence of proof of actual reduction to practice, the filing date, in most cases, acts as the date of invention.\textsuperscript{222} Courts have also added that to constitute anticipatory prior art, the single prior art reference must enable one skilled in the art to make the invention.\textsuperscript{223}

4.2.3 Nonobviousness

4.2.3.1 General provisions and case law

Apart from being new, an invention must also sufficiently advance the useful arts. The doctrine of obviousness compares the claimed invention with the state of the prior art to make that assessment. Obviousness recognizes that an invention generally is a new combination of several elements already in prior art. To merit a patent however, this combination must be nonobvious from the viewpoint of one of ordinary skill in the art, at the time of invention.\textsuperscript{224} 35 U.S.C. § 103(a) contains the requirement of nonobviousness. According to the section:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

In making the assessment of differences, Section 103 requires consideration of the claimed invention "as a whole". This is to avoid evaluation of the invention part by part as a new combination can be nonobvious even if the component parts, taken separately, might be obvious.\textsuperscript{225} The nonobviousness requirement can be seen as "casting a broader net" than the novelty requirement since it recognizes that the limitations of a claimed invention may be scattered throughout more than one prior art reference.\textsuperscript{226} The US courts have contributed to the assessment that only prior art references analogous to the claimed subject matter may be used under Section

\begin{footnotes}
\footnote{\textsuperscript{220} Id., at 210.}
\footnote{\textsuperscript{221} Id., at 211.}
\footnote{\textsuperscript{222} Id., at 212.}
\footnote{\textsuperscript{223} Carlson, at 108.}
\footnote{\textsuperscript{224} Adelman, at 286.}
\footnote{\textsuperscript{225} Id., at 287.}
\footnote{\textsuperscript{226} Halpern, at 234.}
\end{footnotes}
The term "analogous" means prior art in the same field of endeavor, or reasonably pertinent to the problem with which the inventor is involved."\textsuperscript{227}

The relevant time for the assessment of obviousness is, according to Section 103, "the time the invention was made". This is difficult since, as Adelman puts it, "a patent examiner or court must enter a state of 'self-induced amnesia.'" The claimed invention must be forgotten and its differences from the prior art evaluated at a time before its creation.\textsuperscript{228}

Patent examiners and courts do not evaluate the invention according to their own capacity. Instead, Section 103 provides that the matter is to be seen from the perspective of "a person having ordinary skill in the art", in US patent law often abbreviated PHOSITA.\textsuperscript{229}

To prove obviousness under Section 103, it is permissible to combine the teachings of several prior art references.\textsuperscript{230} However, the CAFC has in certain cases declared that there must at the time of the invention, in the prior art, exist a specific teaching, suggestion or motivation (TSM) to a person having ordinary skill in the art, that he should combine the prior art references to make the invention and in so doing have a reasonable expectation of success. In the absence of any such teaching, suggestion or motivation, prima facie obviousness can be overcome. This is called the TSM-test.\textsuperscript{231} The CAFC has explained the rationale behind a rigorous application of the TSM-test as guarding against a hindsight-based obviousness analysis.\textsuperscript{232}

The second sentence of Section 103(a) provides that "[p]atentability shall not be negatived by the manner in which the invention was made." This phrase was intended to place inventions inspired by a "flash of genius" on a par with those created through exhaustive research and development.\textsuperscript{233}

The factual inquiries used when assessing nonobviousness in US patent law were set forth in the Supreme Court case Graham v. John Deere Co.\textsuperscript{234} The inquiries are: 1. the scope and content of the prior art, 2. the differences between the prior art and the claim at issue in the patented invention, 3.

\textsuperscript{227} Id., at 235.
\textsuperscript{228} Adelman, at 288.
\textsuperscript{229} Id., at 288-289.
\textsuperscript{230} Halpern, at 236.
\textsuperscript{231} Wong, Ha Kung and Lau, Dana, Combine and Conquer: Handling Biotech Combination Inventions in the Wake of KSR, Nature Biotechnology, vol 27 May 2009, p. 446 - 448, at 446.
\textsuperscript{233} Adelman, at 307.
\textsuperscript{234} Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 86 S.Ct. 684 (1966).
the level of ordinary skill in the art, and 4. any available objective evidence of nonobviousness.\textsuperscript{235} These four inquiries are called the Graham factors.\textsuperscript{236}

The fourth inquiry, available objective evidence of nonobviousness, are also called secondary considerations. In Graham, the Supreme Court stated that such considerations may have relevancy (emphasis added), but the US courts, especially the CAFC, have since then in reality treated these considerations as fullworthy Grahams factors.\textsuperscript{237} The objective evidence of nonobviousness to be considered in US patent law are commercial success, long-felt need/failure of others, copying, and licensing/acquiescence. Regarding the first two of these, see under 3.3.5 above. If a competitor copied the claimed invention, especially after first having tried to design around the patent, that is an indication of nonobviousness according to US law.\textsuperscript{238} The same is true for a situation where a competitor has accepted a licence. The argumentation is that a firm would not pay royalties on a patent unless it thought the patent was valid.\textsuperscript{239} Some references also mention other examples of secondary considerations, e. g. praise by other scientists and "teaching away", i. e. the inventor came up with the invention despite that prior art or other scientists pointed in other directions or discouraged the research path that lead to the invention.\textsuperscript{240}

4.2.3.2 Nonobviousness in biotechnology

According to Adelman, the search for a coherent nonobviousness doctrine in biotechnology has proven elusive. This is demonstrated in US law not least by the complex provisions of 35 U.S.C. § 103(b), a standard of nonobviousness for certain biotechnologies.\textsuperscript{241} Section 103(b) states i. a. that a biotechnological process under certain circumstances shall be considered nonobvious notwithstanding Section 103(a) if the process uses or results in composition of matter that is new and nonobvious, claims to the process and composition of matter are contained in the same patent application, or in separate applications with the same filing date and the process and the composition of matter were owned by the same person when it was invented.\textsuperscript{242} This is developed in detail in the rest of the subsection. Connarn explains that Section 103(b) was passed by the US Congress in 1995 in the Biotechnological Process Patents Act (BPPA). Prior to the enactment, the courts were relying heavily on chemical process patent cases in their analysis. As a result of the

\textsuperscript{235} Halpern, at 234-235.
\textsuperscript{236} See Halpern, at 239.
\textsuperscript{237} See Halpern, at 235 and 239; and see also Adelman, at 334-335.
\textsuperscript{238} Halpern, at 240.
\textsuperscript{239} Id., at 241.
\textsuperscript{240} See e. g. Wong and Lau, at 448.
\textsuperscript{241} Adelman, at 348.
\textsuperscript{242} 35 U.S.C. § 103 (b).
amendment, the rules of Section 103 are now different for the biotechnology field than for all other fields of invention.\footnote{Connarn, Kristin, Section 103 (b): Obviously Unnecessary?, Journal of High Technology Law, 5/2005, pp. 287 - 301, at 291-292.} Eight years after the enactment, there were still no cases decided based upon Section 103(b).\footnote{Id., at 301.} The enactment of Section 103(b) is interesting because it illustrates the tendency to special provisions in the field of biotechnology, and because it underlines the connection in US patent law between biotechnology and (other) chemical inventions. Minβen asserts that DNA and proteins in the United States, notwithstanding an intense debate, more or less are treated as "complex" chemical substances.\footnote{Minβen, part 1, at 218.Traditionally, this has been the case also in Europe, allowing e. g. for absolute product protection on genes [see e. g. SOU 2006:70, The Committee on Patent Protection for Biotechnological Inventions, at 19].} Aerts adds that as late as 2001 the USPTO stated that "[p]atent law provides no basis for treating DNA differently from other chemical compounds that are compositions of matter."\footnote{Aerts, at 351.} None of the other references neither introduces nor discusses or comments on Section 103(b). For this reason it will be disregarded for the rest of the thesis.

The CAFC case In re Deuel\footnote{In re Deuel, 51 F.3d 1552 (Fed.Cir.1995).}, decided in 1995, is an illustration of the view that genes are to be treated as chemical substances. The case concerned a claimed invention relating to isolated and purified cDNA molecules encoding a protein, HGBF, that stimulates cell division and thus facilitate repairing and replacing of damaged or diseased tissue.\footnote{Adelman, at 360.} The question was whether the combination of a method of gene cloning, together with a reference disclosing a partial amino acid sequence of a protein, may render cDNA molecules encoding the protein prima facie obvious under 35 U.S.C. § 103.\footnote{Id., at 364.} The USPTO examiner and the BPAI maintained that "when the sequence of a protein is placed in the public domain, the gene is also placed in the public domain because of the routine nature of cloning techniques."\footnote{Id., at 363.} The appellants referred to the doctrine of structural similarity for chemical inventions and asserted that the prior art did not suggest the claimed compounds to a person of ordinary skill in the art. The CAFC stated that the prior art did not disclose any relevant molecules that might render the claimed cDNA molecules obvious. The court stated that:

"A prior art reference disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein. No particular one of these DNAs can be obvious unless there is something in the prior art to lead to the particular DNA and indicate that it should be prepared."\footnote{Id., at 365.}

The USPTO's focus on known methods for potentially isolating the claimed molecules were, according to the court, misplaced because the claims at issue defined compounds, not methods. The
existence of a general method of isolating cDNA or DNA molecules was essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggested the claimed DNAs. The CAFC reversed the rejection of the claims at issue.

Adelman questions if In re Deuel overlooked a prior and better test, namely In re O'Farrell, where the court, instead of deeming the process irrelevant, acknowledged it and stated that "all that is required [for obviousness] is a reasonable expectation of success. Adelman asserts that "the Deuel rule" is unique to the United States.

A Supreme Court case decided in 2007 concerning a combination invention in the mechanical arts has had an impact also on the biotechnology industry. The case, KSR v. Teleflex, more specifically concerned the question whether an adjustable pedal assembly used in the automotive industry was obvious to a PHOSITA in view of combined prior art references. At the time, the Supreme Court had not ruled on a patent law case about the assessment of nonobviousness for 40 years. The CAFC, applying the TSM-test in a strict manner, found lack of obviousness, but the Supreme Court reversed. The Court stated that the TSM-test in this case, though appropriate, was applied too rigidly. The approach should be "expansive and flexible." Inferences and creative steps that a person of ordinary skill in the art would employ should be taken into account. Note that the PHOSITA in this case were characterized as capable of being creative. The Court referred to the four inquiries put forward in Graham v. John Deere Co. as the proper method to assess nonobviousness. The court also stated i. a. that combining known elements is obvious when the combination yields predictable results. However, the Court also indicated that it would be "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." Thus, the Court still required the identification of some reason for combining the elements in prior art.

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252 Id., at 366.
253 Id., at 367.
255 Id.
257 Wong and Lau, at 446.
260 Wong and Lau, at 446.
261 Platt, at 10.
262 Id.
263 Teitelbaum and Cohen, at 1105.
264 Wong and Lau, at 446.
KSR v. Teleflex is according to some commentators expected to affect many types of biotechnological inventions, especially since, as the field continues to mature, the emergence of combination inventions should become more pronounced. In the CAFC case Pharmastem Therapeutics v. Viacell, following KSR v. Teleflex, the Federal Circuit declared that "routine research to prove what was already believed to be the case" did not merit a finding of nonobviousness. Wong and Lau recommend patent applicants to document proof of the unpredictability of their experiments, to be able to establish the necessary lack of reasonable expectation of success. Other commentators stress that the TSM test is still a legitimate method of demonstrating obviousness, but that failure to prove the existence of a teaching, suggestion or motivation can not in itself determine an argument for invalidity under 35 U.S.C. § 103. The Graham analysis permits more than one way of proving obviousness, including recourse to common sense and solutions that are obvious to try. The Supreme Court treated the TSM test as one way of finding obviousness among many.

The BPAI case Ex parte Kubin in 2007 was also influenced by KSR v. Teleflex. The case concerned a patent application for an isolated and characterized human cDNA sequence encoding the previously unknown amino acid sequence of a known human protein, NAIL, which is involved in the immune process. The applicants Kubin and Goodwin referred to In re Deuel in which the CAFC stated that known methods of isolating a DNA molecule do not preclude claims to the DNA molecule itself. Even if the procedures described in one of the references may have been obvious ways to isolate the protein, they say nothing about the sequence of the cDNA. Moreover, none of the references provided the cDNA or amino acid sequences of the protein. Therefore, under Deuel, the claims at issue should not have been rejected for obviousness. The BPAI on the other hand, said that In re Deuel was no longer controlling due to the increased level of skill in the art. The board also pointed to the factual differences between the two cases and referred to the Supreme Court decision in KSR v. Teleflex, which appeared to weaken the Deuel decision under an "obvious to try" rationale. The board referred to the reasoning in KSR, in which, in commenting on whether a patent claim could be proved obvious merely by showing that a combination of claim elements was obvious to try, the Court said that when there is a need to solve a problem, and there are a finite

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265 Id.
267 Id.
268 Weingaertner and Conrad, at 298.
269 Id.
272 Id.
number of identified and predictable solutions to a problem, there is good reason to pursue the
known options. If this pursuit leads to the anticipated success, then the success was likely to be the
product of ordinary skill and common sense. In such a case, the fact that the combining of the claim
elements was obvious to try might show that the combination was obvious. Applying the reasoning
in KSR to Kubin, the BPAI stated that the relevant problem was the isolation of the cDNA, there
were only a limited number of methods available to do so and there was a reasonable expectation
that at least one of the methods would prove successful. Thus, isolating the cDNA was the product
of ordinary skill and common sense. Therefore, the claims were obvious.\footnote{273}

Yamanaka fears that Ex parte Kubin is the end for biotechnological patents claiming DNA
sequences since claims now can be rejected on the basis of a known protein and standard cloning
techniques, unless a combination of known components can be shown to yield unpredictable
results.\footnote{274} Other commentators see Kubin as a sensible corrective to Deuel in which the CAFC
made the criterion nonobviousness "largely inoperable for DNA sequence patents."\footnote{275} They also
assert that most DNA sequence patents are not based on prior characterization of a protein.\footnote{276} Ex
parte Kubin is at present under appeal at the CAFC.

Adelman calls into question if In re Deuel still is "good law" after KSR. v. Teleflex. According to
him, the BPAI and the CAFC seem to have different views on this. The BPAI has stated that under
KSR, the "obvious to try" test now may be appropriate in more situations than previously.\footnote{277} The
CAFC, on the other hand, has held that Deuel "is consistent with the legal principles enunciated in
KSR.\footnote{279}

4.2.4 Utility

4.2.4.1 General provisions and case law

The ultimate rationale for the utility requirement is to secure a quid pro quo for society.\footnote{280} The
criterion is governed by 35 U.S.C. § 101. As already outlined above, the Section provides that
"[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition
of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." Consequently, an invention has to be "useful" to be granted a patent. There are no other provision in the Patent Act defining the said requirement. Instead, the concept has developed in case law and the principles derived from there have subsequently been incorporated into the USPTO patent examining procedure.

According to Halpern, lack of utility is seldom used as an invalidating defense in patent litigation. Unlike mechanical and electrical inventions though, the requirement poses greater concern for chemical and biological inventions. This is so because these latter inventions can not be manifested through drawings, and they often possess "an evolving utility" rather than a once and for all end result.\textsuperscript{281} Minβen agrees that the few disputes occurring about the utility requirement for the most part concerns biotechnological and chemical inventions. This has prompted a slightly more restrictive standard on utility for these inventions in both European and US patent law. The reason is that inventors in fast evolving technologies, due to competition, have a tendency to apply for patents prematurely, i. e. before function and use for the invention is properly established.\textsuperscript{282}

The utility requirement in US patent litigation is often used together with the disclosure requirement in 35 U.S.C. § 112. USPTO usually rejects patent applications who fail to demonstrate utility both under Section 101 and on account of inadequate disclosure under Section 112. The reason is that Section 112 demands that the disclosure teaches how to use the invention as claimed.\textsuperscript{283} Section 112 states i. a. 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."\textsuperscript{284}

US case law has provided that patentable inventions must demonstrate a "practical utility"; in other words have some "real world use". This is also incorporated into the USPTO patent examining procedure. Again, this demand has been more discussed in relation to biotechnological and chemical inventions than regarding other types of inventions.\textsuperscript{285}

\textsuperscript{281} Halpern, at 232.
\textsuperscript{282} Minβen, part 1, at 201-202.
\textsuperscript{283} Minβen, part 1, at 218.
\textsuperscript{284} 35 U.S.C. § 112, first paragraph.
\textsuperscript{285} Minβen, part 1, at 219.
There are no provisions in US law that demand the explicit disclosure of a function of a gene sequence or a protein in the patent claims. Thus, absolute product protection is not precluded in the United States.\textsuperscript{286}

In Brenner v. Manson\textsuperscript{287}, decided in 1966, the Supreme Court raised the standard for utility in US patent law considerably. The case concerned a patent for a chemical invention, a process to prepare a type of steroid already in the prior art. The applicant Manson maintained that a similar steroid was being tested for tumor-inhibiting effects on mice. The Supreme Court held that Manson had not exhibited adequate evidence of any tumor-inhibiting effects in the steroid at issue in the patent application. The intentions of Congress in 1790 for granting a patent monopoly was interpreted as meaning that an invention should present "substantial utility". This standard is not met until a process is refined and developed to the point that a "specific benefit" exists in its currently available form. Manson's invention was too undeveloped to produce a quid pro quo for society and did not deserve patent protection.\textsuperscript{288}

4.2.4.2 Case law and USPTO Guidelines on biotechnology

Whereas Brenner v. Manson concerned the standard of the qualitative meaning of the concept of utility, the CAFC began to develop a more liberal standard on the evidence needed to prove utility. In In re Brana\textsuperscript{289}, which concerned a pharmaceutical invention, the court held that the USPTO has the initial burden of challenging a presumptively correct assertion of utility. Only after the USPTO provides evidence that a person of ordinary skill in the art would reasonably doubt the asserted utility, does the burden to prove utility shift to the applicant. The court also accepted post-filing date evidence to substantiate doubts as to the enabling disclosure under Section 112. According to the court an invention does not have to have been performed in a practical context. It is enough that it is performable. Finally, approval by the US Food and Drug Administration (FDA) is not a prerequisite for finding a compound useful within the meaning of the patent laws.\textsuperscript{290}

Shortly after In re Brana, the USPTO presented new examination procedures including a rather low utility standard requiring only a weak specific and credible utility, and in principle discarding the substantial utility in Brenner v. Manson. USPTO specifically explained that expressed sequence tags (EST's), short sub-sequences i. a. used as research tools to discover and isolate genes and

\begin{itemize}
  \item Id., at 218.
  \item Minj\textsuperscript{en}, part 1, at 222-224.
  \item In re Brana, 51 F.3d 1560 (Fed.Cir.1995).
  \item Minj\textsuperscript{en}, part 1, at 226-227.
\end{itemize}
determine gene sequences, should not be rejected for lack of utility only because a patent application did not disclose the corresponding whole gene sequence and its function. 291

The debate about patents on research tools and EST's however became intense in the United States. It was i. a. asserted that basic research tools should be open to the public. Following this debate and the large number of gene related patent applications in the late 1990s, the USPTO finally in 2001 made a sharp turn in their position and promulgated new examination guidelines for the utility requirement, in many aspects going back to the reasoning in Brenner v. Manson. The new guidelines made it easier to reject patent applications on EST's, and were incorporated into the MPEP. 292 According to MPEP § 2107:

"An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention […], and (ii) the utility is specific, substantial, and credible. 293

"Specific" means that the utility must be well-defined and specifically connected to the claimed invention. "Substantial" implies that there must be a "real world use" without further research being necessary. "Credible" finally, means that one of ordinary skill in the art (PHOSITA) in view of the disclosure and any other evidence of record (e.g. test data, affidavits or declarations from experts in the art etcetera) finds at least one of the alleged uses credible. A patent application can also make an assertion of utility (potential uses), but these must also be specific, substantial and credible. 294

The Utility Examination Guidelines apply to all areas of technology. However, the USPTO noted that "they are particularly relevant in areas of emerging technologies, such as gene-related technologies, where uses for new materials that have not been fully characterized are not readily apparent." 295

Since the USPTO's guidelines primarily are directed to its own examiners, and are not binding on courts, there were some uncertainty if the courts would accept them. It took several years before the CAFC considered the matter. 296 Rasmussen v. SmithKline Beecham Corp. 297 called into question if it is still enough that an invention is performable to fulfil the enablement requirement under Section 112, and whether post-filing date evidence are permissible. Minßen however, is of the opinion that

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291 Id., at 228-229.
292 Id., at 229-230.
294 Minßen, part 1, at 231-232.
295 Aerts, at 351.
296 Minßen, part 1, at 233-234.
297 Rasmussen v. SmithKline Beecham Corp., 413 F.3d 1318 (Fed.Cir.2005).
earlier case law, e. g. In re Brana, still is controlling until the questions have been examined by an enlarged CAFC panel in an en banc decision.298

A decisive case for the current interpretation of utility under 35 U.S.C. §§ 101 and 112 was In re Fisher299, decided by CAFC in 2005. The case concerned a patent application for EST sequences. The court applied a strict interpretation of the utility standard established in Brenner v. Manson.300 CAFC defined "substantial utility" in the following manner:

"[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public."301

"Specific utility" was commented and defined in this way:

"[A]n application must disclose a use which is not so vague as to be meaningless. [...] Thus, in addition to providing a 'substantial' utility, an asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public."302

In summary: "substantial" means "significant and presently available benefit to the public", and "specific" means "well-defined and particular benefit to the public". The court held that the application at issue lacked both substantial and specific utility. The EST's in the application was comparable to "research-intermediates" which earlier case law, e. g. Brenner v. Manson, already had stated lacked utility. The court also noted that the appellant Fisher had not provided any concrete evidence as test data, expert-testimonies or declarations.303

Although In re Fisher, according to Minβen, represents the law as regards utility in the US, the court was actually divided 2-1. Judge Randall Rader dissented, stating in short i. a. that the EST's were patentable research tools (if only to be used in laboratories) that actually did have a well-defined and particular benefit to the public. He also stated that science evolves in small steps and criticized the consequences that only the inventor who takes the last step should be awarded a patent. Finally, he asserted that a stricter interpretation of the nonobviousness requirement would be a better way to reject unreasonably broad patent claims for simple inventions, but regretted that "this court has deprived the Patent Office of the obviousness requirement for genomic inventions".304

298 Minβen, part 1, at 235-236.
299 In re Fisher, 421 F.3d 1365 (Fed.Cir.2005).
300 Minβen, part 1, at 239.
301 Adelman, at 145.
302 Id.
303 Minβen, part 1, at 240.
304 Id., at 241-243. Randall Rader no doubt aimed at In re Deuel when stating that "this court has deprived...". Incidentally, Rader is one of the co-writers of Patent Law, used as reference in this thesis. It is probably not a coincidence that In re Fisher is commented with the question if "the current utility standard [should] be revised, at least
Minßen maintains that the current USPTO Utility Examination Guidelines and the outcome in In re Fisher show the return to the rigorous utility standard established in Brenner v. Manson. At least at first impression it will be almost impossible to be granted a patent on many research tools that 'only' can be used to develop technologies in laboratories. EST’s can only be patented if the function of the corresponding gene sequences are disclosed in the application. Applications claiming whole genes and proteins are also rejected referring to the specific, substantial and credible-standard, as long as the application only discloses a general use for the gene or protein. Adelman agrees: "[P]atents appear to be unavailable for ESTs that attempt to claim entire genes or proteins based only upon the EST, or are not directed to either a known target or known gene." Regarding evidence, Minßen concludes that current law follows In re Brana, i. e. the USPTO has the initial burden of challenging a presumptively correct assertion of utility. Concerning techniques, not only in vivo and in vitro methods (traditional wet-lab techniques), but also in silicio (computer-assisted or -simulated) methods are permissible, provided they are credible.

The majority opinion in In re Fisher is nowadays often cited in USPTO- and CAFC-decisions. A reservation is that the applicant in Fisher, according to the majority's opinion, failed completely to show specific, substantial and credible uses for the EST's. Therefore, there probably is a certain room for interpretation. Nevertheless, the standard for utility in the United States has been raised.

5. EPC Contrasted with US law

5.1 Introduction

Whereas the US references certainly demonstrate an awareness that patents should deliver a quid pro quo to society, at the same time there appears to exist a somewhat more favourable attitude towards granting patents in the United States than in the EPC system. Among the references discussing the matter, there is a consensus that US patent law has applied, and to some extent still is applying, more liberal standards, especially regarding patentable subject matter and the criterion nonobviousness. See e. g. Adelman who, commenting on the US situation, asserts that "[i]n recent years […], the patent system has demonstrated an increasing permissiveness towards patent eligible when an invention fairly qualifies as a research tool". A student commentator is quoted who proposes that the utility doctrine should account for "an inventions 'real world uses' in a research and laboratory setting, even if the invention does not result in immediate public benefits" (Adelman, at 153).
subject matter. […] The present state of affairs suggests that few, if any, restrictions restrict the range of patentable subject matter.”

See also e.g. Cornish on nonobviousness:

"It is widely considered that the US Patent Office treats the threshold of nonobviousness as a low one and that accordingly it is accepting applications for inventions in genetics that would not pass muster elsewhere, including the EPO.”

However, comments on patentability standards have a short shelf life when discussing fast evolving technologies. It should be apparent from the outline above, that in the last few years the standards for granting a patent in biotechnology have been raised, in both legal systems. This is also certified by several of the references. Today, the gap in the standards applied within the EPC and in US law respectively is no doubt not as evident as e.g. ten years ago. This is also indicated already from the results of the so called Trilateral Project B3b in 2006, a cooperation between EPO, USPTO and the Japanese patent office (JPO), comparing the examination of hypothetical patent applications on DNA fragments. The USPTO and the EPO concurred in their opinions in all of the five hypothetical cases. An interesting point though is that, as a reason for rejection, the USPTO mainly referred to lack of utility and enablement, whereas the EPO and the JPO mainly pointed to lack of inventive step/nonobviousness. These remarks notwithstanding, as is noted in the UK Nuffield Council of Bioethics' report The Ethics of Patenting DNA, even if the interpretation on inventive step differ slightly, this might still be to a sufficient degree to make a real difference to a prospective patentee's chances of success.

Above, EPC and US patentability criteria in biotechnology have been outlined separately. In this section, some of the differences and similarities between the jurisdictions are summarized and commented, criterion by criterion. The focus is on the elements that influence the overall standard of patentability, and to what extent they do so. A discussion about patentable subject matter is also included. This is motivated primarily by the fact that particularly in US patent law, patentable subject matter is closely related to the novelty and utility criteria.

5.2 Patentable subject matter

Adelman is quoted above on patentable subject matter in the United States. Koktvedgaard agrees, asserting that "[t]he United States have traditionally had a broader patentability concept than the

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309 Adelman, at 58. In this context he comments on US patent law overall, not on patent law related to any certain technology.
310 Cornish, at 887-888.
There is a consensus among the references that this is a fact. If we consequently accept that, then we might instead ask - why? Is it because patent rights were established already in the US Constitution, and the first US Patent Law was instituted as early as 1790? The wording of the Constitution seems to be favorable towards patents, even if the notion of a balancing of interests was there from the start. This might be part of an explanation, even though patents existed in Europe long before 1790.

Has the question put above instead something to do with the phrasing of 35 U.S.C. § 101? It is a fact that EPC Article 52 defines patent eligibility in the negative and expressly excludes i. a. discoveries, scientific theories and mathematical methods. In this way, the difference between patentable inventions and non-patentable discoveries becomes clear, even if a reference calls the qualification "as such" in EPC Article 52(3) "enigmatic". On the other hand, 35 U.S.C. § 101 defines what is to constitute patentable subject matter and mentions the word "discovers" as a ground for obtaining a patent. Furthermore, "invention" is defined in 35 U.S.C. § 100(a) as "invention or discovery". Whereas the EPC accordingly explicitly excludes discoveries as patentable, the US Patent Law explicitly includes discoveries in patentable subject matter. Has this had an influence on the overall attitude towards, and delimitation of, patent eligibility? Or is it just semantics, having in mind that US courts have held that patent protection is not available for the laws and products of nature, natural phenomena and mathematical formulas? Ha seems to think that the phrasing of Sections 100 and 101 are important. However, she points out that the US Supreme Court has held that there is a distinction between the discovery of inanimate things and the discovery resulting from the intervention of man. Iatskaia discusses the European attitude: "The European society seems to apply a more formal approach to what constitutes an invention, particularly if it is a biotech invention."

Domeij also calls attention to the phrasing of Section 101, the fact that patentable subject matter in the United States is decided by utility, or as the provision phrases it: "useful process, machine…etcetera" (emphasis added). Since e. g. business methods have been found to be useful, they have also been found to be patentable. Ballardini comments on the whole provision in 35 U.S.C. § 101 when stating that it "suggests a very broad interpretation of patentable subject matters." She also comments on the US method of developing...
the law: "[N]o ultimate boundary for patentable objects has ever been defined […] such interpretation has rather been an 'evolving concept', subject to constant changes in relation to both economical circumstances and technological developments."  

When discussing case law on patentable subject matter in biotechnology one must first and foremost mention Diamond v Chakrabarty, the holding that paved the way for biotechnological patents not only in the United States but also subsequently in many other countries. The US Supreme Court interpreted Congress in 1952 to mean that patentable subject matter is a very broad concept. A correspondingly far reaching case on patentable subject matter does not exist within the EPC legal system.

Bilski v. Doll (formerly In re Bilski) restricts process patent eligibility in the United States. The case brings the US practice in this context closer to the European rules. However, this hinges on the future outcome of the US Supreme Court decision in the case.

In Europe, the implementation of the Biotechnology Directive into the EPC probably can be seen both as an extension and a limitation on patentable subject matter. However, the scope of patentable subject matter in biotechnology is no doubt still wider in the United States.

5.3 Novelty

The key question when assessing novelty - is the invention anticipated in prior art? - is in most cases pretty straightforward to interpret, at least compared to the other two patentability criteria. US law requires identity of invention in a single prior art reference and EPC law provides that information must directly and unambiguously disclose the invention to be comprised in the state of the art. This is probably the main reason why, on the whole, the provisions, and the way they have been interpreted in case law, do not differ very much between the EPC and the US patent law. There is a prominent difference though - EPC is based on "first to file" whereas US law applies "first to invent". However, none of the references mention this element as something that affects the overall standard for patentability.

320 Id.
321 See e. g. Tu Nguyen, Thanh, in Lidgard, Hans Henrik (ed.), Protecting and Transferring Biotech Inventions, Studentlitteratur, Lund 2004, at 45.
323 Ballardini, at 364.
A minor difference, but a difference that probably do affect the standard of patentability though, is that US patent law in prior art only include knowledge or use that have occurred in the United States. This is in contrast to the EPC that impose no territorial constraint at all and where the inquiry is the same in respect of publications or actual embodiments or uses. The standard for assessing novelty in this respect is accordingly less rigorous in the United States than in the EPC system. On the other hand, EPC law does not, as Section 112 in the US Patent Act, demand a best mode disclosure of the invention. The way to optimize an invention can in Europe be kept as a trade secret.

5.4 Inventive step/Nonobviousness

Despite that one of the references asserts that nonobviousness "lies at the heart" of the US patent system, nonobviousness is not even mentioned in 35 U.S.C. § 101. It is "new and useful" inventions that are to be awarded patents. Is this of any significance? None of the references discusses this question directly. MacQueen instead draws attention to the wording of EPC Articles 52 and 56 compared to 35 U.S.C. § 103. EPC considers the need for "inventive step", i. e. inventiveness on the part of the applicant. US law, on the other hand, focuses on "nonobviousness", i. e. so long as the result is not obvious to a PHOSITA, the criterion is satisfied. Seen this way, the formulations in the respective provisions appear to imply in itself a lower bar to patentability in the US law. The question though is, again, if this is of any practical importance. MacQueen argues that it is: "[t]his […] is a lower threshold and consequently means that genetically engineered products remains, potentially at least, more easily patentable in the US than in Europe.

In any case, In re Deuel set a low standard in 1995 for the assessment of nonobviousness in the United States. The holding was that known methods of isolating a DNA molecule do not preclude claims to the DNA molecule itself. Cornish (2007) goes even further in his remarks: "In the United States it is currently assumed that novel genetic information must be taken to be nonobvious." Domeij (also 2007) agrees, discussing the development not only in the US, but also in Europe and Japan: "Very likely, the demand for inventive step has been lowered in case law." Bernitz (2007) concurs about Europe: "It should be undisputed that the standards on inventive step have been lowered […] within the EPO."

324 Cornish, at 184.
325 Domeij, at 40.
326 MacQueen, at 494.
327 Id.
328 Cornish, at 888.
329 Domeij, at 91.
330 Bernitz, at 151.
Thus, three references in 2007 maintain that the standard for inventive step/nonobviousness has been lowered. A year later, the Swedish Government Commission on Patent Protection for Biotechnological Inventions instead asserts that EPO's case law in recent years have raised the standard for inventive step. Two law review articles by Minβen, also published in 2008, agree with this assertion. The differences in conclusions drawn is of course related to the period considered. It should however be apparent from the developments in case law and agency guidelines that the bar for overcoming the inventive step/nonobviousness-requirement in the most recent years has been raised, both in the EPO and in the United States. The development of case law in the US is still a bit shaky, due to pending appeals, but the direction on the whole is evident.

Within the EPO, the "reasonable expectation of success" approach is prevailing in biotechnology, which is apparent from the outcomes in T 923/92, T 182/03 and e. g. T 150/03 on homologues. In the United States, Ex parte Kubin applies this approach, but the case is under appeal. Kubin in part builds on the reasoning in KSR v. Teleflex. The CAFC has said that In re Deuel is consistent with the legal principles enunciated in KSR. Platt questions whether KSR v. Teleflex will influence the interpretation of the EPC equivalent to the TSM-test, namely the could-would approach.

The US patent law gives greater weight than the EPO to so called objective indications, or secondary considerations. According to Adelman, "[t]hese objective indicia are no longer merely 'secondary', but are essential to the obviousness inquiry." In the EPO, however, they are still regarded as secondary, and one of the European references is even critical of that.

In summary, even if US law at the present is tending to apply more stringent demands on nonobviousness, the standard for this criterion is not yet as high in the United States as in the EPC system.

5.5 Industrial application/Utility

US patent law has emphasized utility, and as early as 1966, in Brenner v. Manson, the standard for this criterion was raised, demanding a "substantial" utility. Europe, on the other hand, long relied on

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332 Minβen, part 1, at 203 and part 2, at 380.
333 Platt, at 11.
334 Adelman, at 335. See also Halpern, at 239.
335 Paterson, at 560.
336 Torremans, at 73.
the "made or used in any kind of industry"-requirement in EPC Article 57, which is not a very high standard.\footnote{See e. g. Westerlund at 59.}

After a downturn following In re Brana in 1995, and the subsequently issued USPTO examination procedures, the US application of the law picked up again. USPTO's new examination guidelines for utility in 2001, i. a. establishing the "specific, substantial, and credible" standard, and the case In re Fisher in 2005, have raised the level compared to the mid 1990s.

In Europe, the Biotechnology Directive, i. a. incorporated in EPC Rule 29(3) demanding that the industrial application of genes must be disclosed in the patent application, and EPO cases, especially ICOS (O.J.EPO 2002 p. 293), Max Planck (T 870/04) and Zymogenetics (T 898/05), have contributed to an elucidation of the industrial application criterion in the EPC system. Article 57 EPC have been interpreted to demand a "practical application", meaning a profitable use and a practical way of exploiting the invention in at least one field of industrial activity. The "specific, substantial, and credible" requirement also seems to have been "imported" into EPC law.\footnote{See V28 seven transmembrane receptor/ICOS, O.J.EPO 2002 p. 293, at 304. The fact that the Opposition Division in this case used the phrase "specific, substantial and credible" of course does not mean that the requirement is interpreted in the exact same manner in the EPO as in the United States.} Finally, Rule 29(3) is consistent with Article 57 and must be strictly interpreted. According to Minβen, focus of the EPO case law has shifted from the reproducibility to the usefulness of inventions.\footnote{Minβen, part 2, at 374.} EPC Article 57 has been attached greater importance for the patentability of biotechnological inventions.\footnote{Id., at 373.} The Swedish Government Commission on Patent Protection for Biotechnological Inventions concludes that the EPO case law in recent years has raised the standard also for industrial application.\footnote{SOU 2008:20, The Committee on Patent Protection for Biotechnological Inventions, at 186-187.} Minβen concurs, and opines that the interpretations of industrial application in the EPO and utility in the United States nowadays show "striking similarities".\footnote{Minβen, part 2, at 380-381.}

While prioritizing utility, possibly the nonobviousness criterion in US patent law has been underplayed. Minβen suspects that the CAFC in In re Fisher was desperately searching for an instrument to reject a large number of trivial gene-related patent applications.\footnote{Minβen, part 1, at 253.} This is also what Judge Randall Rader seems to imply in his dissenting opinion in the case. He also asserts that using Section 103 would have been a better method to achieve the desired result:

\footnote{Minβen, part 1, at 253.}
"The patent office has seized upon this utility requirement to reject these research tools […] The utility requirement is ill suited to that task […] because it lacks any standard for assessing the state of the prior art […] The proper tool […] is the obviousness requirement of 35 U.S.C. § 103." 344

5.6 Concluding remarks

Most references commenting on the European situation seem rather content with the way the patent system has handled the challenges of biotechnology patents, i.e. the discussion about unfounded or overly broad patents, the ethical concerns etcetera. See e.g. Cornish who recommends "adhering to the conceptual framework which has evolved […] over two centuries" and who sees signs of that, at least in Europe. 345 See also Aerts who opines that "the patent systems in Europe and the United States have been quite well able to handle patent applications for DNA sequences." 346 On the other hand, the commentators on the US development seem more divided.

In either case, it is clear that it is primarily patent office guidelines and case law that have developed and adapted the law. What Aerts calls "the hybrid structure of European patent law" 347 became apparent when the Biotechnology Directive was adopted and was to be implemented. According to the PATGEN-project at the University of Sussex, UK, the more rigorous EPO examination standards are not attributable to the Directive but to the initiatives of the EPO itself. 348 In the United States, proposals to amend the Patent Act, i.e. to establish a first-to-file system, have been introduced in Congress in 2005 and 2007, but not passed. A similar proposal, though, have been reintroduced this year. 349

6. Patentability in the Post-Genomic Era

The number of patents in the US, Europe and Japan rose 40 % between 1992 and 2002. 350 The increase in the number of patent applications have since continued on a worldwide basis. 351 However, there is a wide divergence in the number of granted patents between the US and other regions. 352 Looking e.g. at patents on human DNA, out of approximately 6000 patent families in

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344 In re Fisher, 421 F.3d 1365 (Fed.Cir.2005), at 32.
345 Cornish, at 896.
346 Aerts, at 360.
347 Id., at 351.
350 Domeij, at 91.
351 See Minjën, part 2, at 387.
2005, 94 % had protection granted by the USPTO, 13 % by the EPO and 9 % by the JPO.\textsuperscript{353} It is difficult to establish the reasons for this. Differences in the patentability standards are of course only one of several possible explanations. Hopkins lists four reasons for the lead of the USPTO over the EPO in granted patents: 1. More patent applications in the US because it offers the largest market for healthcare globally, 2. The US has relatively low patenting costs, 3. The EPO takes longer time to examine patents, and 4. The higher bar for patentability that the EPO appears to be enforcing.\textsuperscript{354}

The patenting costs are probably influential. An article in Nature Biotechnology in 2008 asserts that the patenting costs are nearly five times as high in the European Union as in the United States.\textsuperscript{355} The examination time is also quite possibly an explanation. Even if Gowers, a report to the British Treasury in 2006, maintains that the speed of the patent process is hampered at both the USPTO and the EPO by large backlogs that impose delays of up to three years\textsuperscript{356}, the examination time in the EPO is considerable. In 2008, on average, a granted patent was published in approximately 43 months after the application was received. The average processing time in biotechnology, however, was as long as 60 months.\textsuperscript{357}

Concerning human gene sequences there was a marked increase in the number of applications in 1998 - 2001, after which the number fell sharply. One reason for the increase in the end of the 1990s might have been that there was a belief that patent applications on gene sequences did not have to be well-founded as regards industrial applicability. Another possible reason is that the human genome was soon to be published within the HGP (popularly called the HUGO project), after which patenting human genes would be thwarted.\textsuperscript{358}

The differences in the total number of patents granted probably have several reasons. The divergence in the share of granted patents though, should be more closely related to the patentability standards. According to a study by Gowers, between 83 and 98 per cent of patent applications were granted in the USA, whereas the corresponding share at the EPO was about two-thirds of the applications.\textsuperscript{359}

\begin{itemize}
\item \textsuperscript{353} SOU 2008:20, The Committee on Patent Protection for Biotechnological Inventions, at 181.
\item \textsuperscript{354} Hopkins, at 185.
\item \textsuperscript{355} Lawrence, Stacy, Biotech Patents - business as usual?, Nature Biotechnology, vol 26 December 2008, p. 1326.
\item \textsuperscript{357} European Patent Office, Facts and Figures 2009, Munich 2009, at 14.
\item \textsuperscript{358} SOU 2008:20, The Committee on Patent Protection for Biotechnological Inventions, at 51-52.
\item \textsuperscript{359} Gowers Review of Intellectual Property, at 37. Note that the numbers concern patents in all technical areas, not only biotechnology.
\end{itemize}
The Human Genome Project (HGP), an international scientific research project aiming at identifying and mapping the human genome, was completed in 2003. At that point, about 20 percent of the human gene sequences were patented. One of the consequences of the completion of the HGP is that few, if any, product patents on human genes will be granted in the future. Due to corresponding research in other organisms, the number of such patents will probably also diminish. Another reason why product patents on genes will be harder to obtain in the future is the existence of homologues - similar genes in other organisms. Finally, the technique for identifying genes is today so advanced that isolating and purifying a gene may lack inventive step.

Hopkins summarizes that "[t]he context for patenting DNA sequences has changed markedly since the 1990s." The article assigns this to both the publication of the human genome and a raised bar to patentability due to changes in i. a. guidelines and case law. In other words, the scientific and legal developments have pulled in the same direction.

Today, the most common claims in gene-related patent applications can be divided into three groups: 1. DNA coding for industrially applicable protein products, 2. DNA as diagnostic tools for gene tests, and 3. DNA and RNA sequences participating in important biological processes, or controlling these. Consequently, biotechnology no longer focuses on the identifying and mapping of genes as such, but rather the function of genes. This new field of research is called functional genomics and is part of the post-genomic era, the next era in biotechnology.

Due to this changed focus in science and the raised patentability standards, more narrow and robust patent applications on e. g. diagnostic and therapeutic uses for genes and proteins are expected. The European Patent Office has also stated that it intends to continue to focus on quality over quantity. In 2010, the EPO plans to:

"[L]aunch a set of measures intended to raise the bar on patent quality and improve the efficiency of the granting process, offering better protection to inventors and ensuring that patents are granted only for innovations which have sufficient inventive merit and meet society’s needs."

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363 Hopkins, at 187.
364 Minßen, part 1, at 211-212.
365 Id., at 206.
366 Minßen, part 2, at 384.
7. Conclusions

It has been possible to work according to the method set out in the introduction. The constant changes in both biotechnology and patent law have secured enough references to achieve the aim of the thesis. For the author, it has been an inspiring project.

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