The patentability of inventions relating to the fields of medicine, pharmaceuticals and biotechnology is not positively regulated in the European Patent Convention (EPC). Generally, patentable subject matter which refers to the above fields has to be out of the range of the exclusions of patentability implemented in the EPC. In the following, the recent developments in the application of said exclusions of patentability regarding medical methods, medical applications, genetically altered organisms by e.g. recombinant DNA technology, and the human body or parts thereof in the jurisprudence of the Boards of Appeal of the European Patent Organisation (EPO) will be discussed.

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Introduction

The patentability of inventions relating to the fields of medicine, pharmaceuticals and biotechnology is not positively regulated in the European Patent Convention (EPC). Generally, patentable subject matter which refers to the above fields has to be out of the range of the exclusions of patentability implemented in the EPC. The most relevant exceptions to patentability in the EPC for medical, biotechnological, and pharmaceutical inventions are Art. 52(4) EPC concerning the exclusion from patentability of methods practised on the human or animal body, Art. 53 a) EPC concerning the exclusion from patentability of inventions the publication or exploitation of which would be contrary to "ordre publique" or morality and Art. 53 b) EPC concerning the exclusion from patentability of inventions which relate to plant or animal varieties or essentially biological processes for the production of plants or animals. As one consequence thereof, in contrast to US patent practice, methods of medical treatment or diagnostic methods on a living body are not patentable inventions under the EPC. In the following, the recent developments in the application of said exclusions of patentability regarding medical methods, medical applications, genetically altered organisms by e.g. recombinant DNA technology, and the human body or parts thereof in the jurisprudence of the Boards of Appeal of the European Patent Organisation (EPO) will be discussed.

1. Medical Methods

When assessing patentability of medical applications and medical methods a main focus is the fulfilment of the criterion of industrial application according to Art. 52(4) EPC, which stipulates that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are not to be regarded as inventions which are susceptible of industrial application. Therefore, since Art. 52(4) EPC forms an exclusion clause, the principle of narrow interpretation of such exclusion clauses is to be applied in respect of the scope of the exclusion from patentability under Art. 52(4) EPC concerning medical methods. As a result, patents may be obtained only for surgical, therapeutic or diagnostic devices or products in the use of such methods. Further, methods for measuring or recording characteristics of the human or animal body are patentable provided that such methods are of a technical character and are susceptible of industrial application.

1.1 Diagnostic Methods

Regarding the question whether a method is a diagnostic method within the meaning of Art. 52(4) EPC, the Enlarged Board of Appeal of the EPO has pointed out in its Opinion of December 16, 2005 (“Diagnostic Methods”, G 1/04, OJ EPO 2006, 334) as follows:

“In order that the subject matter of a claim relating to a diagnostic method practised on the human or animal body falls under the prohibition of Article 52(4) EPC, the claim is to include the features relating to:

(i) the diagnosis for curative purposes stricto sensu representing the deductive medical or veterinary decision phase as a purely intellectual exercise,
(ii) the preceding steps which are constitutive for making that diagnosis, and
(iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.”

In its above Opinion the Enlarged Board of Appeal clearly points out that several method steps are required to define a diagnostic method within the meaning of Art. 52(4) EPC due to the inherent and inescapable multi-step nature of such a method. According to the Enlarged Board or Appeal, the criterion “practised on the human or animal body” in
Art. 52(4) EPC is to be considered only in respect of method steps of a technical nature and does not apply to a method consisting of the diagnosis *stricto sensu* representing a purely intellectual exercise. In the above Opinion, the Enlarged Board of Appeal also clarifies that for reasons of legal certainty the European patent grant procedure may not be rendered dependent on the involvement of practitioners, since it is almost impossible to give a definition of such a practitioner on a European level within the framework of the EPC. Accordingly, it is stated in said Opinion that whether or not a method is a diagnostic method within the meaning of Art. 52(4) EPC may neither depend on the participation of a medical or veterinary practitioner nor on the fact that all method steps can also be practised by medical or technical support staff, the patient himself or herself, or an automated system.

The principles outlined in the above Opinion *G1/04* of the Enlarged Board of Appeal have been applied to subsequent decisions of the Technical Boards of Appeal of the EPO. In the Decision *T 504/03* (not published) the concerned Technical Board of Appeal decided that a method which pertains to the analysis of a data set, wherein the information providing intermediate results which, on their own, do not enable a decision to be made on the treatment necessary, is not to be considered a diagnostic method practised on the human or animal body, which is excluded from patentability by Art. 52(4) EPC. In particular, it is stated that said method does not include any features relating to the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision phase.

Further, it has been stated in the Decision *T 1197/02* (not published) of the Technical Boards of Appeal that in a claim concerning a diagnostic method only the steps strictly describing the examination phase involving the collection of data, the comparison of these data with standard values, the finding of any significant deviation and the attribution to a clinical picture have to be taken into account for determining the diagnostic character of the claimed method. Therefore, since intermediate steps are not to be considered when assessing the diagnostic character of the method, it has been stated in the Decision *T 143/04* (not published) of the Technical Boards of Appeal that a data processing using an automated apparatus is not actually part of the examination phase which involves the data collection phase, but it results from a subsequent, technical step, intermediate between the data collection and the comparison of these collected data with standard values and therefore is not to be considered when assessing the diagnostic character of a diagnostic method.

Moreover, in the Decision *T 330/03* (not published) the concerned Technical Board of Appeal denied the presence of features relating to the diagnosis for curative purposes *stricto sensu* for a method which may be performed on a human body, but the information which it yields provides only intermediate results by measuring at least one parameter of a sample and does not include the step of comparing this parameter with a standard value, nor the finding of any significant deviation during the comparison. The same line of argumentation was used in the Decision *T 41/04* (not published) of the Technical Boards of Appeal which also referred to the provision of solely intermediate results as not being a diagnosis for curative purposes *stricto sensu* in the sense of the above Opinion *G1/04* of the Enlarged Board of Appeal, and therefore not being a diagnostic method which is excluded from patentability by Art. 52(4) EPC.

### 1.2 Surgical Methods

According to a definition given in the above Opinion *G 1/04*, methods of surgery within the meaning of Art. 52(4) EPC include any physical interventions on the human or animal body in which maintaining the life and health of the subject is of paramount importance.
In particular, a method is considered to fall under the prohibition of Art. 52(4) EPC if it includes at least one feature defining a physical activity or action that constitutes a method step for the treatment of the human or animal body by surgery.

Applying the principle that the wording “medical method claims” must be narrowly interpreted, the Technical Boards of Appeal outlined in the Decision T 9/04 (not published) that a method for the production of diagnostic images is not a method contravening Art. 52(4) EPC, since said method does not include or inevitably require any surgical steps.

In the Decision T 5/04 (not published) the concerned Technical Board of Appeal decided that a method for internal registration and measurement of various parameters, wherein one or a series of sensors are placed at one or more points along the internal respiratory flow path, is considered to be a method for surgical treatment and as such is excluded from patentability under Art. 52(4) EPC. It is stated in said Decision that what actually counts for the assessment of Art. 52(4) EPC is that the sensors are placed inside the body and that this feature is part of the method as claimed, because it is not necessary that the intervention be invasive or the tissues be penetrated in order to regard a method as a surgical treatment. The placing of sensors in one or more positions inside the respiratory flow path of a patient by means of a flexible tube implies, according to the above Decision of the Technical Boards of Appeal, a direct intervention on the living body and therefore involves at least one surgical step within the meaning of the case law of the Boards of Appeal.

Further, in the Decision “Hair removal method/ THE GENERAL HOSPITAL CORP.”, T 383/03 (OJ EPO 2005, 159) of the Technical Boards of Appeal it is stated that if a method involving a physical intervention on the human or animal body is clearly neither suitable nor potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well-being of a person or animal, then the method does not fall under the exclusion from patentability provided for in Art. 52(4) EPC. In the above Decision the concerned Technical Board of Appeal differentiates between surgical methods, which are excluded from patentability according to Art. 52(4) EPC in order to ensure that those who carry out methods as cited in Art. 52(4) EPC as part of the medical treatment of humans or veterinary treatment of animals should not be inhibited by patents, and cosmetic methods which are characterized by the fact that the purpose of the claimed method is to improve the aesthetic appearance of the person treated rather than to cure an underlying malady and therefore are not patentable inventions under the EPC. In the Decision T 1172/03 (not published) the concerned Technical Board of Appeal states that the patentability of a surgical method claimed as a cosmetic method must be excluded, if the cosmetic use of the method is not expressed as a technical feature inherent in the claimed method, but only expressed in the claim as a mere intention of the person using the method.

Moreover, in the Decision T 623/05 (not published) of the Technical Boards of Appeal it is stated that a method for positioning a patient in a radiation therapy is not a surgical method since said method is not suitable for maintaining or restoring the health of a patient.

It should be noted that recently the following question has been referred to the Enlarged Board of Appeal in the Interlocutory Decision T 992/03: “Is a claimed imaging method for a diagnostic purpose … to be excluded from patent protection as a "method for treatment of the human or animal body by surgery” pursuant to Article 52(4) EPC if such step does not per se aim at maintaining life and health?” The case before the Enlarged Board of Appeal is pending under Ref. No. G 1/07.
1.3 Therapeutic Methods

Regarding the exclusion of therapeutic methods from patentability under the EPC, it is outlined in the above Opinion G1/04 of the Enlarged Board of Appeal that a method claim falls under the prohibition of Art. 52(4) EPC if it includes at least one feature defining a physical activity or action that constitutes a method step for the treatment of the human or animal body by therapy. It is further explained that methods of therapy referred to in Art. 52(4) EPC concern the curing of a disease or malfunction of the human or animal body and cover prophylactic treatment such as immunization against a certain disease.

In the Decision T 238/06 (not published) the concerned Technical Board of Appeal explained that, since a method for treating a gas for use in an endoscopic procedure consists of method steps of purely technical nature, the method cannot be considered as being practised on the human or animal body, and therefore is patentable under Art. 52(4) EPC. Further, the Technical Boards of Appeal stated in the Decision T 1102/02 (not published) that a method for determining a function designating how a respiratory system of a living creature influences a predefined gas flow pattern by connecting said creature to a ventilator system, is not concerned to be a therapeutic method within the meaning of Art. 52(4) EPC.

Further, in the Decision T 1123/06 (not published) of the Technical Boards of Appeal which states that a method for preparing a three-dimensional model of a part of a body comprising the steps of measuring out certain parts of a body is not a therapeutic method due to the fact that said method is not suitable for maintaining or restoring the health of a patient reference is made to the above Decision T 383/03 of the Technical Boards of Appeal.

2. Medical Applications

Regarding the patentability of medical uses, it should be noted that Art. 54(5) EPC provides an exception from the general principle that product claims can only be obtained for novel products. In particular, Art. 54(5) EPC stipulates that the general rules of law relating to novelty do not exclude the patentability of any substance or composition, which is comprised in the state of the art, for use in a method referred to in Art. 52(4) EPC, i.e. medical methods, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

2.1 First Medical Use

A first medical use claim confers protection to a known substance or composition used for the first time as a surgical, therapeutic and/or diagnostic substance and therefore confers a purpose-limited product protection. In particular, a first medical use for a known substance X may be claimed as a “pharmaceutical composition comprising substance X”. In this context, it should be noted that product claims for the first medical use also need to fulfil all other requirements of patentability, i.e. novelty, inventive step, industrial applicability, and enablement.

2.2 Second Medical Use

Since medical methods of treatment are excluded from patent protection under the EPC, there has been developed an “auxiliary system” for such kind of inventions. A claim which takes the form of a use of a compound, a substance, or a composition for the preparation of a medicament for a specific therapeutic use, is regarded as patentable in the sense of Art. 52(4) EPC according to an old Opinion of the Enlarged Board of Appeal “Second medical indication/EISAI” G 5/83 (OJ EPO 1985, 64).

The jurisprudence regarding these so called “Swiss-type claims” is based on Art. 54(5) EPC which explicitly confers novelty to
medical products which are obtained through the use of known substances and compositions provided this use is new. Since the mere manufacturing of a product does not necessarily comprise any action on an individual human or animal body and, therefore, does not constitute a treatment of such a body by therapy, the Swiss-type claims define a patentable industrial activity outside the scope of the exclusion from patentability under Art. 52(4) EPC. According to European patent practice a patentable Swiss-type claim contains the following essential elements:

(i) The use of a known compound or composition;
(ii) in the manufacture of a medicament;
(iii) for a new and inventive therapeutic application.

In this context, it should be noted that any tool, substance or composition which is utilized during this therapeutic use is considered to be a medicament according to element (ii) of a Swiss-type claim as outlined above, in the case law of the Technical Boards of Appeal. In principle, the medicament as such being a product does not underlie specific limitations when compared to other products.

Regarding the Swiss-type claim, it is noteworthy that the changes of the EPC introduced by the EPC 2000 revision which will enter into force by December 13, 2007 at the latest, will result in a patentability of claims directed to a substance or composition for a second or further medical use, thereby not requiring a Swiss-type claim for a second medical use of a substance any more. However, using a Swiss-type claim will still be allowable.

Regarding element (iii) of a Swiss-type claim as outlined above, it should be noted that according to case law of the Technical Boards of Appeal, the use of medicaments may be called a therapeutic application whenever the human body is suffering from a disease, illness, pain or discomfort or incapacity, and the administration thereof could provide or contribute to the restoration of fitness. Accordingly, it is stated in the Decision T 443/01 (not published) of the Technical Boards of Appeal that even a partial healing is to be construed as therapy or therapeutic use. Additionally, it is stated in said Decision that the term “therapy” is not restricted to curing a disease and removing its causes, but that this term also encompasses treatments which are designed to lessen symptoms.

When assessing novelty of a second medical use, it should be noted that in its Decision T 932/00 (not published) the concerned Technical Board of Appeal denied novelty of the use of a known pharmaceutical combination for avoiding a special side effect of one component. Additionally, it is stated in the Decision T 708/02 (not published) of the Technical Boards of Appeal that for a therapeutic application to be construed as a novel further medical use, this new property or this new technical effect of a known substance must lead to a truly new therapeutic application. Accordingly, the mere explanation of an effect obtained when using a known substance, even if the explanation relates to a pharmaceutical effect which was not known to be caused by that substance, cannot confer novelty on a known treatment, if the skilled person was already aware of the occurrence of the desired effect when applying the known treatment.

Another Decision of the Technical Boards of Appeal, T 906/01 (not published), outlined that clinical tests cannot be considered to be a prior use made available to the public and therefore as prior art according to Art. 54(2) EPC due to the fact that the development and testing phases of medical products or devices are necessarily surrounded by secrecy and it is a prima facie assumption that any person involved in a medical purpose is obliged to confidentiality. The Technical Boards of Appeal stated in the Decision T 591/01 (not published) that the feature "topic" cannot serve to distinguish the claimed composition from identical compositions used in the state
of the art for administration per os, and therefore is not suitable for establishing novelty. Further, in the Decision “Method of administration of IGF-I/Genentech Inc.” T 1020/03 (to be published) the Technical Boards of Appeal ruled that novelty of the application might lie only in the dose to be used or the manner of application.

Regarding inventive step of a second medical use, the concerned Technical Board of Appeal has outlined in the Decision T 210/02 (not published) that although it is generally not required to present in vivo experiments in cases of claimed subject matter relating to the second medical use, the mere allegation that the claimed effect occurs is not sufficient to support an inventive step as required by Art. 56 EPC. Additionally, it is stated in the Decision T 1212/01 (not published) of the Technical Boards of Appeal that commercial success and scientific awards can only ever be secondary indications of inventiveness, which are usually only of importance in cases where an objective evaluation of the prior art have not provided a clear answer. In the Decision T 230/01 (not published) the Technical Boards of Appeal acknowledged inventive step of a use of a medicament at dose levels that are significantly lower than what has been recommended in the prior art.

Concerning sufficiency of disclosure of second medical uses, it should be noted that under Art. 83 EPC the patent application must disclose the suitability of the industrial application of the claimed therapeutic use, if this is not already known to the skilled person at the priory date.

As outlined in the Decision T 609/02 (not published) of the Technical Boards of Appeal, it is required that in the case of a claim relating to a second medical use, the patent application has to provide some information in the form of, for example, experimental tests showing that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease. This mechanism may be either known from the prior art or demonstrated by the patent application per se. Showing a pharmaceutical effect in vitro may be sufficient, if for the skilled person this observed effect directly and unambiguously reflects such a therapeutic application, or if there is a clear and accepted established relationship between the shown physiological activities and the disease.

3. Genetically altered Organisms

Regarding patentability of genetically altered organisms such as transgenic organisms, a main focus lies on the fulfilment of the criteria outlined in Art. 53 EPC for exceptions to patentability of inventions the publication or exploitation of which would be contrary to "ordre publique" or morality (Art. 53 a) EPC), or of plant or animal varieties (Art. 53 b) EPC). The criteria of Art. 53 EPC for exceptions to patentability regarding biotechnological inventions are further specified by Rules 23b to 23e EPC which entered into force on September 1, 1999, in order to implement the Biotechnology Directive of the European Union (Directive 98/44/EC – OJ EPO 1999, 101) in European patent law. In this context, it should be noted that the changes of the EPC introduced by the EPC 2000 revision which will enter into force by December 13, 2007 at the latest, will result in a change of the numbering of the Rules of the EPC, i.e. Rules 23 b to 23 e EPC will be renumbered to Rules 26 to 29 EPC.

In this context, it should be noted that Art. 53 b) EPC stipulates clearly that a European patent shall be granted for microbiological processes or the products thereof.

3.1 Genetically altered Animals

As mentioned above, Art. 53 a) EPC denies patents to inventions the publication or exploitation of which would be contrary to "ordre publique" or morality and this can be evoked to stop a patent from being granted for an invention which causes suffering to animals without some counterbalancing benefit. It has been decided by the Technical
Boards of Appeal in the Decision T 866/01 (not published) that euthanasia compositions which are used in veterinary practice to produce humane death in lower mammals such as rodents do not seem to infringe the fundamental principles of "ordre publique" and morality, and therefore do not contravene Art. 53 a) EPC which is to be construed narrowly.

According to Rule 23d d) EPC, a European patent shall not be granted under Art. 53 a) EPC for processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal and also animals resulting from such processes. It has been outlined in the Decision “Transgenic animals/HARVARD” T 315/03 (OJ EPO 2006, 15) of the Technical Boards of Appeal that in order to evaluate the question whether an invention falls under the exception of patentability according to Rule 23d d) EPC three features to be analysed:

(a) likely animals suffering;
(b) likely substantial medical benefit;
(c) and the necessary correspondence between the two in terms of the animals in question.

Applying these principles the Technical Boards of Appeal ruled in the above Decision T 315/03 that a method for producing a transgenic rodent is not a patentable invention according to Art. 53 a) EPC due to the fact that the term “rodent” embraces a multiplicity of various animals so that it is doubtful that a substantial medical benefit may be derived from applying a claimed process resulting in a suffering, i.e. a development of neoplasms, to all rodents. However, the same method claimed for producing a transgenic mouse is regarded as a patentable invention since all the animals within the genus mouse are closely related to each other in most relevant biological aspects, and this makes it credible that any member of the genus could be used as a model system for cancer studies in a manner similar to that taught in the patent using particular mouse examples.

Further, the Technical Boards of Appeal regarded in the Decision T 606/03 (not published) a transgenic mouse for which the modification in genetic identity results in a mutated phenotype wherein it is likely that the mutated mouse will suffer, but it is not likely that all mutated mice will be of medical benefit, as falling within the category of exceptions to patentability according to Art. 53 a) EPC. However, mice which carry a genetic modification in an intron that does not effect their metabolism with the consequence that the claimed mice do not suffer from the presence of the genetic modification in their genome, do not fall within this category. This is not affected by the fact that mice which can be derived from these claimed mice by acquisition and expression of a gene, will be mutated mice and some of them at least are likely to suffer. The above Decision T 606/03 is explained by the fact that these subsequent mice are not claimed and, therefore, do not fall within the invention, and thus, are outside of the Board's power of investigation.

Accordingly, it is outlined in the above Decision T 315/03 that Rule 23d d) EPC should be applied to ensure that any patent should only extend to those animals whose suffering is balanced by a medical benefit.

Further, it has been stated in the above Decision T 315/03 that the principles laid out in the old Decision “Onco-mouse/HARVARD”, T 19/90 (OJ EPO 1990, 476) of the Technical Boards of Appeal, are still applied, i.e. that the decision whether or not Art. 53 a) EPC is a bar to patenting depends mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other.
3.2 Genetically altered plants

It is stipulated in Art. 53 b) EPC that a patent shall not be granted if the claimed subject matter is directed to plant varieties.

According to an old Opinion G 1/98 (OJ EPO 2001, 111) of the Enlarged Board of Appeal a correct interpretation of Art. 53 b) does not exclude the granting of patents for transgenic plants, if specific plant varieties are not identified, even if the claims embrace *inter alia* plant varieties. It is further stated in the above Opinion that the exception to patentability in Art. 53 b) EPC applies to plant varieties irrespective of the way in which they were produced. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability.

Recent Decisions of the Technical Boards of Appeal, i.e. the Decision T 475/01 (not published) and the Decision T 179/01 (not published), confirmed the patentability of claims defining plants having an acquired tolerance to a herbicide by virtue of being transformed as being not excluded from patentability under Art. 53 b) EPC together with Rule 23c b) EPC.

Additionally, in the above Decision T 475/01 the concerned Technical Board of Appeal stated that the above principles are also to be applied to plants in the form of seeds.

3.3 Plant or animal varieties

According to Art. 53 b) EPC, a patent shall not be granted if the claimed subject matter is directed to plant varieties.

Concerning plant varieties it is stipulated in Rule 23b(4) EPC that the term "plant variety" means any plant grouping within a single botanical taxon of the lowest known rank. This definition in the EPC is based on a definition provided in the above Opinion G 1/98 of the Enlarged Board of Appeal which took said definition from Article 2(2) of the International Convention on the Protection of New Varieties of Plants (UPOV) of 1961.

Regarding animal varieties, it should be noted that different terms are used in each official language of the EPO of Art. 53 b) EPC which are inconsistent and denote different taxonomic categories. In particular, in the German and French texts of Art. 53 b) EPC, the words used in place of "animal varieties" are respectively "Tierarten" (i.e. animal species) and "les races animales" (i.e. animal breeds).

In the above Decision T 315/03 of the concerned Technical Board of Appeal states that the principles outlined in the above Opinion G 1/98 of the Enlarged Board of Appeal concerning plants and "plant varieties" should be followed in the case of animals, i.e. a patent should not be granted for a single animal variety (or species or race, depending on which language text of the EPC is used) but can be granted if more than one variety may fall within the scope of its claims.

It is further outlined in the above Decision T 315/03 that since according to Art. 177(1) EPC, the three texts of the Convention, i.e. in the English, French and German languages, are equally authentic, the strict compliance with Art. 177(1) EPC would lead to the absurd result that the outcome of an Art. 53 b) EPC objection would depend on the language of a case, with German having the highest taxonomic order "species" ("Tierarten") and thereby offering the widest objection.

In this context, it should be noted that due to the changes of the EPC introduced by the EPC 2000 revision which will enter into force by December 13, 2007 at the latest, the words used in place of "animal varieties" in Art. 53 b) EPC will be respectively "Tierrassen" (i.e. animal breeds) and "les races animales" (i.e. animal breeds) so that both, the French and German versions of Art. 53 b) EPC, refer to the same taxonomic category.
3.4 Process for the production of plants and animals

Art. 53 b) EPC excludes from patentability essentially biological processes for the production of plants or animals provided that this provision does not apply to microbiological processes or the products thereof. Further, it is defined in Rule 23b(5) EPC that a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena or such as crossing or selection. Additionally, it is stipulated in Rule 23b(6) EPC that “microbiological process” means any process involving or performed upon or resulting in microbiological material.

In the Decision T 1054/96 (not published) of the Technical Boards of Appeal it is stated that a process by which a transgenic plant is prepared by transformation and regeneration is not excluded from patentability by Art. 53 b) EPC. In particular, it is outlined in the above Decision that the step of transforming the host plant requires that DNA be introduced into it, i.e. that a number of mere technical manipulations such as isolating the transforming DNA, making the host permeable to said DNA and screening the transformants have to be performed. Since genetic engineering steps are performed in the above process, the claim cannot be considered to be directed to an essentially biological process for the production of plants, which would be excluded from patentability under the provisions of Art. 53b) EPC.

4. The Human Body or Parts thereof

According to Rule 23e(1) EPC the human body, at every stage 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. It is further stated in Rule 23e(2) EPC that an 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.

Additionally, according to Rule 23d a) to c) EPC European patents shall not be granted under Art. 53 a) EPC in respect of biotechnological inventions which concern processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, and uses of human embryos for industrial or commercial purposes.

4.1 Stem Cells

Concerning the patentability of a human embryonic stem cell culture under the EPC the Technical Boards of Appeal decided in the Interlocutory Decision “Stem cells/WARF” T 1374/04 (OJ EPO 2007, 313) that in said question an important point of law arose, which has to be decided by the Enlarged Board of Appeal. Accordingly, the concerned Technical Board of Appeal referred in said Interlocutory Decision several questions to the Enlarged Board of Appeal and thereby took the option of referring this issue to the EPO's highest instance, i.e. the Enlarged Board of Appeal, whose interpretation of the law is not only binding for the decision to be taken by the concerned Technical Board of Appeal on the pending appeal, but also has an impact on all future cases and legislation processes under the EPC. Therefore, it is the practice of the EPO to base future proceedings on the legal interpretations given by the Enlarged Board of Appeal.

In the referral concerning the patentability of a human embryonic stem cell culture under the EPC the concerned Technical Board of Appeal inter alia raises the questions whether Art. 53 a) EPC forbids patenting claims related to human embryonic stem cell cultures, and whether it is of relevance that after the filing date the same products could be obtained without having to recall to a method necessarily involving the destruction of human embryos. The case before the Enlarged
Board of Appeal is pending under Ref. No. G2/06. In this context, it should be noted that according to the EPO’s practice so far, Rule 23d c) EPC is interpreted to exclude from patentability all claims to the industrial and commercial use of human embryos and also all claims to associated products which necessitate the direct and unavoidable use of a human embryo such as, for example, embryonic cells.

4.2 Germ Cells

Regarding the patentability of human germ cells, it should be noted that recently a patent (EP-B1-1 257 168) has been granted which claims a method for the cryopreservation of human sperm cells. As a reaction to the grant of this patent, members of the European Parliament and representatives of Greenpeace have filed oppositions stating that the patent also covers non-patentable human germ cells. In said opposition proceedings no decision on said question has been made so far.

4.3 Human Genes

Rule 23e(3) EPC stipulates that if an element isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene constitutes a patentable invention, the industrial application of the sequence has to be disclosed in the patent application. This refers to the general principle that it is required that the description of a European patent application should, where this is not self-evident, indicate the way in which the invention is capable of exploitation in industry. Accordingly, a sequence or partial sequence of a gene may constitute a patentable invention under the EPC provided that the function and industrial application of the sequence or partial sequence of a gene is disclosed in the patent application.

Recently, patents relating to the human BRCA1 gene isolated from the genome, mutant forms of that gene and its use in the diagnosis of predisposition to breast and ovarian cancer, i.e. EP-B1-0 705 902 and EP-B1-0 705 903, have been granted, but subsequently have been restricted during opposition proceedings. During the opposition proceedings the European patent EP-B1-0 705 902 was restricted to a gene probe of a defined composition and no longer included claims for therapeutic and diagnostic methods. Further, the European patent EP-B1-0 705 903 related after the opposition proceedings to a gene probe of a defined composition for the detection of a specific mutation in the breast and ovarian cancer susceptibility gene, and no longer included claims relating to diagnostic methods. Appeals were filed against the decisions of the respective Opposition Divisions. Oral proceedings regarding EP-B1-0 705 902 will be held in September 2007. A date for the oral proceedings in the appeal procedures concerning EP-B1-0 705 903 has not yet been fixed.

5. In silico inventions

Regarding in silico inventions, it should be noted that, according to Art. 52(1) EPC, for a European patent to be granted an invention has to satisfy inter alia the requirement of being susceptible of industrial application. According to Article 57 EPC, this requirement is fulfilled if the invention can be made or used in any kind of industry, including agriculture. In this respect, Rule 27(1)f) EPC prescribes that the description should indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry. Rule 23e(3) EPC, which is in relation to biotechnological inventions, similarly requires that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Therefore, any invention, like e.g. a polypeptide or a nucleic acid, has to be characterized as having technically useful properties or a credible function in order to be
a patentable invention in compliance with Art. 57 EPC.

Applying the above regulations in the EPC it is stated in the Decision T 898/05 (not published) of the Technical Boards of Appeal that the disclosure of the function of a newly discovered protein is of utmost importance when examining the issue of "industrial applicability" as the function is the gateway to understanding the concrete benefits which may derive from exploiting the invention industrially. In the case of the above Decision T 898/05 a receptor was identified as a putative member of a certain receptor family based on computer-assisted sequence homology studies and on tissue distribution studies and it was assigned a role in proliferation, differentiation and/or activation of immune cells and thus a possible role for its ligands in therapeutic conditions associated with the functioning of the immune system. However, no experimental evidence for the suggested role of the receptor and/or its ligands is made available in the patent application. The concerned Technical Board of Appeal stated in the above Decision that the fact that a function is based on computer-assisted methods, rather than on the basis of traditional wet-lab techniques, does not mean that it has to be automatically disregarded or excluded from a careful and critical examination. Their probative value has to be examined on a case-by-case basis regarding the nature of the invention and the prior art relating thereto.

Further, it should be noted that according to Art. 83 EPC the European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Additionally, according to Art. 84 EPC the claims which shall define the matter for which protection is sought, shall be clear and concise and be supported by the description. In the Decision T 29/06 (not published) the Technical Boards of Appeal stated that an information, which gives only a general idea of the structure and organisation of a plasmid with no detailed indication as to the nucleotide sequence, in particular of the non-coding portions of the DNA molecule, is too vague and imprecise to enable the skilled person to construct the plasmid. Therefore, no patent protection can be obtained for such a claimed subject matter under the EPC.

Additionally it is outlined in the Decision T 609/02 (not published) of the Technical Boards of Appeal that if the description of a patent application provides no more than a vague indication of a possible medical use for a chemical compound yet to be identified, the claimed invention is not disclosed sufficiently for it to be carried out by a person skilled in the art pursuant to Art. 83 EPC. Since sufficiency of disclosure must, in principle, be shown to exist at the effective date of a patent, later more detailed evidence cannot be used to remedy a fundamental insufficiency of disclosure (i.e. lack of enablement).

In the old Decision “Triazole herbicides/AgrEvo UK Limited” T 939/92 (OJ EPO 1996, 309) of the Technical Boards of Appeal it is stated that if a claim concerns a group of chemical compounds per se, an objection of lack of support by the description pursuant to Art. 84 EPC cannot properly be raised for the sole reason that the description does not contain sufficient information in order to make it credible that an alleged technical effect (which is not, however, a part of the definition of the claimed compounds) is obtained by all the compounds claimed.

It is further outlined in the above Decision T 939/92 that the question as to whether or not such a technical effect is achieved by all the chemical compounds covered by such a claim may properly arise under Art. 56 EPC, if this technical effect turns out to be the sole reason for the alleged inventiveness of these compounds, since in order to fulfil the criteria of inventive step according to Art. 56 EPC the problem underlying an invention has to be solved over the whole range claimed. Accordingly, it is stated in the Decision T 1329/04 (not published) of the Technical
Boards of Appeal that the definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may, in the proper circumstances, also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve.

6. Conclusion

As a result of exclusions from patentability for inventions relating to the fields of medicine, pharmaceuticals and biotechnology under the EPC, subject matter which might be patentable under US patent law, like e.g. medical methods of treatment, are not open to protection conferred by a European patent. However, since said exclusion clauses are to be interpreted narrowly, the jurisprudence of the Boards of Appeal of the EPO demonstrates the limitations of said exclusions from patentability. For example, medical methods are only excluded from patentability if they fulfil as a multi-step method the criterion of containing a step practised on the human or animal body. Novel medical applications of a substance may be patented under the EPC either as a first medical use, when a medicament comprising the substance is novel and inventive, in the form of a purpose-related product claim or as a second medical use claim, i.e. a claim directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application. Genetically altered organisms such as transgenic organisms may be patented according to the EPC as long as the publication or exploitation of said organisms is not contrary to "ordre publique" or morality, e.g. by causing suffering to animals without counterbalancing benefit. Further, an element isolated from the human body or otherwise produced by means of a technical process may constitute a patentable invention under the EPC provided that the function and industrial application of the sequence or partial sequence of a gene is disclosed in the patent application. In view of the fact that under the EPC patents shall not be granted in respect of biotechnological inventions which concern processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, and uses of human embryos for industrial or commercial purposes, cases regarding the patentability of methods concerning the treatment of human sperm cells and human stem cells are pending before the Boards of Appeal of the EPO in order to establish the possibilities and limitations regarding the patentability in this field of technology.