

# Biotechnology and Patents

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**Abstract:** Legal nature, macro and micro economic importance of patents, differences in propensity towards patenting and their consequences. Brief comparison of US and European patent law with regard to patentability of biotechnological inventions. The regime adopted under the EU Biotechnology Directive, especially as regards the patentability of DNA sequences, as well as plants and animals. Addressed were also the issues of prior informed consent in case of the use of biological material of human origin and the implications of early publication of raw sequence data.

**Keywords:** Biological inventions · Biotechnology · DNA sequences · Patents

## 1. Patents as Exclusive Rights and Promoter of Innovation

The recent outcry from the media and politicians which followed the grant of the European Patent No. EP 0695351 B1 for 'Isolation, Selection and Propagation of Animal Transgenic Stem Cells' to the University of Edinburgh on December 8, 1999, and which revealed an astonishing ignorance of the basic principles controlling the patent system calls for some clarifying introductory remarks.

Patents are construed as exclusive rights, which confer on the patentee the right of exclusive use of the patented invention, *i.e.* an instruction how to solve a specific problem with technical means, provided the invention meets the patentability criteria of novelty, inventive activity (non-obviousness) and industrial applicability (utility). Third parties may use the patented invention only with the consent of the patentee. However, a patent does not contain a permission to actually use the invention at hand. The latter, without exception, is subject to compliance with laws regulating, for instance, drug marketing authorization, animal welfare, protection of environment, and the like. Moreover, it must respect the rights of third parties, for instance of owners of dominant patents. As an instrument of economic policy, patents are

aimed at rewarding the inventor, creating an incentive for innovation and securing the necessary investment in research and development, as well as production and marketing. Patents also act against secrecy and constitute a first-class source of scientific and technical information: Applicants are required to disclose the invention in a manner sufficiently clear and complete to be carried out by an average expert and this information is made available to the public 18 months after the application or priority date, at the latest. If necessary, the written description may be complemented by deposit of biological material in publicly accessible depository institutions.

## 2. Patents as Pillars of the Biotechnology Industry

The success story of modern biotechnology industry is closely linked with the evolution of modern patent law. Although inventions related to biological material were not explicitly excluded from patent protection, they were not regarded patentable for many decades, either on the grounds that they were not 'technical' (the European approach) or that they were 'a product of nature' (this was the US doctrine). Despite the fact that the first known patent on a living organism, a yeast, was issued in Finland already in 1843 and Louis Pasteur was issued a patent for 'yeast free from organic germs of disease' in the US in 1873, for a long time the only important exception was made for processes in the traditional fermentation industry, such as for the

production of alcohol, beer, vinegar, yeast and the like [1]. These attitudes experienced a first radical change when, in 1969, the German Federal Supreme Court (Bundesgerichtshof) in its *Red Dove* decision introduced a dynamic notion of patentable invention, which clearly extended the field of technology so as to cover also biological phenomena and forces, by defining it: '...[a] teaching to methodically utilize controllable natural forces to achieve a causal, perceivable result,..., provided that teaching meets the general prerequisites of industrial application, novelty, [etc.] [2].'

Whereas the *Red Dove* decision had no spectacular economic implications, this was different with the 1980 landmark decision of the US Supreme Court in the *Diamond vs. Chakrabarty* case. The US Supreme Court in this decision gave the decisive push for the rise of the biotechnology industry, when it opened the way for protecting biological material owing its existence to human intervention by declaring 'anything man-made under the sun' eligible for patent protection [3]. This was the signal for venture capitalists to pour money into the efforts of predominantly academic researchers, equipped with the necessary knowledge, enthusiasm and, last but not least, patent applications, to establish an entirely new branch of industry. Without the *Chakrabarty* decision of the US Supreme Court and the patent granting practice of the US Patent and Trademark Office (US PTO), which followed suite, one would have hardly ever heard of companies such as Amgen, Biogen, Chiron or Genentech, to name but a few – in alphabetical order – which

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now represent a multibillion US \$ of market capitalization and the products of which are now responsible for a multibillion US \$ turnover per year. The activities of the new biotechnology industry and its partners, be they 'classical' pharmaceutical companies or academic institutions, have been secured by patents granted on basic recombinant DNA technology, monoclonal antibodies technology, DNA sequences of different origin, pharmaceutically useful proteins, as well as transgenic animals and plants. Patents have also been instrumental for the establishment of the so-called new genomic industries, which followed in the 1990s and are represented by companies such as Affimetrix, Human Genome Sciences (HGS), Incyte Pharmaceuticals, Millennium, Myriad [4], and, for instance, more recently Celera [5] and many others.

### 3. Macro-Economic Importance of Propensity Towards Patenting

The contribution of publicly funded basic research to the development of industrial biotechnology seems beyond doubt. It has empirically been proven that some 26 non-patent references were cited per biotechnology patent, which is nearly triple the number of 10 non-patent references cited per typical drugs and medicine patent [6]. However, national economies seemingly do not benefit to the same extent from the achievements of their basic researchers. This is indicated by the fact that, for instance, the United Kingdom is clear second to the United States in authorship of cited research papers in US patents in 'human molecular and cell technology,' but poor third to the United States and Japan in owning those patents (71.2% US, 12.3% Japan, 2.8% UK, 2.5% Germany) [7]. In other words, the contribution of the researchers from the United Kingdom to the scientific base of modern industrial biotechnology is considerably larger than the UK's proprietary share in and thus eventually its benefit from industrial biotechnology. This is also reflected by the fact that the UK accounts for about 7% of all academic citations, but it holds only 3% of the world's patents. In the case of Japan, the ratio is quite the opposite: It has 4% of academic citations, but about 14% of all patents, which might indicate a much more efficient appropriation and transformation of its own, as well as alien, unprotected, research results [8].

These empirical findings, which may not differ essentially as regards the situation in France, Germany and some other

European countries, mirror a whole range of factors: Such as the general attitude of academic researchers towards patenting – in 1992 18.1% of all patents in the field of genetic engineering were in the hands of US academic inventors [9] – and the availability of the infrastructure necessary for patenting and commercializing of inventions at universities [10], the legal framework for patenting and licensing of publicly funded research results [11], availability of venture capital and the like. Irrespective of the affiliation of inventors, the pace of patenting activities and the number of patent applications filed in the area of biotechnology have also been decisively influenced in favor of the United States by the more predictable and overall more favorable US patent law and practice. Therefore, in the following, the legal situation in the US and Europe is briefly compared.

### 4. Inventions Eligible for Patent Protection

#### 4.1. General

The main difference between the two systems exists in their approach as regards the eligibility of inventions for patent protection. Whereas the US Patent Statute (35 United States Code - USC) does not contain any explicit exclusions from patentability and, thus, entirely relies on courts to draw the limits inherent to the principles of the patent system, European patent law, as represented by the European Patent Convention (EPC), is characterized by a number of such exclusions, which to a large extent affect inventions in the area of biotechnology. Under the EPC, inventions, the publication or exploitation of which would be contrary to 'ordre public,' i.e. the basic foundations of our legal system or morality, are excluded from patent protection, provided that the exploitation is not deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States (Art. 53 a). Also excluded from patentability are inventions of plant or animal varieties and essentially biological processes for the production of plants or animals (Art. 53 b). The same applies to methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. However, substances or compositions for use in any of these methods, in particular drugs and intermediaries used in their production, are eligible for patent protection (Art. 52 (4)). Finally, under Art. 52 (2) (a) (3) EPC, discoveries

and scientific theories as such may not be regarded as inventions, a principle which is inherent to all patent systems and which was expressly affirmed by US courts as early as 1862 [12].

#### 4.2. USA

As a consequence of the holding of the *Chakrabarty* Court in the US, all kinds of biological material, including higher life forms are deemed patentable subject matter under the current US Statute [13]. Patents have been routinely granted for plants, including claims related to plant varieties since 1985 [14] and since 1987, in principle, also for animals [15]. As regards patents for plants and plant varieties, this practice has now been approved by the Court of Appeals for the Federal Circuit on a motion for summary judgement in *re Pioneer Hi-Bred International, Inc. vs. J.E.M. AG Supply, Inc., Farm Advantage, Inc., Larry Benz, Merle Pruett, Kevin Wolfswinkel, Tim Kamstra, and Tom Eischied Seed and Chemicals* [16].

#### 4.3. European Patent Office

Claims related to biological material other than animals or plants so far had not encountered any other difficulties as those generally related to the patentability requirements of novelty and inventive activity, in the European Patent Office (EPO) patent granting practice either. About 3000 patents have been granted for monoclonal antibodies, cell lines, plasmids, and DNA sequences of various origin [17].

As regard generic inventions in animals and plants, due to interpretation of exclusionary provisions related to plant or animal varieties, the situation in Europe, however, differed significantly. When in 1995 a Technical Board of Appeal of the European Patent Office departed from the former EPO case law [18] and in its *Plant Cells/Plant Genetic Systems (PGS)* decision rejected a claim that related to a non-biologically transformed plant, possessing in its genome a stably integrated DNA nucleotide sequence encoding a protein having specific useful properties, as a claim directed to 'plant varieties' and as such being banned from patent protection under Article 53 (b) EPC [19], inventors of generic, i.e. generally applicable inventions in transgenic plants and animals were practically left without adequate protection [20]. Although the same Technical Board of Appeal in 1997 in its *Transgenic Plant/Novartis* case maintained all of its *PGS* decision arguments, it nonetheless referred four Article 53 (b) EPC related questions

to the Enlarged Board of Appeal for binding interpretation [21]. On December 20, 1999, the Enlarged Board of Appeal finally rejected the *PGS* doctrine and clarified that 'a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53 (b) EPC even though it may embrace plant varieties' [22]. The Enlarged Board of Appeal in particular emphasized that it was not the wording but the substance of a claim which was decisive in assessing the subject matter to which the claim is directed. This, however, may not result in equating the subject matter of a claim with the scope of a claim, but in identifying the underlying invention. In this respect it was relevant how generic or specific the claimed invention is. This was not a question of form but of substance: The applicant may claim his invention in the broadest possible form, *i.e.* the most general form for which all patentability requirements are fulfilled. The Board then went on to state: '[I]f he has made an invention of general applicability, a generic claim is not the consequence of the verbal skill of the attorney, as the referring decision seems to suggest [...], but of the breadth of application of the invention' [23].

In the context of interest the Enlarged Board of Appeal also held, *inter alia*: '3.8 It has already been stated that the subject matter of a claim covering but not identifying plant varieties is not a claim to a variety or varieties [...]. It follows that such an invention cannot be protected by a plant breeder's right, which is concerned with plant groupings defined by their whole genome but not by individual characteristics [...]. Whereas in the case of a plant variety, the breeder has to develop a plant grouping fulfilling in particular the requirements of homogeneity and stability, this is not the case with a typical genetic engineering invention... The inventor in the latter case aims at providing tools whereby a desired property can be bestowed on plants by inserting a gene into the genome of those plants. Providing these tools is a step which precedes the further step of introducing the gene into a specific plant. Nevertheless, it is the contribution of the inventor in the genetic field which makes it possible to take the second step and insert the gene into the genome of any appropriate plant or plant variety.' [24]

Thus, the Enlarged Board of Appeal secured the patentability of generic inventions in plants and animals, brought the interpretation of Article 53 (b) EPC in line with the respective provisions of the

EU Directive 98/44/EC on the legal protection of biotechnological inventions [25], to be discussed later on, and implicitly affirmed the conformity of the new Implementing Rules to the EPC, by which the Administrative Council of the European Patent Organization on June 16, 1999 transformed the EU Directive into the Implementing Regulations to the EPC [26]. As result, some 1500 applications related to transgenic plants and some 600 related to transgenic animals can now be examined [27].

With regard to the patentability of animals the EPO in the *Harvard 'Onco Mouse'* case of 1990, in which an invention related to a method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms and to transgenic animals produced by said method, held that the exclusions under Article 53 (b) are to be applied to certain categories of animals only, but not to animals as such [28]. Moreover, in examining whether the exploitation of the invention at hand would contradict the exclusionary provision of Article 53 (a) EPC, the Board held that a test had to be performed on a case-by-case basis, whereby 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, had to take place. It also has to be observed that the Board addressed the question, but left it unanswered, how those categories of animals which are to be excluded from patent protection under Article 53 (b) EPC, namely 'animal varieties,' 'races animales' and 'Tierarten', used in the three authentic languages of the EPC, which clearly differ in scientific terms, are to be defined.

#### 4.4. The Regime Under the European Directive

##### 4.4.1. Background and Basic Principles

Since the advent of the modern biotechnology in the late 70s and early 80s the Commission of the European Communities has been aware of the existing gaps between the US and the European patent situation. It therefore envisaged the adoption of a Directive on the legal protection of biotechnological inventions with the aim to, on the one hand, provide for high and harmonized standards of protection, comparable to those in force in the USA and Japan, and, on the other hand, establish a balance between the commercial needs of researchers and industry and the ethical concerns of some

parts of the public at large, which have been strongly opposed to the idea of patenting living matter. Consequently, the Directive eventually adopted after ten years of tense discussions in the Council and the European Parliament in July 1998, had to provide for clarification in two directions: namely, what has to be viewed as patentable and what has to be excluded from patentability in respect to inventions related to biological material, *i.e.* 'any material containing genetic information and capable of reproducing itself or being reproduced in a biological system' (Article 2 (1) (a) of the Directive). Since the European Patent Convention (EPC) does not form part of the legal order of the European Union and, thus, the European Patent Office (EPO) is not bound by legal instruments of the Union, it was of utmost importance that, as reported above, the Administrative Council of the European Patent Organization, in order to comply with the requirement for uniformity in harmonized European patent law [29], with effect as of September 1, 1999, transformed the EU Directive into the Implementing Regulations to the EPC, by introducing the new Rules 23b–23e. According to the Rule 23b (1) second sentence, the EU Directive 98/44/EC shall also be used as a supplementary means of interpretation of the EPC Rules. Thus, whatever is reported on the EU Directive in respect of patentability requirements, is equally valid for the EPC.

Under the basic rule applied in the Directive, inventions which satisfy the usual patentability requirements constitute patentable subject matter 'even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.' This holds true also for biological material which previously occurred in nature, if it is isolated from its natural environment or produced by means of a technical process (Article 3 (1) (2); Rule 23c (a) EPC). The Directive, thus, confirms the long-standing practice on the patentability of naturally occurring substances [30] and imposes its application on all naturally occurring biological material as defined in Article 2 (1) (a) (Rule 23b (3) EPC).

##### 4.4.2. Important Limitations

The omnipresent preeminence of the fundamental principle of safeguarding the dignity and integrity of the person, which have to be respected under all circumstances, this basic rule, however, has experienced some important limitations:

Recital 16 and Article 5 (1) (Rule 23e (1) EPC) have reconfirmed the never questioned principle that the human body, at the various stages of its formation and development, including germ cells, cannot constitute patentable inventions. The same applies to the simple discovery of one of its elements, including the sequence or partial sequence of a gene. This latter rule only reflects and confirms the established case law in the EU Member States, which relates to the delimitation between patentable inventions and unpatentable discoveries: *i.e.* it had been held as non-patentable discovery to recognize, isolate and sequence a genomic DNA sequence, if the inventor did not indicate the method for its repeatable production and the purpose it can be used for [31]. Such DNA sequences lack novelty only if their existence has recognizably been made publicly available prior to the filing or priority date. This is not automatically the case, even if they were contained in a publicly accessible gene bank [32].

Based on the same ethical considerations the Directive and the EPC Rules also exclude from patent protection certain categories of process inventions, the exploitation of which has specifically been declared as being contrary to *ordre public* or morality. This applies to processes for cloning human beings, uses of human embryos for industrial or commercial purposes, and 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 of animals resulting from such processes (Article 6; Rule 23d EPC). Thus, the new rule did not maintain the *Onco-Mouse* weighing up test as a general principle to be applied under Article 53 (a) EPC. However, neither the general exclusion of therapeutic and surgical methods, nor the new specific exclusionary provisions result in a total lack of protection for methods and substances involved in somatic gene or somatic cell therapy. Since substances or compositions for use in such methods are patentable, not only methods for their production, but also intermediaries and, eventually the endproduct – the drug itself – involved in somatic gene therapy and somatic cell therapy, such as vectors, somatic cells, as well as transformed somatic cells, to be injected, infused, *etc.* can be patented. Outside patent protection, contrary to the situation in the USA where the inventors do not experience any specific limitations [33], remain only entire therapeutic methods, including the steps of removing human tissue and injecting, *etc.*, the drug [34].

#### 4.4.3. DNA Sequences

Taking into account the key role which in particular DNA sequences, but also other elements of the human body play in the development and production of new valuable drugs and which is expected to become even more important in the future, the Directive and the new EPC Rules provide for further important clarifications by declaring elements isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene, as, in principle, patentable, even if the structure of that element is identical to that of a natural element (Recitals 17, 20 and 21; Article 5 (2); Rule 23e (2) EPC). Here again, the European law maker has approved the practice of the EPO, as well as of national patent offices and courts and thus terminated the debate which continued to question the legal basis for issuing patents on DNA sequences of human origin. However, the explicit confirmation of the patentability of DNA sequences of human origin under the EU Directive is made dependent on some additional requirements so far not explicitly provided for either under the EPC and its new Implementing Rules, or in the US patent law. First, under Recital 23, which sets out the rule that a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention, the notion of the patentable invention itself seems to have experienced a more stringent authentic interpretation, making the indication of '*a function*' to one of its integral parts. In this context '*a function*' according to the prevailing view may not be equated with '*biological function*' of for instance an Expressed Sequence Tag (EST) or the gene of which it is a part, but has to be understood as any function responsible (causal) for a technically applicable result, *e.g.* to be used as a specific diagnostic marker, or for the specific identification for forensic purposes [35], and secondly, the patentability requirement of industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application as filed (Recital 22; Rule 23e (3) EPC). Moreover, in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, the requirement of industrial application is met only if the application specifies which protein or part of a protein is produced or what function it performs (Recital 24, which, however, has no counterpart in the new EPC Rules). It goes without saying that

the European law maker by introducing these rules reacted to the attempts to get patents issued on large numbers of ESTs and Single Nucleotide Polymorphisms (SNPs), for which, after very controversial debates [36], the United States Patent and Trademark Office in 1997 started to issue patents [37]. It remains to be seen whether these stricter rules of the EU Directive will suffice to successfully contain the strong efforts of genomic industries to make ESTs and SNPs proprietary information, which due to the then limited access to it, could seriously hamper the development of new therapies [38]. To counteract these efforts, pharmaceutical industry and academic research institutions for the first time have joined forces and recently established a consortium to create a public database of genetic mutations [39].

#### 4.4.4. Prior Informed Consent

Quite apart from the above considerations, which are all linked to the basic principles of patent law, the patenting of inventions based in biological material of human origin or which use such material is also explicitly made dependent on the fact that the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law (Recital 26). Thus, in the case of patent applications of this kind, a *prior informed consent* is required, but the rules are left to be set forth by the legislation of the EU Member States. Although at present no such specifically patent-oriented rules exist in any of the EU Member States and notwithstanding all doubts whether a Recital of a Directive could oblige national law makers at all, one should always be aware that a prior informed consent is required under the principles of the constitutional law and the law of medicine [40] or the laws regulating clinical testing of pharmaceuticals [41] whenever an intervention in the human body is at hand. This is also clearly laid down in Article 5 of the Convention of the Council of Europe on Human Rights and Biomedicine of April 4, 1997. Therefore, even absent specific patent rules on prior informed consent, researchers and applicants are well advised and on safer grounds if their research activities are backed by a prior informed consent of the person from whom the biological material involved in patent application is derived. Otherwise they may be faced with objections reasoned by, for instance, Article 53 a) EPC.

#### 4.4.5. Plants and Animals

Whereas the provisions of the Directive which relate to the patentability of the human body and its elements, by and large, explicitly confirmed the past patent granting practice, especially of the EPO, provisions which relate to the patentability of higher life forms, namely plants and animals can be viewed as aimed at correcting the case law of the Boards of Appeal of the EPO, as reflected in the reported *Plant Cells/Plant Genetic Systems (PGS)* decision. Although under Article 4 of the Directive plant and animal varieties as well as essentially biological processes for the production of plants or animals remain explicitly excluded from patentability, generic inventions in plants or animals are explicitly declared patentable subject matter. Under Article 4 (2) inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety (Rule 23c (b) EPC). Recitals 29–31 serve the same purpose by clarifying that a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties of plants and is therefore not excluded from patentability even if it comprises new varieties of plants (Recital 31). In view of the already reported *Plant Cell/Novartis II* decision of the Enlarged Board of Appeal of the EPO, the new Rule 23c (b) EPC is in conformity with Article 53 b) EPC and thus secures for the future the patentability of generic inventions in animals and plants under the EPC.

#### 4.4.6. Scope of Protection

Notwithstanding the remarkable number of patents already issued on various types of biological material and despite the many infringement cases in which courts of various EU Member States have already handed down their decisions, many issues related to the scope of protection of patents granted on biological material have remained unclear. In particular, it was unclear whether a product patent on biological material covers also biological material derived from that material through propagation or multiplication; further, whether biological material derived through propagation or multiplication from the biological material directly obtained by a patented process still meets the criterion of being 'directly' obtained by that process; finally, do the effects of a patent on genetic information cover all materials in which that information has been incorporated?

The Directive offers answer to all of these questions and in doing so in fact considerably strengthens the position of the patent owner in the field. Under Article 8 (1) the effects of product patents issued on biological material which owes specific characteristics to the invention, extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics. Article 8 (2) clarifies further that process patent protection extends also to biological material obtained through propagation or multiplication of the material directly obtained by the process in identical or divergent form, as long as it possesses the same characteristics. Thus, process patent protection covers also the second, third, *etc.* generations of plants or animals, as long as the other requirements are met. Eventually, Article 9 stipulates that the protection of patents issued on genetic information extends to all material in which that information is incorporated and in which it is contained and performs its function. The only, however, most important exemption of this scope of protection rule is the *human body*, which never can be affected by any patent, as explicitly clarified by the reference to Article 5 (1) in Article 9.

It goes without saying that the established far-reaching scope of protection will necessarily result in increased numbers of dependencies. In order to contain the effects of patents issued on biological material within acceptable limits, the European law maker, first, in Recital 25 addressed the issue of patents granted on partly overlapping sequences. According to the rule established thereunder sequences will have to be considered as independent in patent law terms, when they overlap only in parts which are not essential to the invention. By adopting this rule the Directive may offer an acceptable solution for the conflict between patents granted on ESTs and SNPs, on the one hand, and those granted on full-length sequences. Whether this solution will meet the expectations, will to a large extent depend on how the notion of 'essential' will be interpreted. In this latter regard, a recent Statement adopted by the Intellectual Property Rights Committee of the Human Genome Organization (HUGO) suggested that the notion 'are not essential to the invention' is to be interpreted in the light of the function *unambiguously* disclosed by the respective applicant (patentee) and *not on the basis of its objective (natural), not disclosed, importance* as

such, and that claims of the broad 'having' and 'comprising' type, which cover not only the disclosed DNA sequence and its use but also products 'having' or 'comprising' that sequence, should be allowed only exceptionally when the information disclosed for the overlapping part is *sufficiently enabling* to the entire claimed invention [42]. Further limitation of the patent right exist under the Directive in the form of the so-called farmers' privilege, alien to patent law as yet, and entirely modeled according to the respective rules of the Council Regulation (EC) No. 2100/94 of July 27, 1994 on Community Plant Variety Rights [43]. Moreover, the Directive has established a regime of compulsory cross-licenses between dependent plant breeder's rights and patents and *vice versa* (Articles 11 and 12).

#### 5. Some Other Aspects

A joint statement released on March 14, 2000, by the US President Bill Clinton and the UK Prime Minister Tony Blair, requires that at the end of this contribution, which deliberately avoided to specifically address the patentability requirements and the differences existing in this respect between the US and the European law, at least one aspect of one single patentability requirement is addressed. The two leaders stated, *inter alia*, that to realize the full promise of the human genome research, one of the most significant scientific projects of all time, '[r]aw fundamental data on the human genome, including the human DNA sequences and its variations, should be made freely available to scientists everywhere. Unencumbered access to this information will promote discoveries that will reduce the burden of disease, improve health around the world and enhance quality of life for all' [44]. This very much applauded moral exhortation, which is in line with a number of statements of the Human Genome Organization (HUGO) [45] and a so-called Bermuda Agreement of 1996 of researchers participating in the Human Genome Project [46], and which does not question the patentability of 'gene-based inventions', however, raises the issue of legal consequences of the suggested behavior of researchers. In particular, will they be the same in the United States as in the United Kingdom and the rest of Europe? Due to differing novelty requirements in the US patent law, on the one hand, and the European patent law, on the other hand, they will differ considerably:

Whereas researchers and their institutions under the US patent law, thanks to the existing twelve months 'grace period' (35 USC. § 102 (b)) combined with the first-to-invent principle, will still be able to acquire proprietary rights in the released data in the USA by filing patent applications within twelve months after the data release on Internet, in Europe, where the novelty destroying state of the art comprises everything made available to the public by means of a written or oral description, by use, or in any other way, before the filing date (Article 54 (2) EPC), they will remain virtually empty-handed. Virtually and not entirely, because Article 54 (5) EPC allows patent protection for substances or compositions for use in therapeutic and diagnostic methods, provided that use in such methods is not comprised in the state of the art. Thus, even published raw sequence data, provided all other patentability requirements are met, is still eligible for a purpose bound product protection. Also, patents can be obtained for further new and inventive uses of such substances, in which case dependent patents are at issue. Strictly speaking, even in Europe it is not all over with the publication, but most things are. Whether and for how long this imbalance to the disadvantage of European researchers, and in fact the economy as a whole, will continue to exist remains to be seen. At present the so far very controversially discussed issue of a possible introduction of a general 'grace period' into the EPC is under consideration by the EPO, which has been mandated this task by the Intergovernmental Conference of EPO Member States for preparing the revision of the EPC which took place in June 1999 [47].

## 6. Concluding Remarks

It is beyond doubt that patents have been instrumental for the advent and rise of the new biotechnology industry and the genomic industries. It is also undisputed that only thanks to patents a remarkable number of products, primarily important drugs, has reached the world markets and contributed to essential improvements in medicine, pharmaceuticals and agriculture. There are good reasons to believe that this situation will continue in the future. However, as regards patenting in the area of genomics, the law maker, administrators of law, *i.e.* patent offices and courts are entrusted with great responsibilities. It is up to them to balance the system in a way so as

to strictly commensurate the scope of patent protection to the actual contribution to the art by the inventors and to deny patents whenever purely speculative 'inventions' are at stake. The temptation of genomic industries to appropriate as much as possible of genomic information is understandable, but it should be equally understandable that the public at large, in this context composed not only of academic researchers but equally of pharmaceutical industry, has a legitimate interest to see most of raw sequence data treated as pre-competitive information kept in the public domain.

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- [13] H.T. Markey, *IIC* 1989, 20, 372; H. Nies, *IIC* 1990, 21, 480.
- [14] *Ex parte Hibberd*, *USPQ* 227, 443 (PTO Bd App 1985).
- [15] *Ex parte Allen*, *USPQ* 2d, 2, 1485 (PTO Bd App. 1987).
- [16] *USPQ* 2d, 53, 1440 (Fed. Cir. 2000).
- [17] Notice of the EPO of July 1, 1999, *OJ EPO* 1999, 573 at 574. Best guidance to respective decisions is given by the Catchword Index in H.-R. Jaenichen, 'The European Patent Office's Case Law on the Patentability of Biotechnology Inventions,' with Annotations on the US case law by L.A. McDonell and J.F. Haley, 2nd ed. Carl Heymans Verlag KG, Cologne, Berlin, Bonn, Munich 1997, 373.
- [18] *OJ EPO* 1984, 112 - Propagating Material/CIBA GEIGY; *OJ EPO* 1990, 71 - Hybrid Plants/Lubrizol; *OJ EPO* 1990, 476 - Onco Mouse/Harvard.
- [19] *OJ EPO* 1995, 545.
- [20] Cf. P. Lange, *GRUR Int.* 1996, 586; U. Schatz, *GRUR Int.* 1997, 588; T. Roberts, *EIPR* 1996, 531; J. Straus, *GRUR Int.* 1998, 1.
- [21] *OJ EPO* 1998, 511.
- [22] *OJ EPO* 2000, 111 - Transgenic Plant / Novartis II (headnote I).
- [23] No. 3.1 second paragraph of the Reasons (at *OJ EPO* 2000, 124).
- [24] *OJ EPO* 2000, 134.
- [25] Of July 6, 1998, *OJ EC* No. L 213/13 of 30.7.1998.
- [26] *OJ EPO* 1999, 437; cf. also the Notice of July 1, 1999, *OJ EPO* 1999, 573.
- [27] Cf. *OJ EPO* 1999, 574.
- [28] *OJ EPO* 1990, 576 - Onco-Mouse II.
- [29] Notice of July 1, 1999, *OJ EPO* 1999, 573 (No. 3).
- [30] Reference is made here only to the decisions of the German Federal Supreme Court and the German Federal Patent Court reported in F.K. Beier, R.S. Crespi, J. Straus [1], pp. 102 ss., and to the Guidelines for Examination in the EPO Part C. IV 2.3 (December 1994).
- [31] Cf. e.g. House of Lords *In re Asahi Kasei Kogyo Kabushiki Kaishaka* (1991) R.P.C. 485, at 539.
- [32] Technical Board of Appeal (TBA) EPO, *OJ EPO* 1990, 335.
- [33] J.K. Flanagan, *J. Patent Trademark Office Soc.* 1998, 10, 739.
- [34] S.J.R. Bostyn, *IPQ* 1999, 1, 1; J. Straus, *GRUR* 1996, 10.
- [35] Cf. A. Oser, *Int. Rev. Ind. Property Copyright Law* 1999, 30, 1; J. Straus, *GRUR* 1998, 314, at 319.
- [36] J. Straus, *OECD Science Technology Industry Review* 1996, 19, 45, 49.
- [37] J.J. Doll, *Science* 1998, 280, 689; M.A. Heller, R.S. Eisenberg, *Science* 1998, 280, 698.
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- [41] See the surveys in B.M. Knoppers, M. Hirtle, M. Larneau, S. Laberge, *Genomics* 1998, 50, 385; A. Eser, 'Legal Aspects of Experimentation on the Living: A Comparative Survey,' in 'The Ethics of Life,' UNESCO Paris 1997, 185; J. Straus, 'Wem gehört das Genom?', in 'Gene, Neurone, Qubits & Co.,' S. Hierzel Verlag Stuttgart, Leipzig, 1999, p. 217, 222.
- [42] The HUGO Intellectual Rights Committee is chaired by this author. The Statement has not yet been published.
- [43] *OJ EC* No. L 227/1 of 1.9.1994, as amended by Regulation (EC) No. 2506/95, *OJ EC* No. L 258/3 of 28.10.1995.
- [44] M. Wrong, V. Griffith, *Financial Times* of March 15, 2000, p. 1.
- [45] *Genome Digest* April 1995, 6; *Genome Digest* July 1997, 3; cf. also E. Marshall, *Science* 1997, 276, 1189.
- [46] D.R. Bentley, *Science* 1996, 274, 533.
- [47] Cf. *OJ EPO* 1999, 545, 549.