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Patenting of Biological Material and Biotechnology

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One of the major challenges faced by developing countries due to globalization and TRIPS regulations is understanding of intellectual property rights (IPR) laws of different countries in context of recent innovations in biotechnology and bioinformatics. While biotechnology involves application of technology on biological organisms, viz., microorganisms, plant and animals and biological material of DNA, RNA and proteins, patenting laws of different countries are solely based on non-biological objects and inventions. Hence biotechnological inventions and their interpretations are discussed in context of laws of different countries for granting patent claims although basic criteria are the same. Patenting and protection of plants, animals, cloning, expressed sequence tags (ESTs) have been discussed in the context of TRIPS regulations, EPO directive and USPTO guidelines. With the large scale sequencing of genomes of various species, a new scientific discipline of bioinformatics has emerged that encompasses biological information, acquisition, processing, storage and distribution, analysis and interpretation of data. Thus inventions relating to tools of bioinformatics, methodology and interpretation as business methods are analysed with regard to patenting.

Key words: Bioinformatics, biotechnology, cloning, DNA, intellectual property rights, TRIPS, WTO

Biotechnology is the synergistic union of the biological sciences and technology based industrial art. It is the utilization of biological processes for the exploitation and manipulation of living organisms or biological systems in the development or manufacture of a product or in the technological solution to a real-world problem. Patent laws in most of the countries are tuned for non-biological material. In biotechnology, the basic aspect is biological material or biological process or biological product with industrial application. But the issue of whether living organisms, such as, microorganisms, plants or animals, or naturally occurring substances, such as DNA and proteins, cloning and bioinformatics may constitute the subject of an invention is still very controversial and hence considered separately. Differences in interpretation of the same invention by different patent offices are commonly observed in many aspects.

Microorganisms

Louis Pasteur, the famous French scientist, received US Pat No 141,072 on 22 July 1873, claiming 'yeast, free from organic germs of disease, as an article of manufacture'. With the phenomenal growth of genetic engineering in the late 1970s, the patentability of living microorganisms came into the scene, which involved Ananda Chakrabarty's invention of a new *Pseudomonas* bacterium genetically engineered to degrade crude oil. USPTO rejected the claim on *Pseudomonas* bacterium, but the Supreme Court decision went in favour of Chakrabarty in a landmark case, *Diamond (USPTO commissioner)* v *Chakrabarty* (inventor)[1]. Chakrabarty's *Pseudomonas* bacterium manipulated to contain four plasmids controlling the breakdown of hydrocarbons was 'a new bacterium with markedly different characteristics from any found in nature'. The Supreme Court stated that new microorganisms not found in nature were either 'manufactured' or 'composition of matter' within the meaning of US Patent Act §101 and thus patentable. The 'product of nature' objection therefore failed and the modified organisms were held patentable.

Following the US Supreme Court decision in Chakrabarty case, European Patent Office (EPO) and the Japanese Patent Office (JPO) also started granting patent protection for microorganisms in 1981[2]. A provision of EPC, Article 53(b) is relevant here which states that patents shall not be granted for plant or animal varieties or essentially biological processes for the production of plants or animals, however, the

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provision does not apply to 'microbiological processes or the products thereof.'

The microorganisms and microbiological inventions can be patented in India provided the strain is new under Patents Act, 1970, amendment 2002, implemented from 20 May 2003[3]. However, under Section 5 of Patents Act, inventions relating to substances prepared or produced by chemical processes, which include biochemical, biotechnological and microbiological, no patent shall be granted in respect of claim for the substances themselves, but claims for the methods or processes or manufacture shall be patentable. Earlier the inventions on microorganisms were not patentable and this was one of the TRIPS regulations under the Article 27.3(b) that 'parties may exclude from patentability plants and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes'[4]. Thus one of the conditions of TRIPS regulations has been met and enforced in the country. Inventor has to deposit the new strain in any recognized international depository. Budapest Treaty is an international convention governing the recognition of microbial deposits in officially approved culture collections which was signed in Budapest in 1973 and later on amended in 1980. Because of the difficulties and on occasion of virtual impossibility of reproducing a microorganism from description in the patent specification, it is essential to deposit a strain in a culture collection centre for testing and examination by others. It obviates the need of describing a microorganism in the patent application and further samples of strains can be obtained from the depository for further working on the patent. There are 34 International depositories for deposition of microbial cultures. India signed the Budapest Treaty on 17 December 2001. In India, Microbial Type Culture Collection and Gene Bank (MTCC) at the Institute of Microbial Technology (IMTECH), Chandigarh, is a recognized international depository of microorganisms.

Plants

The US Plant Patent Act (PPA), enacted in 1930, allowed patenting of asexually propagated plants, and over 6,500 of such plant patents have been granted mostly for ornamental and fruit trees[5]. Plant Variety Protection Act (PVPA) was enacted in 1970[6]. In 1985, the US Board of Patent Appeals allowed patent protection for asexually, sexually or *in vitro* propagated plants[7]. In the Hibberd case involving a tryptophan-overproducing mutant, the US Patent Office in 1985 ruled that plants could be patented. Following the principle established in the Chakrabarty case, it was decided that normal US utility patents could be granted for other types of plants also, e.g. genetically modified plants. It was affirmed by a ruling of US Supreme Court on 10 December 2001 that plant utility patents could be granted to sexually reproduced plants in an infringement lawsuit for sexually reproduced corn hybrids against J E M. A G Supply Inc by Pioneer Hi-Bred International Inc . The court held that newly developed plant breeds fall within the subject matter of 35 USC §101 and neither the PPA nor the PVPA limits the scope of its coverage[8]. Among transgenic plants, herbicide-resistant cotton, canola, soybean, etc; insect-resistant potato, cotton, maize, etc. have been patented. In Japan also plant patents are allowed.

Plant patents have been granted by EPO from 1989. According to EPC Article 53(b) patents shall not be granted for plant or animal varieties or essentially biological processes for the production of plants or animals, [9]. In 1995, Green Peace brought a case against a patent on plants incorporating a transgene conferring herbicide resistance granted to Plant Genetic Systems, Belgium. The EPO's Technical Board of Appeal did not uphold any of Green Peace's arguments on the morality point [A provision of EPC Article 53(a) denies patentability to "inventions, the publication or exploitation of which would be contrary to '*ordre public*' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States"]. But, it did confirm in its ruling that plant varieties could not be patented[11]. Recently, Indian wheat variety '*Nap Hal*' was in news because EPO granted patent on this traditional land race to Monsanto in 2003[3]. This particular variety has good biscuit making qualities. Opposition was filed and in 2004 the patent has been revoked.

Life forms of plants and animals except microorganisms are not patentable in India. Also a method or process of agriculture and horticulture is non-patentable. However, methods for rendering plants free of diseases or putting an additive value to a plant can be claimed for patenting[3]. In pursuance to the TRIPS Agreement Article 27.3(b) plants and animals were left out of the compulsions of strict patent regime. However, members shall provide for

the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof[4].

How to Protect Plant Varieties?

India and so many other countries do not protect plants by strict patenting system. But there is a mandate in the TRIPS Agreement that plant varieties must be protected. In pursuance to the TRIPS Agreement, India has enacted 'Protection of Plant Varieties and Farmers' Rights' (PPVFR) Act, 2001, a *sui generis* system of plant variety protection. This law is unique which has brought forth the farmers rights under the gambit of law. The model for this was the UPOV Act, an International Convention [Convention of the Union for the Protection of New Varieties of Plants; original in French 'Union International pour la Protection des Obtentions Vegetales' (UPOV)] was held *albeit* with few countries to negotiate and provide for the protection of new varieties of plants in Paris in 1961 and came into force in 1968. It was revised in Geneva in 1972, 1978 and 1991. The 1978 Act came into force in 1981 and the 1991 Act in April 1998. There are two main Acts of 1978 and 1991[10]. The Convention had already 54 countries party to it as on 15 April 2004[11]. Under the UPOV, a plant variety qualifies for protection when it meets three essential criteria, (i) distinctiveness, (ii) uniformity and (iii) stability, and the variety should be new in commercial sense. Application for its protection can be filed in the country where developed or in any other UPOV member country[12].

The Indian PPVFR Act along with rules, 2003 is in place but yet to be enforced. This act tends to provide a balance between the rights of breeders and farmers. Plant variety protection (PVP) may be provided to new varieties, extant varieties (already in cultivation or of common knowledge) or farmers' varieties. The essential features are same as distinctiveness, uniformity, stability for extant and farmers varieties, but novelty feature is included in the newly developed variety. It will provide maximum protection for 18 years to trees and vines and 15 years to other crop varieties. Broadly, the Indian Act features a combination of provisions from the UPOV 1978 and UPOV 1991 versions. It provides protection to essentially derived variety and also elaborates provisions for the protection of farmers' rights[13].

Animals

The question of whether multicellular animals could be patented was examined by the USPTO in 1980s. In 1987, *Ex Parte Allen* case, the key issue was the patentability of polyploid pacific coast oysters that had an extra set of chromosomes[14]. The applicant sought to patent a method of inducing polyploidy in oysters as well as the resulting oysters as products-by-process. However, USPTO rejected the patent application on the ground of obviousness. On 12 April 1988, USPTO issued the first patent on transgenic non-human animal 'Harvard Mouse' (US Pat No 4,736,866) developed by Philip Leder (Harvard University) and Timothy Stewart. The 'Harvard Mouse' was created through a genetic engineering technique of microinjection. To the fertilized egg, a gene known to cause breast cancer was injected and then this egg was surgically implanted into the mother so that she may bring it to the term. The resulting transgenic mice were extremely prone to breast cancer. After initial reluctance by the EPO, European patent was issued in 1992. By 2002, more than 300 patent applications for transgenic animals have been filed but so far few have been granted by EPO[5].

The new provisions of EPC in 1999, Rule 23c states that inventions concerning biological materials, such as DNA, microbiological process, plants, and animals are patentable only if 'the technical feasibility of the invention is not confined to a particular plant or animal variety'[15]. Further, the EPC has prohibited patents on plants and animals as per EPC Article 53 (b) mentioned in the category of plants and on *ordre public* or morality [Article 53 (a)]. EPC has stated that certain inventions are excluded from patentability whose exploitation is contrary to *ordre public* or morality, namely, processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; use 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 animals resulting from such processes[16].

In Japan, animals became patentable subject matter after 1988 when the 'Harvard Mouse' patent was issued by USPTO. By the end of 1998, nineteen animal patents were issued by JPO, majority of them were the products of genetic engineering[17].

Indian Patents Act, 1970, amendment 2002, has excluded from patentability under Section 3(j), plants and animals as a whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals and Section 3(i) 'any process for medical, surgical, curative, prophylactic (diagnostic, therapeutic), or other treatment of human beings, or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products'[3]. This is in pursuance to the TRIPS Agreement Article 27.3 (a) and (b). Further TRIPS Article 27.2 mentions that States may exclude from patentability inventions, whose commercial exploitation within their territory needs to be prevented to protect *ordre public* or morality including to protect human, animal or plant life or health or to avoid serious prejudice to the environment' provided that such exclusion is not made merely because the exploitation is prohibited by law[4]. Thus, human beings or their treatment procedures are neither patentable in India nor anywhere else. Modified animals are patentable in USA, Japan, Korea, Hungary, South Africa and few other countries. Like-wise patent offices of USA, Japan and Australia grant patents on human body parts such as limbs, organs and tissues. The making of human body parts is not viewed as invention since they exist in nature, but modified or isolated body parts are viewed as multicellular organisms and treated as such for patentability if they meet the statutory requirements[18].

Cloning

Cloning is the process of transferring nucleus of an adult multicellular organism's cell to an unfertilized egg of the same species while transgenic cloning is when a particular gene is added to the nucleus of an adult organism cell before its transfer to an unfertilized egg of the same species. Dolly, the first mammal sheep, was created in 1997 by cloning. Creation of animals by cloning is patentable in some countries. However, patenting of human cloning issue varies in different countries. Japan banned human cloning in 2001, but had permitted researchers to use human embryos that were not produced by cloning. Recently in July 2004, Japan Government Science Council has permitted limited cloning of human embryos for scientific research. Britain and South Korea also allow cloning of human embryos for therapeutic purposes. However, United States prohibits any kind of human embryo cloning but allows patenting of animal cloning.

In the controversial issue of cloning, no attempt has been made to implement strict legislation in US, but in Europe, a directive (98/44/EC) was adopted on the legal protection of biotechnology inventions in July 1998[19]. Another major difference is that US patents on the human embryonic stem cells have been granted while in Europe the ethics of stem cells patentability is still a controversial subject of debate. The ethical aspects of patenting involving human stem cells have been analysed by the European Group of Ethics (EGE), the main advisory body on biotech ethics of the European Commission. The EU Directive (98/44/EC) requires that its member states harmonize their laws relating to the patenting of biotechnological inventions. In the chapter on patentability of naturally occurring genes, the directive reaffirms that naturally occurring substances are considered to be patentable inventions provided they are isolated from their surroundings. In addition, 'a mere DNA sequence without indication of a function does not contain any technical information and is therefore not patentable… the 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, '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 though its structure is identical with that of a natural element.

The EPO has incorporated the provisions of the EU Directive into their Implementing Regulations in 1999[20]. By 30 July 2000, the member states were to alter their national law in line with the directive. However, only few have implemented the Directive in full. In UK, common rules are found in the Patent Act 1977, and the provisions of Directive, which address patentability were introduced into UK law in July 2000. The new 'Patent Regulations 2000' are in the Section 76 A.02 of the UK Patent Act[21]. It states that an invention shall not be unpatentable solely on the grounds that it concerns (i) a product consisting of or containing biological material; or (ii) process by which biological material is produced, processed or

used. However, it then sets out the following as not being patentable inventions:

(a) The human body, at the simple of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;
(b) Processes for cloning human beings;
(c) Processes for modifying the germ line genetic identity of human beings;
(d) Uses of human embryos for industrial or commercial purposes;
(e) 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;
(f) Any variety of animal or plant of any essentially biological process for the production of animals or plant, not being a micro-biological or other technical process or the product of such a process.

Biological Compounds

Biological compounds, such as DNA, RNA and proteins, are not themselves living, but naturally occurring. The ability to isolate genes and produce the proteins they encode has enormous commercial impact. The availability and scope of patent protection on genes and genome-related technologies is considered vital for the survival and success of the biotechnology industry. Under US patent law, DNA sequences are considered chemical compounds by USPTO and are patentable as compositions of matter[22]. In its 'Utility Examination Guidelines', the USPTO explained that isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is different from the naturally occurring compound as it is processed through purifying steps that separate the gene from other molecules naturally associated with it and hence eligible for patent protection. If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable since one of the requirements of a patent is utility[23].

However, EPO differs in this respect of utility or usefulness criteria, which stipulates that for patentability inventor has to show its industrial application for grant of a patent. As per EPC Implementing Regulations of EU directive (98/44/EC) in 1999,[20] the new provisions are summarized as follows:

The definition of biotechnological invention, according to Rule 23b, is invention that concerns 'a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used'. This includes DNA-related inventions, such as an isolated DNA fragment and the gene it encodes or DNA sequence analysis protocols and its software products. The definition of biological material is 'any material containing genetic information and capable of reproducing itself or being reproduced in a biological system'. For example, plasmid, which is simply a piece of DNA containing a group of genes which cannot reproduce by itself, but it can be reproduced in a biological system, such as bacteria. The biological materials, such as, DNA, protein, plasmids, are patentable if the materials are isolated from its natural environment or produced by means of a technical process. Rule 23e further pronounces that the simple discovery of one of the elements of the human body, including the sequence or partial sequence of a protein or a gene, cannot constitute patentable invention if industrial application, i.e., utility, of the claimed gene or protein sequences or a partial sequence is not disclosed in the patent application.

Thus USA and Europe grant patents on all plants of a particular species in to which a specific new gene is inserted by biotechnological means. In this way, a gene can be patented along with legal claims over the isolated gene and DNA sequences, the genetic engineering tools that use the sequences and over the plants derived from these tools. The USA and Europe have also granted patents on transgenic plants.

Indian Patent Act, 1970, Section 5 allows inventions on isolation for a substance like DNA. Gene sequences are patentable if function has been ascribed to that gene sequence[3].

The JPO also points out that since 'the aim of the patent law is to develop industries, only inventions that are useful or having industrial applicability are patentable'[24]. Quite frequently patentability of inventions of the expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs) whose specific functions are often unclear or unknown are often raised and hence further discussed.

ESTs

An EST is part of a sequence from a cDNA molecule of expressed gene, therefore, it can be used to identify and locate an expressed gene. The patenting of ESTs has proved to be controversial

since National Institute of Health, USA, first filed patent applications on a large number of ESTs in 1991 and 1992[25]. USPTO in 1995 issued two-prong test of Utility Examination Guidelines as the described utility is specific to a particular purpose and the described utility credible[26].

On 6 October 1998, the first 'EST patent', 'Human Kinase Homologs' (US Pat No 5,817,479), was issued to Incyte Pharmaceuticals Inc . By late 1998 patent claims for over 1.2 million DNA sequences were filed. By the end of 2000, the USPTO had received patent applications on millions of gene fragments; one application alone covering more than 20,000 [27].

The patentability of ESTs has been challenged on three points:

(i) ESTs are obvious and the creation of ESTs does not involve any inventive step,

(ii) ESTs lack both substantial and credible utility. The process from EST to full-length cDNA or genomic sequence is not straightforward, and

(iii) It is easy to give a list of potential uses without knowledge of their true biological functions[28]. In early 2001, the USPTO published its new 'Utility Examination Guidelines'[29] which re-affirmed that ESTs are patentable subject matter, if an EST meets the statutory requirement on utility, novelty, non-obviousness and enablement. Nevertheless, a mere assertion of the utility of an EST as a probe without further disclosure of its specific function is considered not enough by USPTO to satisfy the utility and enablement requirements. The patentability of ESTs and DNA fragments has been further studied by the Trilateral Patent Offices (USPTO, EPO, JPO)[30] which can be summarized as: Isolated and purified nucleic acid molecule-related inventions, including full-length cDNAs and SNPs, of which function or specific, substantial and credible utility is disclosed, which satisfy industrial applicability, enablement, definiteness and written description requirements would be patentable as long as there is no prior art (novelty and inventive step) or other reasons for rejection (such as, where appropriate, best mode [US] or ethical grounds [EPC/JP])[31].

The utility requirement in US is met when a DNA-related invention has well-established utility, i.e., specific, substantial and credible. For example, a claim to a DNA fragment whose use is disclosed simply as a 'gene probe' or 'chromosome marker' would not be considered specific in the absence of a disclosure of a specific DNA target. According to the EPO, utility is defined as industrial applicability, which includes any kind of industry, such as agriculture. In the case of DNA patents, EPO requires that the specific industrial application of a DNA sequence or a partial DNA sequence of a gene must be disclosed in the patent application[32]. In Japan, utility means industrial applicability as prescribed in the main paragraph of Article 29(1) of the Japanese Patent Law[33], which states, "any person who has made an invention which is industrially applicable may obtain a patent." DNA fragments, genes, and recombinant proteins are considered to be chemicals by the JPO. Examination practices regarding the requirement for industrial applicability of conventional type chemicals require that at least one use be described in the specifications as filed.

Bioinformatics and Patenting

Bioinformatics is a scientific discipline that encompasses all the aspects of biological information: acquisition, processing, storage, distribution, analysis and interpretation. For bioinformatics the patent offices have created separate units. EPO has a separate set of examiners from the computer science and biotechnology directorates. USPTO has an entire art unit (Group Art Unit1631) - equivalent to an EPO Directorate[34]. There are three basic types of inventions on bioinformatics, which can seek patent protection.

The Tools of Bioinformatics

Computer software is one of the central tools of bioinformatics and the way in which it is treated by the patent offices varies in different parts of the world. In the USA, as early as 1969, the transformation of a computer by a computer program (using electronic signals) was recognized as patentable subject *(in re Bernhart*[35]). USPTO in 1996 issued Examination Guidelines for Computer Related Applications[36]. Generally under these guidelines, if a claim contains a mathematical algorithm, but is limited to a practical application in the technological arts, it might be statutory and thus have patentable utility under §101.

In Europe, computer software until very recently has been considered unpatentable. EPC disqualifies computer programs from patentability as such under Article 52 (2). Also excluded are aesthetic creations, discoveries, scientific theories, mathematical methods and other activities that are essentially non-technical in character. Despite this, applicants have been able to obtain patents covering computer programs from the EPO by not claiming computer programs 'as such' which is in the exclusion list but claiming in a technical context. The computer programs are patentable as long as they are technical in nature[37].

The Methods of Bioinformatics

A second development in bioinformatics is the move towards the patenting of business methods. This is especially pertinent because classical biotechnology claims, e.g. methods for generating a tangible such as RNA, DNA or protein might not provide adequate protection for the true product of bioinformatics - information. In the USA, business methods are patentable subject matter. By contrast, the patenting of business methods is amongst the exclusions found in Article 52(2) EPC, in other words, they are unpatentable 'as such' under the EPC. A patentable business method (or computer program) at least as far as the EPO is concerned, must have technical elements - for example, it must be at least partly computer implemented[38]. A biological assay that involves bioinformatics need not be claimed as a conventional biological method but a biological assay that involves bioinformatics which can be claimed as a computer implemented procedure in the same style as a business method to claim the processing of data to produce a result and this type of claim might be desirable to cover the activities of customers of bioinformatics processes.

The Product of Bioinformatics

Bioinformatics produces information. In Europe, however, information as such is unpatentable under EPC Article 52 (2) because of its abstract nature. However, the EPO has allowed claims directed to data in two well-known decisions of the Technical Boards of Appeal T1494/97 and T163/85 (BBC), dating from 1990 due to the technical content. It was structured in such a way that it controlled the apparatus used to interpret the data[39]. In the USA, claims have been obtained to business methods and to methods in which the resulting product is information. Subtle differences in claim language can mean the difference between allowed subject matter and disallowed subject matter, and between claiming and not claiming the invention. For example, in the USA, a claim to a computer readable medium with sequence data on it is considered to be non-statutory descriptive matter, however, a claim to a software program on a disk might be statutory. The latter lies in the technological arts because software programs are technological; the former, however, merely relates to information on a medium. The applicant must therefore ensure that, if information is to be claimed, it is claimed such as to make it technological in nature. For example, nucleic acid and protein sequence data, which is a primary data that lack any annotation is non patentable. However, elements of information of this type can be combined with other sources of data to provide useful further information, which can be termed secondary information, about the function of a gene or a polypeptide. It is knowledge of function that allows us to do something useful. This information is not abstract but technical and genetic inventions that concern diagnosis of diseases, therapy, biotechnology, genetic engineering and many other established technical fields are based on an element of knowledge of gene function. Data can be technical if they provide functional information of any useful sort.

Under the Indian Patents Act, 1970, Section 3 (k) a mathematical or business method or a computer program *per se* or algorithms are not inventions and hence unpatentable.

Conclusion

In the present era, patenting of biological organisms, cloning, genomics, bioinformatics have become important aspect areas. Thus, effective management of proprietary DNA portfolio is vital to the success of biotech companies. DNA patent is no longer a mere property, but is now the core of modern biotech companies. Biotechnological inventions were earlier interpreted in different ways by different patent offices of the world but discussions and unification of ideas have emerged in some cases while differences on stem cell research, human cloning and some other aspects still persist. In the near future, these will also be solved and common grounds will be laid in the context of present TRIPS regulations.

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