1. The growing importance of biotechnology.

Biotechnology is, and will become even more in the future, important for many kinds of scientific research in the agricultural, food and medical sectors.

Life science and biotechnology are widely regarded as one of the most promising frontier technologies for the coming decades and the explosion in the knowledge on living systems is set to deliver a continuous stream of new applications.

Let us think about global health care: in this sector there is a huge
need for novel and innovative approaches to meet the needs of ageing populations and poor countries. Biotechnology research could be the right and most appropriate answer to the above needs.

Biotechnology is also a fast-growing sector of science and industry. If we take a look at the figures for industrial products, we can see that in recent years the world-wide biotechnology-based products market has grown at an annual average rate of 15% to reach a value of about € 30 bn. Biopharmaceuticals dominate this market (with € 20 bn), with agriculture-related products making-up the balance. Biopharmaceuticals account for less than 5% of the total pharmaceutical market, but are growing at 2.5 times its overall growth rate (1).

There is little doubt that biotechnology presents a significant potential for growth and creation of wealth. For example, eventually, a substantial part of Europe’s gross domestic product could be generated by and spent on biotechnology products.

2. The need to protect R&D investments in the biotechnology sector: the patent system.

Biotechnology is one of the most R&D-intensive areas, in particular in the biopharmaceutical sector.

This high level of research and development (R&D) brings with it that huge amounts of financial and human resources are invested in the development of new products and processes, for which the investors wish to obtain some return.
The rate of investments required urges for a system where the providers of the financial resources have a means to recoup their investments. How can the investors in the biotech sector recover R&D investments?

Biotech investors – as well as other kinds of investors – can recover their R&D investments through the patent system. Indeed, the patent system has been chosen by almost all States as the most important means to recover the investments in the biotech sector too. Many States have been prompted to take such step as a consequence of their implementing the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement) of the World Trade Organization (WTO). As is known, the TRIPS Agreement was signed by all WTO member countries in 1994 and covers all types of intellectual property including patents, copyright and trademarks. It requires intellectual property rights to be protected in all WTO member countries.

Indeed, art. 27 of the TRIPs Agreement states that “patents shall be available for any inventions, whether products or processes, in all fields of technology” (ii).

The patent system is capable of providing at least a forecast of return of investment to investors/inventors. Indeed, by granting a patent, patent offices grant inventors monopoly rights over the invented products or processes. That means that only the inventor-patentee has the right to produce and sell the patented product and thus commercially exploit the protected invention. No other person can carry out said activity (iii). By acquiring monopoly rights, inventors-patentees gain an advantage over competitors and are able to recover the investments made to realise the
inventions.

Thus the patent system stimulates innovation and R&D in the biotech sector (as well as in other fields of technology) by providing a return on investment possibilities for those who take the risk of investing in new products and processes.

3. The impact of the biotech sector on patentable subject matter.

What is the subject matter of a patent? In other terms, what can be patented?

According to art. 27 of the TRIPs Agreement (and to most national patent laws), only “inventions” can be patented. That means that “discoveries” – which are different from inventions - cannot be patented.

Under traditional patent law the difference between “discoveries” and “inventions” is very important. Usually, inventions are defined as “an original solution of a technical problem” (iv) (an invention can be a product, but also a process of making a product).

For example, the European Patent Office (EPO) (v) has traditionally held that an invention must be “technical” in order to be called a patentable invention, technical meaning as having technical character, or providing a technical contribution (vi). In other terms, an invention is something which is “created” by the inventor.

On the contrary, making a discovery is revealing something which already exists in nature, but which has not yet been discovered. A mere discovery – which cannot be patented – is distinct from an invention

4
because no inventive activity is required to produce it. A discovery is, in other words, the mere knowledge about something existing in nature, whereas an invention implies the ability of a human being to use this knowledge in a technical way. Thus, Einstein could never have patented the famous law $E=mc^2$, nor could Newton have patented the law of gravitation. As confirmed by the US Supreme Court in the famous leading case Diamond / Chakrabarty “such discoveries are ‘manifestations of ... nature, free to all men and reserved exclusively to none’” (vii).

Having said that, we must wonder whether biotechnological products and processes – such as the ones related to DNA sequences or single genes - are inventions or discoveries. The answer to such question is critical, because – depending on which answer is given – it follows whether a product or a process can be considered patentable or not patentable.

On the one hand, there are several legislators, scholars and professionals, who think that – for example – someone who identifies a particular DNA sequence or a single gene does not make an invention, but only a discovery. Indeed, a DNA sequence or a gene pre-exists in nature, so that the researcher who identifies them merely discovers something that was already existent. It follows that – according to this opinion – the mere act of individuating a DNA sequence or a particular gene (which is typical in the biotech sector) cannot be considered an invention, but it is just an unpatentable discovery.

On the other hand, others think that – in certain cases - a DNA sequence or a single gene can be deemed as an invention and thus could be patented. For example, according to art. 3.2 of the Directive 98/44/EC on
biotechnological inventions (viii), “biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature” (emphasis added).

Those who share this opinion put forward the following two examples, in order to show the difference between discoveries and inventions and to confirm that – in certain cases – biotechnological products and processes should be considered inventions (ix).

The first example is the following.

Suppose someone walking in the woods finds a fungus. It looks very appealing, and that person – who has a terrible headache – eats the fungus, and his headache disappears instantaneously. That person has made a discovery, i.e. has discovered that the fungus is useful as a cure against headache, he has acquired knowledge about that fungus, without being capable of using this knowledge in a technical way.

A different situation would be the following.

The same hypothetical person walks in the woods, and sees the appealing fungus. He takes the fungus to his private laboratory, analyses it, and is able to extract, isolate and purify by a technical process a substance which happens to be useful as a cure against headache. In this case an invention has been made. More has been done than merely discovering the fungus: a substance has been extracted, isolated and purified, and it has been made possible to reproduce that invention. In other terms, such an invention – which combines a natural element with a technical process enabling it to be isolated or produced – can be subject of a patent application (x).
The problem described by the above examples is sometimes called the “product of nature” doctrine. According to such doctrine, products of nature as such are not patentable, but products derived from nature are. Such doctrine has been recognized in case law for many years (xi). The “product of nature” doctrine, for example, prevents geologists from patenting a mineral discovered in the earth and biologists from patenting a plant found in the wild.

The same arguments are valid with reference to the patentability of DNA sequences. According to art. 5 of the EC Directive, if someone discovers the existence in the human body of a specific DNA sequence without more, that is a simple discovery (xii). The scenario would be different if a researcher manages to isolate a DNA sequence from its natural environment and separates the exons (i.e. the parts of the sequence which do not code for a protein) from the introns (i.e. the parts of the sequence which code for a protein). In such a case, the researcher would achieve an invention, as he manages to isolate via a reproducible technical process the DNA sequence from the human body, as well as makes a selection in the sequence (i.e. selecting those parts of the sequence which are of interest). Accordingly, the DNA sequence which the researcher isolates would not be a mere discovery, but an invention, which provides teaching for methodical action; thus, the isolated sequence would not be a product of nature, but a product derived from nature (see again art. 5.2 of the EC Directive) (xiii).

We have seen that there are two opposite opinions on whether to consider biotech products and processes discoveries or inventions.
Many patent offices – especially in industrialized countries (including the European and the US patent offices) – considered and consider most biotech products and processes as patentable inventions.


Art 27.3(b) of the TRIPs Agreement states that “Members may also exclude from patentability: […] (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes […]” (emphasis added). This article has been defined as the “biotechnology clause” (xiv).

On the one hand, this article states that certain products or processes related to living matter may be excluded from patentability (e.g. plants and animals as such and essentially biological processes for the production of plants or animals); on the other hand, however, the said article provides that micro-organisms and microbiological processes must be patentable and does not exclude from patentability other kinds of biotech inventions (such as genes and gene sequences)(xiv).

Therefore, we have seen that micro-organisms and microbiological processes must be patentable in all WTO Member States.

However, the TRIPs Agreement does not provide any definition of micro-organism or microbiological process, which leaves room to different
interpretations, as has been noted in the context of WTO/TRIPs discussions. Indeed, in the medical literature there is still no unanimously accepted definition of micro-organism, neither a certain boundary between microbiology and biology. For example micro-organisms have been defined as unicellular structures with very reduced dimensions and not visible to the naked eye (which is a very broad definition). Another broad definition of micro-organism has been provided by the decision of the Technical Board of Appeal of the EPO in the Plant Genetic Systems case: “the term ‘microorganism’ includes not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory. Plasmids and viruses are also considered to fall under this definition”(xvi).

The extension of the concept of micro-organism to animal cells and plants has been strongly criticized, especially in developing countries.

On the contrary, many authors in industrialized countries stress the opportunity of maintaining the wording of art. 27.2(b) of the TRIPs Agreement as such (i.e. without a precise definition), as microbiology is a fast-moving field of science and accordingly to provide a fixed and immutable definition of micro-organism and microbiological process would reduce discretional powers of States at the implementation stage (xvii).

Moreover art. 27.3(b) of the TRIPs Agreement provides that States can exclude from patentability “essentially biological processes for the
production of plants or animals” (xviii): it follows that those processes which are not “essentially biological” must be considered as patentable.

Obviously, the correct meaning of the said article depends on the interpretation of the words “essentially biological”.

An interpretation is given by the EC Directive, whose art. 2.2 states that “a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection” (emphasis added). It follows that – according to the EC Directive – genetic engineering processes and most modern biotech processes (which obviously do not consist entirely of natural phenomena) must be considered as patentable. Also the EPO shares the above opinion. For example, in the Plant Genetic Systems case the Technical Board of Appeal provided a definition of what does not constitute an essentially biological process: “a process for the production of plants comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result” (xxx). Therefore, according to the EC Directive and the EPO case law, in order to consider the said inventions as patentable, it would be sufficient that only one segment of the production process is not biological (xxx).

However, the above view has been criticized by some commentators, who think that the said TRIPS provision should be interpreted in the opposite way. For example, some authors believe that States should be free to consider as “essentially biological processes” (and, as such, not
(patentable) whatsoever process which includes at least a biological phase (e.g. the reproduction of plants) (xxi).

4. The impact of the biotech sector on patentability requirements (xxii).

According to art. 27 of the TRIPs Agreement (and most national patent laws) an invention can be patented if the same is (i) new, (ii) involves an inventive step and (iii) is capable of industrial application (xxiii). Thus, (i) novelty, (ii) inventive step (originality) and (iii) industrial application are the patentability requirements.

The application of traditional patent rules on patentability requirements to biotechnological inventions raises other important issues.

The subject matter in question – i.e. genetic and biological resources and products derived from those resources – has unique features, which makes it difficult to use the usual patterns of interpretation.

(i) Novelty

First of all, we must wonder whether biotechnological products or processes are “new” according to traditional patent rules.

Let us consider the following example.

Quite often biotechnologists wish to patent the gene or DNA sequence they have managed to identify, isolate it from an organism and insert into another life form.

Is that gene or sequence “new” according to traditional patent rules?

According to some, the answer is no: they believe that the above gene or DNA sequence merely consist of a biological material which pre-
exists in nature and accordingly cannot be considered novel according to patent law.

Conversely, others think that the above gene or DNA sequence – even if pre-existent in nature - can be deemed “novel” (in a certain way) and thus patentable, because the substance in question was not readily available to the public (xxxiv). For example, in the Relaxin case the Opposition Division of the EPO stated that “[…] if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if this substance can be properly characterized by its structure and it is new in the absolute sense of having no previously recognized existence, then the substance per se may be patentable […]” (emphasis added) (xxv).

In other terms, a substance - which already existed in nature, but whose existence and function are unknown and thus not available to the public (such as a DNA sequence never identified before and/or whose function was not previously known (xxvi)) – can be considered in a certain way “novel”, as if it was a book left in an old library and never opened by anybody. In the context of DNA sequences, it has been held in EPO case law that the mere fact that a DNA sequence claimed was already existing in a DNA library is not novelty destructive vis-à-vis the sequence claimed, as the sequence – which is present in the DNA library – is not readily available to the public. In particular, in the Alpha Interferons/Biogen case the EPO stated that “DNA sequences according to claim 1(b) had not been made available to the public by this publication itself or through this publication from the [Lawn gene] bank. […] The mere existence of a DNA sequence
coding for a polypeptide of the IFN-α type, within multitude of clones of [the] gene bank cannot automatically mean that the chemical compound (polynucleotide) concerned does become part of the state of the art. The latter would only then be the case if the existence of the compound concerned had recognisably been made publicly available” (xxvii).

This latter view is shared by many legislators and patent offices, especially in industrialized countries (e.g. European countries, the US patent office and the EPO) (xxviii).

(ii) Inventive step (originality)

Moreover, we must verify whether biotechnological products or processes involve an inventive step.

Let us once more consider the above example of identifying and isolating biological material and inserting the same into another organism.

Is the said activity “original” according to traditional patent rules?

According to some, said activity quite often cannot be considered as “original” and involving a real inventive step. In particular, it has been said that the results obtained in those cases are easily achievable by whatsoever equipe of biotechnologists, provided that the same is well-equipped and adequately financed (xxxix). For example, in view of the modern automated techniques, where computers do the whole sequencing process, it could be rather difficult to prove that the mere preparation of the DNA sequence is sufficient to make the invention original (xxx). According to this opinion, should such activities obtain patent protection, the originality requirement would inevitably be watered down, since companies seek and obtain thousands of DNA sequences of unknown functions that they have been
able to isolate quickly through routine and automated methods.

Conversely, others reckon that the activities at issue – regardless of the degree of their originality - must be considered patentable anyway. In other terms, they think that what patent law should encourage and reward is the considerable economic investments which can lead to valuable technological results, rather than the “flash of genius” (xxxii) of a single inventor. Who shares the above opinion stresses the fact that nowadays scientific progress (which is stimulated by the patent system) is more and more dependant on collective and equip-based works rather than on the contribution of a single “Archimedes”. The above position seems to be indirectly confirmed by Recital n. 2 of the EC Directive, which provides that “in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable” (xxxii).

Needless to say, many patent offices – especially in the industrialized countries – usually consider biotech inventions as original and thus as deserving patent protection.

(iii) Industrial application

Finally, we must wonder whether biotechnological products or processes are capable of industrial application.

As a general remark, an invention is susceptible of industrial application when, *inter alia*, the process of manufacturing the relevant product can be constantly and continuously repeated.

It must be borne in mind that - in general - biotechnological products do not need to be “manufactured” in order to be distributed to, and used by,
Let us take the example of bio-engineered seeds.

These kind of seeds are firstly “manufactured” through a DNA recombinant technique, *i.e.* by identifying and extracting a particular gene from a substance and inserting the same into the new seed. However, the above seed is living matter and thus is capable of self-replicating. Thus, once the seed is firstly “manufactured” in a laboratory, further copies thereof can be easily obtained by third parties without repeating the production process. In order to obtain further copies of the seed, it is enough that a person purchases a bio-engineered seed, plants it on his garden and let it reproduce. In other words, it is not necessary to repeat the DNA recombinant technique in order to obtain other samples of the seed: it is enough to plant it and let it reproduce. So, it is the nature, and not the human being, that “makes” the subsequent generations of the seed (xxxiii).

Having said that, we can understand why someone doubts about whether certain biotechnological inventions really meet the industrial application requirement.

5. *Biotechnological inventions have unique features.*

From the above we can infer that biotechnological inventions have unique features, which makes it difficult to use the usual patterns of (juridical and factual) interpretation. Indeed, we have seen that – in order to deem biotech products or processes as patentable inventions – traditional patent rules regarding patentable subject matter and patentability
requirements must be interpreted and applied in a different way.

Some say that – when dealing with biotechnology – traditional patent rules are interpreted and applied in a more indulgent way than in other industrial fields; in other terms – some say - patenting biotech products and processes is “easier” than patenting inventions related to not-living matter.

Why do biotech inventions have a different sui generis status?

This is due – in particular – to two circumstances.

Firstly, biotech products and processes – as opposed to other kinds of invention - relate to living matter. That makes it compulsory to interpret patent rules in a different way.

Secondly, biotechnology – as we have seen earlier - is one of the most R&D-intensive areas, especially in the biopharmaceutical sector. This high level of R&D brings with it that - for the development of new products and processes – it is necessary to invest huge amounts of financial and human resources, such amounts being more than the amounts needed in other industrial sectors. Accordingly, since the investments required in the biotech sector are higher than in other industrial fields, it follows that – when dealing with patentability of biotechnology – patent offices need to apply and interpret patent rules in a different (and more indulgent) way.

6. **The impact of biotechnology on the scope of patent protection.**

The insertion of living matter in the patentable subject matter (also) entails the reassessment of another traditional patent rule, *i.e.* the scope of
patentee’s rights.

We have seen earlier that – with reference to patentable subject matter and patentability requirements – traditional patent rules must be interpreted in a different and more indulgent way: this entails that the patentability threshold for biotech products and processes is lower than in other fields of technology. Conversely, as we shall see, patented biotech products and processes confer to their patentees a wider scope of exclusive rights. However, the said lowering and widening have the same purpose, i.e. to give biotech investors and inventors a more favourable legal treatment.

We have seen that – according to art. 28 of the TRIPs Agreement - the patentee can prevent third parties from using the patented product or process (xxxiv).

Again, the fact that here the patentable subject matter is related to genetic resources poses questions that are not easy to answer: indeed, in this case the patented product is biological material, which – as such – self-replicates, potentially endlessly (let us think, again, about bio-engineered seeds).

Having said that, is the right of the patentee (to prevent whatsoever use) limited to the first generation of the “product” (e.g. a seed), or should such right be “extended” also to its “sons” and in general to the material which is derived from the original product? Obviously, we would not pose this question in the case of patents related to non-living matter, as in such cases the protected products do not self-replicate.

In this regard, the TRIPs Agreement does not state any provision.
The EC Directive gives an answer to the above question. Indeed, with reference to patented products (being it a biological material or genetic information), the EC Directive states that “the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall 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” (art. 8) (emphasis added) (xxxv). Moreover, with reference to genetic information, art. 9 provides that “the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, [...], in which the product is incorporated and in which the genetic information is contained and performs its function”. Art. 9 of the EC Directive further widens the scope of patent protection: such protection, indeed, covers whatsoever material consisting of, or containing, the genetic information related to the patented product, regardless of the fact that such material directly derives from the said product.

Such extension of protection (xxxvi) is justified in light of the following reason.

Should the said “extended” protection not be granted, the value of a biotechnological patent would be strongly reduced. Taking, as example, the above mentioned bio-engineered seeds, should a third party (that has acquired a patented seed and planted it) be authorised to freely use the subsequent generations of such seed (e.g. by selling the same), the monopolistic position of the patentee would be seriously jeopardised. Indeed – when dealing with living material, which self-replicates – the
possibilities of patent infringement are multiplied with respect to other fields of technology (xxxvii). In particular, the third party who purchased from the patentee the bio-engineered seed and planted it could easily re-sell the subsequent generation of seeds and become a dangerous competitor of the patentee. In such a manner, the patent owner would find itself in competition with a multitude of sellers of its own product, all operating at competitive price: this is known in economics as the problem of the “durable goods monopolist”. The durable goods monopolist is faced with the problem that sales of its own product invite competitors into its market because the good’s durability allows its purchasers to become re-sellers (xxxviii).

In order to overcome the above difficulties, therefore, it would be necessary for the protection to extend – not only to the first product (e.g. the first seed) – but also to the subsequent products which derive from the former (subsequent seeds or plants) (xxxix).

On the contrary, with particular reference to bio-engineered plants, others (xl) think that permitting the above extension of protection (i.e. allowing the holder of a patent related to a gene to prohibit the use of subsequent plants in which the said gene is incorporated) would circumvent the ban of patentability of plants (envisaged by art. 27.3(b) of the TRIPs Agreement and art. 4.1(a) of the EC Directive (xli)) (xlii). Those who share this opinion stress the fact that the said biological material (e.g. plants) – whose commercial use can be prohibited by the patentee – self-replicates and further propagates without a human intervention (and in particular without the relevant intervention of the patentee): accordingly, it would be
unreasonable to allow the patentee to prohibit the use of biological material which has grown and developed without its relevant intervention.

Moreover, the insertion of biotech inventions in the patentable subject matter could (and should) lead the juridical operators to re-adapt and tailor one of the most important principle of intellectual property law: *i.e.* the principle according to which the ascertainment of the infringement is not dependant on the *mens rea* of the infringer (*xliii*).

In particular, how should juridical operators behave if a plant is causally contaminated by genetically modified (and patented) biological material, this contamination being caused by nature and not by human intervention (let us think of cross impollination, which is often favoured by the wind). Is this a case of patent infringement? Should the owner of the contaminated area be considered an infringer?

The answer given by the Canadian Supreme Court in *Monsanto Canada Inc. v. Schmeiser* (*xliv*) is clear: “The general rule is that the defendant’s intention is irrelevant to a finding of infringement. The issue is what the defendant does, not […] what he intends” (point 49). Actually the Canadian Supreme Court position – which ascertained that the farmer Schmeiser (whose farm had been contaminated by Monsanto’s patented product) infringed Monsanto’s patent (related to a genetically modified rape plant) – is much less censurable than it could firstly appear.

To be considered “innocent bystander” (*i.e.* who undergoes the causal contamination of his crops by third parties’ genetically modified plants) it would suffice to prove to have taken steps for the removal of the contaminated plants (which did not occur in the case at issue: on the
contrary, Schmeiser – once aware of the contamination – consciously isolated, saved, treated and replanted the seeds of the contaminated plants).

7. **The conformity of biotech inventions with ordre public and morality.**

According to art. 27.2 of the TRIPs Agreement States may exclude from patentability the inventions which are against *ordre public* or morality. Similarly, art. 6.1 of the EC Directive and art. 53(a) of EPC state that the said inventions are excluded from patentability: this is another patentability requirement in addition to the three requirements analysed above (xlv). All said texts adopted the French term “*ordre public*” instead of the English words “*public order*”. Indeed, the reference to public order would be inappropriate as a translation of the French concept of “*ordre public*”. While “*public order*” may be defined as the maintenance of public safety, “*ordre public*” concerns the fundaments from which one cannot derogate without endangering the institutions of a given society (xlvi).

Having said that, many commentators wonder “where” such requirement should be scrutinised.

Should *ordre public* and morality be dealt with at the patent offices (and in particular during the registration procedures which take place before the said offices)?

Alternatively, should these issues be dealt with exclusively by legislators and regulatory bodies when assessing the relevant risks and deciding whether the manufacture and sale of the products are against the above public interests?
(i) There are many commentators who think that patent registration procedures and in general patent law should take into consideration the environmental, ethical and health-related concerns related to biotech inventions. In particular, they think that patent offices should verify whether the working of a biotech patent violates *ordre public* or morality (xlvii) and accordingly jeopardize public interests.

In other words, according to this view patent registration procedures of biotech inventions should be considered as a “*social and moral filter*” and the patent system should be a “*servant of public policy*” (xlviii): patent offices, therefore, should carefully examine the social, environmental and ethical concerns stemming from the production and sale of biotech products (object of a patent application) and – on the basis of such analysis – grant or reject the patent application.

In this regard it has been said that patent offices would be bound by the principles of international public order, *i.e.* those rules which - enshrining the core juridical values of the international community (*e.g.* the right to a good environment, to health, etc.) – bind all the States and international organizations (xl ix).

With reference to the European experience, a confirmation of such opinion can be found in those rules of the EC Directive which seem to subject the grant of a biotech patent to the conformity of the invention with public interest values (see Recital 38 and art. 6.2).

(ii) On the contrary, another school of thought believes that the patent registration procedure cannot represent the appropriate place wherein to assess the environmental, ethical and social issues mentioned by art. 27.2
Indeed, as is confirmed by art. 28.1 of the TRIPs Agreement, the patentee has not the “positive” right to work and commercially exploit the invention, but a simple *ius excludendi alios* (right of exclusivity), *i.e.* the right to prevent others from using the invention (the grant of a patent, therefore, does not amount to a license to practice the invention). Indeed the right to use the invention – regardless of the grant or refusal of a patent – could be forbidden or limited by national or international legislations on the sale and diffusion of the relevant products (*e.g.* with reference to the biotech field, the Cartagena Protocol on Biosafety of 2000). This is the so-called “neutrality principle” of the patent system (*¹*), according to which such system must be deemed impermeable to facts and acts related to the working and use of the invention. It has been said that what is relevant is the use (lawful or not) that people make of a certain invention, and not whether the said invention is patented or not. The following example is provided: the inventor of a new kind of rifle - although entitled to the patent - nonetheless would not have the right to shoot innocent people (*²*). Also the inventor of a new and original photocopying machine (which – due to its high technical performances - would be able to print high-quality counterfeit banknotes) would be entitled to the patent, but he would not have the right to produce and circulate counterfeit banknotes (*³*).

Moreover, it has been said that patent offices are not adequately equipped and do not have the necessary expertise to deal with the delicate issues related to the risks of the biotech industry.
Those who share this opinion further stress that a biotech invention – even in the absence of patent protection - could be exploited as confidential and secret information: following such a way, therefore, could provide incentives to keep the results of biotechnological research secret and confidential. In this way, however, the risks related to biotechnology would increase, since the public and social control of biotech products and processes would be reduced (on the contrary, such control is guaranteed by the patent system, as this system obliges the patent applicant to immediately disclose and describe the invention (iii)).

(iii) I think that the second opinion is preferable (lv).

First of all, many national and regional legislations expressly provide the exclusion of patentability on ordre public and morality grounds (see again art. 53(a) EPC (lv) and art. 6 EC Directive (lvii)). This confirms that the conformity of inventions with ordre public and morality is a patentability requirement, in addition to novelty, originality and industrial application. Therefore, since patentability requirements are assessed by patent offices, it is evident that the said offices have also the right/duty to examine the above issues, i.e. the social, environmental and health concerns related to the commercial exploitation of the invention (lvii).

Moreover, in order to overcome the above mentioned objection (according to which patent offices would not have the necessary expertise to face the said issues) official examiners could be partnered with groups of technical experts: for example if the invention implies risks for human food security, we could partner patent offices with doctors or university professors having an expertise in such a subject. This already happens in
other fields: for example when examining inventions related to *business methods*, the US patent office often relies on the technical assistance of business experts (lvi).

Secondly, from the EPO case law it results that such office verified whether biotech inventions were contrary to *ordre public* and morality, taking into account issues related to the production, sale and exploitation of the relevant products. The EPO faced the above issues in – among others – the (i) *Onco Mouse Harvard* (II e III) (lix), (ii) *Plant Genetic Systems* (lx), (iii) *Novartis* (lx) and *Relaxin* (lxii) cases.

In particular, in the first case, the EPO (in the second and third decision) (lxiii) carried out a costs/benefits analysis, examining, on the one hand, the advantages for the treatment of cancer and, on the other side, the environmental risks which could stem from the use of the said invention (lxiv): the EPO concluded that the benefits overwhelmed the costs (lxv).

In the *Plant Genetic Systems* case, the EPC excluded that the inventions were contrary to *ordre public* or morality, since the opponent had not provided sufficient scientific evidences with reference to the feared environmental and social risks (lxvi); in the EPO’s view, therefore, it was not necessary to carry out a comparison between the costs (deemed not sufficiently proved) and the benefits (lxvii).

In particular, the EPO decisions in the *Plant Genetic Systems* and *Novartis* cases have been strongly criticised (lxviii). Indeed, in the first case the EPO found that the opponents did not provide certain scientific evidence with reference to the environmental and social damage and in the second case the said office stated that “*there is no consensus in the Contracting*
States condemning genetic engineering in the development of plants under the above criteria” (lxix). However, such decisions were rendered in a research field (i.e. biotechnology), which entails risks per se unforeseeable and, at the current stage of research, not easily demonstrable (lxx): which should make the burden of the proof really hard for the opponents (so-called “probatio diabolica”). We should also remember that, in technological fields such as biotechnology, the scientific uncertainty over possible risks is the rule, as the contrary opinion of a few researchers might suffice to damage the reliability of a thesis deemed by many others as trustworthy (lxxi).

The above issue vaguely recalls the scientific and judicial debate that – with reference to the international trade of agricultural products – has arisen with regards to the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS).

In particular, although this agreement guarantees the right of WTO Members to determine their own acceptable risk level and take those measures deemed more appropriate to protect the life and the health of the people, animals and vegetals (including the ban on the import of dangerous products) – on the other hand the above agreement subjects the said right to some relevant conditions: e.g. the condition that the national measures which ban the sale of a certain agricultural product must be scientifically grounded and not maintained in the absence of sufficient evidence of the related risks (art. 2.2 of the SPS).

The arguments adduced by the WTO dispute resolution bodies in the Hormones, Salmon and Varietals cases (in which such issues have been
debated (lxxii)), as well as in the decision on the European GMO-moratory (lxxiii), are not so different from the arguments adduced by the EPO in the above mentioned Plant Genetic Systems case: indeed, all these controversies ended with the condemnation of the restrictive measures adopted by the States because the said measures did not meet the risk assessment requirements (lxxiv).

Therefore, although rendered in a different legislative context and by different judicial bodies, the above WTO decisions bear some analogies with the Plant Genetic Systems case, thus showing that the EPO and the WTO dispute settlement bodies share analogous exegetical and decisional criteria.

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(ii) Precisely the patentability of biotech inventions – or better, of some biotech inventions – is provided forth by another article of the TRIPs Agreement, i.e. art. 27.3(b) (see infra par. 3.1 of this article).

(iii) According to art. 28 of the TRIPs Agreement, “a patent shall confer on its owner the following exclusive rights:
(a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
(b) where the subject matter of a patent is a process, to prevent third parties not having the
owner’s consent from the act of using the process, and from the acts of: using, offering for
sale, selling, or importing for these purposes at least the product obtained directly by that
process”.


(V) The EPO provides a uniform application procedure for individual inventors and
companies seeking patent protection in up to 37 European countries. It is the executive
arm of the European Patent Organization. The latter is an intergovernmental organisation
that was set up on October 7, 1977 on the basis of the European Patent Convention (EPC)
signed in Munich in 1973: it has two bodies, the above mentioned EPO and the
Administrative Council, which supervises EPO’s activities.

(vi) See the EPO case T 1173/97 *Computer program product/IBM*, decision of
Technical Board of Appeal of July 1, 1998, OJ EPO, 199, 609.

(vii) The *Diamond / Chakrabarty* case was decided by the US Supreme Court on

(viii) The directive was adopted on July 6, 1998 (hereinafter “EC Directive”). The
Kingdom of the Netherlands brought case C-377/98 before the European Court of Justice
against the adoption of the directive with six different pleas (and requested the annulment
of the directive). Eventually, on October 9, 2001, the European Court of Justice dismissed
the application brought by the Netherlands and confirmed the validity of the directive.

(ix) These examples are provided by the European Commission report, above fn.

(x) The EPO Guidelines state that “if a new property of a known material or
article is found out, that is mere discovery and unpatentable because discovery as such has
no technical effect and is therefore not an invention within the meaning of art. 52.1. If,
however, that property is put to practical use, then this constitutes an invention which may
be patentable. For example, the discovery that a particular known material is able to
withstand mechanical shock would not be patentable, but a railway sleeper made from that
material could well be patentable. To find a previously unrecognised substance occurring
in nature is also mere discovery and therefore unpatentable. However, if a substance found
in nature can be shown to produce a technical effect, it may be patentable. An example of
such a case is that of a substance occurring in nature which is found to have an antibiotic
effect. In addition, if a microorganism is discovered to exist in nature and to produce an
antibiotic, the micro-organism itself may also be patentable as one aspect of the invention.
Similarly, a gene which is discovered to exist in nature may be patentable if a technical
effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy” (EPO
Guidelines, C IV 2.3).

(xi) For example, in the landmark German case *Cyclisches Dekapeptid Antamanid*
(decided by the German Federal Patent Court in 1977) it was held that “discovery is the
finding of something existing but heretofore unknown; it is therefore purely perception. A
discover turns into an inventor, however, if he provides – based on his perception –
instructions for purposeful industrial action” (Cyclisches Dekapeptid Antamanid, BpatG., 16 W(pat) 64/75, 28 July 1977, GRUR, 1978, 238; IIC, 1979, 494) (at III.1 of the reasons).

Moreover in the UK (in the American Cyanamid Patent case) the House of Lords – which dealt with a method for the production of the antibiotic porfyromicin – stated that “the priceless strain, being something living, found in nature, cannot be patented: the prosaic process, as applied to the strain, is capable of protection” (American Cyanamid Patent, House of Lords, RPC [1971] 448 (425).

(xii) See Recital 16 and art. 5.1 of the EC Directive.

(xiii) Furthermore in case C-377/98 the European Court of Justice confirmed the above view, stressing that “only inventions, which combine a natural element with a technical process enabling it to be isolated or produced for an industrial application, can be the subject of an application for a patent” (point 72 of the European Court of Justice decision). See also the European Commission report, above fn. 1, pp. 40-41.


(xv) The drafting of this clause – which is no doubt open to divergent interpretations (see S. D. MURPHY, Biotechnology and International Law, 42 Harvard International Law Journal, 2001, pp. 67-68) – reflected, on the one hand, the strong interests of some developed countries in ensuring protection of biotechnological inventions and, on the other hand, the concerns of many developing countries about patentability of life forms.

(xvi) See point 34 of the decision.


(xviii) Art. 53(b) of the EPC provides an analogous rule.

(xix) See point 28 of the decision.

(xx) See also R. PAVONI, Biodiversità e biotecnologie nel diritto internazionale e comunitario, Giuffrè, Milano, 2004, p. 111 (fn. 126).


(xxii) In this paragraph, as well as in parr. 6 and 7 of this article, I further develop the issues which I faced in my previous article La protezione giuridica delle invenzioni biotecnologiche tra TRIPs, Convenzione sulla Biodiversità e UPOV, Rassegna di Diritto Pubblico Europeo – Europa e biotecnologie, luglio-dicembre 2004.

(xxiii) Art. 27 of the TRIPs Agreement states that “patents shall be available for any inventions […] provided that they are new, involve an inventive step and are capable of industrial application”. Moreover art. 52.1 of the EPC states that “European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application”. Another patentability requirement is the description of the invention (see art. 29 of the TRIPs Agreement).
In EPO case law it has been stated that a substance can be deemed novel if the already naturally occurring identical substance was not readily available to the public. See the case T-0206/83 Pyridine herbicides/ICI, OJ EPO, 1987, 5, where the EPO stated that “a compound defined by its chemical structure can only be regarded as being disclosed in a particular document if it has been made available to the public in the sense of art. 54.2 EPC […]”. See also BENT (quoted by C. CORREA, Intellectual Property Rights, the WTO and Developing Countries. The TRIPS Agreement and Policy Options, ZED-TWN, London, 2000, p. 177): according to the said author the concept of “novelty” is not equivalent to “not pre-existent”, “so that the unknown but natural existence of a product cannot preclude the product from the category of statutory subject matter”. The same position is shared by Japan in the context of WTO/TRIPs discussions (see the WTO document IP/C/W/236).

See point 5.1 (on the Relaxin case see also par. 7 of this article). See also the 1990 EPO decision in the Biogen case (case T-301/87).

To the extent that DNA sequences which have not been prepared before are claimed, the invention would fulfil the novelty requirement. In these cases, what is claimed is not the DNA sequence as it occurs in nature. What is claimed are those parts of the DNA sequence or gene (whose existence was not known before) which code for a protein (i.e. the exons): in other terms, what is really claimed is not identical to what is already existing, and as such it should be considered new. See the report released by the European Commission, above fn. 1, p. 44.

See EPO case T-0301/87 Alpha Interferons/Biogen, OJ EPO, 1990, p. 335 (point 5.8 of the reasons).

The EPO also found that certain biotech products or processes could not be considered novel. For example, in a decision of May 3, 2007 the EPO Board of Appeal revoked a patent held by Monsanto on a technique for the genetic modification of soybean plants because of lack of novelty.


See the European Commission report, above fn. 1, pp. 49-50.

This term is used by A. VANZETTI, (Introduction) I nuovi brevetti – Biotecnologie e invenzioni chimiche, Giuffrè, Milano, 1995, p. VII.

The requirement of “economic investment”, therefore, appears to replace the “originality” of the invention.

This is also the case for another intellectual property right, i.e. the sui generis form of protection for the producers of databases: indeed the Directive 96/9/EC offers an extensive right that attaches to a database on the basis of the level of investment by the compiler, measured by whether there has been a “substantial investment” in “qualitative” and/or “quantitative” terms in the “obtaining, verification or presentation of the contents” (art. 7.1). Therefore, while “classic” copyright protects the creativity of an author, database rights specifically protect the qualitatively and/or quantitatively substantial investment in either the obtaining, verification or presentation of the contents: if there has not been substantial investment, the database will not be protected.

See M. RICOLFI, La brevettaione delle invenzioni relative agli organismi
geneticamente modificati, Rivista di Diritto Industriale, 2003, pp. 47-48. In such article this author proposes the arguments already proposed in his previous article *Le nuove frontiere della proprietà intellettuale. Da Chigago al Cyberspazio*, in G. CLERICO – S. RIZZELLO (edited by), *Diritto ed economia della proprietà intellettuale*, Cedam, Padova, 1996, p. 96. In particular in the latter Ricolfi proposed the analogy between copyrighted digital works and biotechnological inventions. Indeed, when dealing with both digital works and biotech inventions, the information incorporated into the product (be it a genetic information or music) is more important than the product itself (such as a bioengineered seed or a musical CD). Moreover in both cases the above information is easily reproducible: either it can be duplicated without costs (digital works) or it self-replicates (biotech inventions).

(XXXIV) See above fn. 3.

(XXXV) Moreover, with reference to process patents, art. 8.2 of the EC Directive states that “the protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics”.

(xxxvi) Which was criticised by the Netherlands in case C-377/98 (see point 23 of the European Court of Justice ruling of October 2001).


(xxxix) See the opinion of Advocate General Jacob in case C-377/98 (point 121).

(xl) See the position taken by the Netherlands and Norway in case C-377/98 (point 125 of the opinion of Advocate General Jacobs), as well as the dissenting opinion of Judge Arbour J. in the Canadian Supreme Court ruling of May 21, 2004 in the *Monsanto Canada Inc. v. Schmeiser* case (point 155 et seq.) (this ruling is available at www.percyschmeiser.com).

(xli) Art. 27.3(b) of the TRIPs Agreement states that “Members may also exclude from patentability: […] plants and animals”. Art. 4.1(a) of the EC Directive states that “the following shall not be patentable: (a) plant and animal varieties […]”.

(xlii) See J. WATAL, *Intellectual Property Rights in the WTO and Developing Countries*, Kluwer Law International, The Hague, London, Boston, 2001, p. 111. In case C-377/98 Advocate General Jacob objected to such position by stressing that the concept of patentability is different from the notion of patent protection (point 126 of his opinion). As he explains, where for example a patented gene which confers resistance to herbicides is incorporated into a plant variety other than by or with the consent of the patent holder, that use of the gene will infringe the patent. That does not mean, however, that the plant variety
will itself be patentable. As Jacob writes, historically many countries prohibited the patenting of pharmaceutical products. However, if an unpatentable pharmaceutical product were manufactured which incorporated a specific chemical compound which had been patented, clearly that patent (on the chemical compound) would be infringed by the manufacture of the pharmaceutical product, notwithstanding that the latter product could not itself benefit from patent protection.

(xliii) See RICOLFI, above fn. 33, pp. 59-60.

(xliv) See above fn. 40.

(xlv) Art. 27.2 of the TRIPs Agreement states that “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment […]”.

Art. 6.1 of the EC Directive states that “inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality […]”.

Art. 53(a) of the EPC states that “European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to ‘ordre public’ or morality […]”.


(xlix) See PAVONI, above fn. 48, pp. 468 et seq.

(li) This principle would be enshrined in Recital 14 of the EC Directive, which states that “whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards”.


(lii) The example is provided by Advocate General Jacobs in his conclusions in
case C-377/98 (point 26).


Art. 29 of the TRIPs Agreement states that “Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application”.

(liv) See also RICOLFI, above fn. 33, p. 34.

This opinion appears to be confirmed also by the European Court of Justice in its final ruling in case C-377/98. In particular the Court stated that “as regards, first, Article 6 of the Directive, which rules out the patentability of inventions whose commercial exploitation would be contrary to ordre public or morality, it is common ground that this provision allows the administrative authorities [i.e. patent offices] and courts of the Member States a wide scope for manoeuvre in applying this exclusion”.

(lv) Also the EPC Guidelines confirm that “the purpose of this [exception] is to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour” (C-IV, 4.1).

(lvi) Art. 6 of the EC Directive states: “1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation. 2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) 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”.

(lvii) See eg the decision of the EPO’s Enlarged Board of Appeal rendered on November 25 2008 in the case G 0002/06. Such decision upheld the July 2004 decision of the Examining Division rejecting a European patent application entitled Primate Embryonic Stem Cells under Article 53(a) and Rule 28(c) [formerly 23d(c)] of the EPC. The invention covered “a cell culture comprising primate embryonic stem cells” which, at the time, required the use and destruction of human embryos as starting material. This was found to be contrary to Article 53(a) of the EPC and more specifically to Rule 28(c) which prohibited inventions for “uses of human embryos for industrial or commercial purposes”. The Board considered whether EPC Rule 28(c) “forbid the patenting of claims directed to products (here human embryonic stem cell cultures) which—as described in the application—at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims”. Noting that the EPC Rule 28(c) prohibition refers to “invention,” not claims, the Board concluded that the use of the undefined “embryo”
need not be claimed to violate the provision. Instead, in the context of the protection of human dignity from which the rule derived, it was the performance of the invention that was at issue, since, to be used as claimed the stem cells must first be created, and the teaching of the application involved destruction of an embryo. The Board made clear its decision did not touch upon the patentability of human stem cells in general, but only those cellular inventions necessarily requiring the destruction of embryos for their creation.


(ix) The Onco Mouse or Harvard mouse is a type of laboratory mouse that has been genetically modified using modifications designed by Harvard University and the company DuPont to carry a specific gene. The activated oncogene significantly increases the mouse’s susceptibility to cancer, and thus makes the mouse suitable for cancer research. In this regard the European patent application n. 8530490.7 was filed in June 1985 by the President and Fellows of Harvard College. It was initially refused on July 14, 1989 by an examination division of the European Patent Office among other things on the grounds that the EPC excludes patentability of animals per se (this was the first decision). The decision was subsequently appealed and the Board of Appeal of EPO held that animal varieties were excluded of patentability by the EPC (and especially by its Article 53(b)), while animals (as such) were not excluded from patentability (this was the second decision of October 3, 1990). The examination division then granted the patent on April 3, 1992 (this was the third decision).

The European patent was then opposed by several third parties, precisely by 17 opponents, notably on the grounds laid out in Article 53(a) EPC. After opposition proceedings took place in November 2001, the patent was maintained in amended form. This decision was then appealed and the appeal decision was taken on July 6, 2004 by the Technical Board of Appeal. The case was remitted to the first instance, i.e. the Opposition Division, with the order to maintain the patent on a newly amended form.

(lx) In 1990 a European patent was granted to Plant Genetic Systems for processes and products relating to conferring resistance to the herbicide Basta by genetic engineering. The patent contained claims to seeds, plants and plant cells that are herbicide-resistant due to having a foreign nucleotide sequence incorporated into its genome, as well as methods for making and using the transgenic plant. The Greenpeace organization filed an opposition in 1992. After the Opposition Division upheld the patent, Greenpeace appealed the decision to the Technical Board of Appeal. The Technical Board of Appeal issued its decision on February 21, 2005. In this case both the morality and the ordre public issues were raised. It was held that “inventions, the exploitation of which is not in conformity with the conventionally accepted standards of conduct pertaining to [the culture inherent in European society and civilization] are to be excluded from patentability as being contrary to morality”.

The opponents had submitted evidence from a survey of farmers in Sweden and a Swiss public opinion poll in support of the contention that the grant of patents for plants
would be immoral or contrary to *ordre public*. However, the Technical Board of Appeal was not convinced, noting that “the results of surveys and opinion polls can fluctuate in an unforeseen manner within short time periods”.

Furthermore the Technical Board of Appeal could see no moral distinction between modifying plant characteristics by genetic engineering and by traditional selective breeding. Genetic engineering simply made the modifications punctual and increased the number of modifications possible. In certain cases there might be a misuse or destructive use of this potential that would render an invention unpatentable as contrary to *ordre public* or morality. However, the production of herbicide resistant plants did not fall into this category: “[…] In the Board’s judgement, plant biotechnology per se cannot be regarded as being more contrary to morality than the traditional selective breeding because both traditional breeders and molecular biologists are guided by the same motivation, namely to change the property of a plant by introducing novel genetic material into it in order to obtain a new and, possibly, improved plant. [point 17.1] […] In the Board’s judgement, none of the claims of the patent in suit refer to subject-matter which relates to a misuse or destructive use of plant biotechnological techniques because they concern activities (production of plants and seeds, protection of plants from weeds or fungal diseases) and products (plant cells, plants, seeds) which cannot be considered to be wrong as such in the light of conventionally accepted standards of conduct of European culture” [point 17.3].

(lxi) See the decision of the Technical Board of Appeal of December 20, 1999. The invention related to transgenic plants containing genes conferring pathogen resistance.

(lxii) In 1991 the EPO granted a patent for a DNA fragment encoding *Relaxin*, a human protein that is only produced by pregnant women. Immediately after the patent grant, opponents challenged the issuance of the said patent on the basis of Article 53(a). The opponents raised three morality arguments against the patent grant: a) patenting of human genes is akin to patenting life which is inherently immoral; b) the specific isolation of the *Relaxin* gene was immoral because it required extracting tissue from a pregnant women, an act that violates human dignity and c) patenting human genes amounts to a form of slavery, whereby humans are being sold piecemeal to commercial enterprises. The EPO rejected all of the arguments of the opponents; and noted that in order for Article 53(a) to be invoked the invention at issue must be universally regarded as outrageous. In particular, the Opposition Division stated that (a) DNA cannot be compared to “life”, DNA being only a chemical substance which incorporates a piece of genetic information and can be used for the production of medically-useful proteins; in this regard the EPO stressed that there cannot be a distinction between patenting human proteins (which is widely accepted) and patenting human genes (point 6.3.4 of the decision); (b) the Opposition Division added that, as long as the subject from whom human tissue was taken consented to the taking of that tissue, there was nothing immoral in the mere act of taking tissue since this is a standard practice in medical procedures (other human substances, such as blood and bones, are usually used for commercial purposes) (point 6.3.1 of the decision); (c) moreover, according to the Opposition Division, no women would be reduced to slavery as a consequence of patenting the objected gene, being those women free to live their lives exactly in the same way as they would have lived before the patent was issued (point 6.3.3 of the desicion).
As far as morality grounds are concerned, see also also the decision of the Technical Board of Appeal of July 6, 2004 in the Onco Mouse Harvard case (mentioned above at fn 59): “the use of animals in medical and scientific research […] is an established feature of European culture. The Board agrees and thus finds that not just animal welfare but also the use of animals for research and testing is established in European culture” (point 13.2.18); “there is nothing before the Board to suggest that such unease could be elevated to the status of moral disapproval in European culture of the use of animals for medical research” (point 13.2.21).

(lxiii) On the contrary, in the first decision of July 14, 1989 (Onco Mouse / Harvard I) the EPO stated that “patent law is not the right legislative tool” to examine whether the invention is contrary to ordre public or morality, thus showing to share the above mentioned “neutrality principle”.

(lxiv) The costs/analysis methodology has been criticized by PAVONI, above fn. 48, pp. 443 et seq., because – generally speaking – it would entail the monetization of public goods (such as the protection of enviroment and health) which cannot be economically assessed. Moreover, if used in the context of patenting procedures, such a criterion would amount to another patentability requirement (which is not envisaged by the TRIPs Agreement, the EC Directive and any other patent law in the world), as well a means of political pressure.

(lxv) See also the decision of July 6, 2004 in the Onco Mouse Harvard case (mentioned above at fn 59), whereby - in granting auxiliary requests - the Technical Board of Appeal held that there was evidence of medical benefit and concluded that the balancing exercise (between benefits and costs) favoured the grant of the claim (points 9.1-9-7 and 13.2.1-13.24). In this regard, see also G. TRITTON, Intellectual Property in Europe, Sweet & Maxwell, London, 2008, pp. 135-136.

(lxvi) In the Plant Genetic Systems case the Technical Board of Appeal stated that “in the present case, no conclusive evidence has been presented by the Appellants showing that the exploitation of the claimed subject-matter is likely to seriously prejudice the environment. In fact, most of the Appellant’s arguments are based on the possibility that some undesired, destructive events (e.g. the transformation of crops into weeds, spreading of the herbicide-resistance gene to other plants, damage to the ecosystem) might occur […]” (point 18.6) (emphasis added). Moreover the Board stated that “it would be unjustified to deny a patent under Article 53(a) merely on the basis of possible, not yet conclusive-documentad hazards […]” (point 18.7).

In the Novartis case the EPO concisely stated that “although the positions adopted in society on genetic engineering are controversial […] there is no consensus in the Contracting States condemning genetic engineering in the development of plants […]” (point 3.9) (emphasis added).

(lxvii) In the Plant Genetic Systems case the Technical Board of Appeal of the EPO stated that “since no sufficient evidence of actual disadvantages has been adduced, the assessment of patentability with regard to Article 53(a) EPC may not be based on the so-called ‘balancing exercise’ of benefits and disadvantages” (point 18.8).

(lxviii) In the Plant Genetic Systems case the Technical Board of Appeal – after stressing that no evidence was brought by the opponents with regards to the risks of using
the invention - stated that “of course, such events [e.g. the transformation of crops into weeds, spreading of the herbicide-resistance gene to other plants, damage to the ecosystem] may occur to some extent. This fact has even been admitted by the Respondents” (!) (point 18.6).

(lxix) See the decision of the Technical Board of Appeal of December 20, 1999 (point 3.9). See also the decision of the Technical Board of Appeal of July 6, 2004 in the Onco Mouse Harvard case (mentioned above at fn 59): “The Board considers the enviromental issues are the utmost of neutral effect on the case. While a risk of release or escape exists, just as there is such a risk with zoo or circus animals, the risk can only be regarded as minimally more than hypotetical when one considers the secure conditions under which laboratory mice are kept and the level of regulation of the use and keeping of animals for experimental purposes in most countries. Further, in the event of release or escape, it must be questionable whether oncomice would cause any damage, let alone any lasting damage, to the enviroment. The only perceivable threat is that, by mating with mice already in the wild, the oncogene would be spread. [However] Against that, there must be the possibility that, because of their manipulated state, oncomice would not survive as long in the wild as non-manipulated mice” (point 13.2.9).

(lxx) See PAVONI, above fn. 48, p. 458. For a thorough review of the cases Onco Mouse II and III, Plant Genetic Systems and Novartis and in general on the oder public and morality exceptions, see also P. DRAHOS, Biotechnology, Patents, Markets and Morality, European Intellectual Property Review, 1999, pp. 441 et seq.


Moreover the above decisions seem to be contrary to the spirit of two international treaties which have an impact on the biotech field. The first is the above mentioned Protocol of Cartagena on Biosafety, whose art. 10.6 states that “lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects”. The other treaty is the Convention of Rio de Janeiro on Biodiversity of 1992, whose Recital 9 states that “noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat”.

(lxxi) See PAVONI, above fn. 48, p. 459.

We should also take into consideration that several scientists and researchers often tailor their opinions and conclusions depending on the will of their financial sponsors. Indeed, from a survey carried out by the US National Institute of Health (NIC) on a sample of 3.247 researchers, some worrying data emerged: i.e. the 15.5 % of the scientists interviewed admitted to have changed the methodology of their own research in order to please their financial sponsor. See the weekly magazine Nature of June 9, 2005.
Hormones case. On January 1st, 1989 the European Community implemented a ban on imports of red meat from animals treated with six growth promotants, both natural and synthetic, cutting off US beef exports to the EC. The products used in the US, three natural hormones and three synthetic products, were said to have been thoroughly tested and have no adverse effects on human or animal health. The EC, however, continued to publicly rule out an end to the hormone ban, stating that economic, environment and consumer concerns should have been considered in addition to the scientific evidence. Therefore, the United States and Canada launched separate WTO dispute settlement panel cases against the EU regime in 1996.

Salmon case. In 1975 Australia placed a ban on the importation of fresh, chilled or frozen Atlantic Salmon *Salmo salar* on quarantine grounds. The ban remained in place following a risk assessment by Australia in 1996 in response to a complaint to the WTO that such a ruling violated the SPS Agreement (Articles 2, 3 and 5).

Varietals case. In this case Japan invoked, inter alia, the precautionary principle in order to justify a measure which aimed at the protection of a series of agricultural products (infested by the so-called “codling moth”).

(lxxiii) See the WTO Panel decision of September 29, 2006 in the case brought by USA, Canada, Argentina against the EC legislation on GMOs. Indeed in 1998 the European Community decided to suspend the sale of agriculture-related GMOs until certain scientific evidence on the health and environmental safety of the said products was not given (this is the so-called “de facto moratory”: the moratory was lifted in 2003): the WTO Panel stated that the said EC decision constituted a disguised restriction on trade and as such it violated the SPS. The first comments of such decision pointed out that the same is contrary to the precautionary principle enshrined in the above mentioned Protocol of Cartagena.

(lxxiv) In this regard it has been stressed that the precaution principle – which is the *summa lex* of international environmental law (according to this principle, in cases of uncertainty concerning the risks stemming from the circulation of a product, the health of consumers must be protected rather than the commercial interests of producers) – was violated by the WTO dispute settlement bodies: on the contrary, for such bodies, in order to justify a ban on imports on health safety grounds, it seems necessary to provide scientific evidence – not of the mere existence of a risk – but of the certain danger of the relevant product. See C. NOIVILLE, *Principe de précaution et Organisation mondial du commerce: le cas du commerce alimentaire*, in *Journal du droit international*, 2000, pp. 263 et seq.