# Ethical approach of the judgment from the Court Supreme of the United States on the patentability of human genes

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**Abstract**

The article discusses ethical and legal aspects of the judgment of the Supreme Court of the United States (U.S.) on the patentability of human genes in trial occurred in June of 2013. Presents the background of the case as well, in general, places the current debate on human genetics patentability. The discussion reports on the judicial conflict developed in the U.S. under different and conflicting positions on the issue of patents, establishing commenting on the decision of the Court. Ahead of the facts and arguments conclude criticizes the judgment, showing that industrial property is at the center of negotiations on patent and pressure surpasses commercial interests to the same human values.

**Key words:** Ethics. Genetics. Products commerce-Genes. Judgment-United States. Legislation as topic-Commerce.

**Resumo**

**Enfoque ético-jurídico da sentença da Suprema Corte estadunidense sobre patentes de genes humanos**

O artigo discute aspectos ético-jurídicos da sentença da Suprema Corte dos Estados Unidos (EUA) sobre patenteamento de genes humanos, em julgamento ocorrido em junho de 2013. Apresenta os antecedentes do caso, bem como, em linha gerais, situa o debate atual sobre a patentabilidade genética humana. A discussão informa acerca do conflito judicial nos EUA em decorrência de posições distintas e discrepantes sobre a questão patentária, comentando a decisão da Corte. Diante dos fatos e argumentos apresentados a conclusão critica a sentença, demonstrando que a propriedade industrial está no centro das negociações sobre patentes e que a pressão dos interesses comerciais sobrepuja até mesmo os valores humanos.

**Palavras-chave:** Ética. Genética. Comercialização de produtos-Genes. Julgamento-Estados Unidos. Legislação como assunto-Comércio.

**Resumen**

**Enfoque ético-jurídico de la sentencia de la Corte Suprema de los Estados Unidos sobre patentabilidad de genes humanos**

El artículo discute aspectos ético-jurídicos de la sentencia de la Corte Suprema de los Estados Unidos (EUA) sobre la patentabilidad de los genes humanos, en juzgamiento ocurrido en Junio de 2013. Presenta los antecedentes del caso bien como, en líneas generales, sitúa el debate actual sobre la patentabilidad genética humanos. La discusión informa acerca del conflicto judicial desarrollado en los EUA en virtud de posiciones distintas y discrepantes sobre la cuestión de las patentes, estableciendo comentarios a la decisión de la Corte. Delante de los hechos y argumentos presentados la conclusión critica la sentencia, demostrando que la propiedad industrial está en el centro de las negociaciones sobre patentes y que la presión de los intereses comerciales sobrepuja hasta mismo los valores humanos.

**Palabras-clave:** Ética. Genética. Comercialización de productos-Genes. Juicio-Estados Unidos. Legislación como asunto-Comercio.

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Declara não haver conflito de interesse.

It can perhaps draw attention that in a publication on bioethical issues is dealt with a judicial decision that resolves a dispute in the field of industrial property. in fact, in the course of recent decades, it has operated a deep transformation in the purposes and methods of the industrial property right. In its traditional conception patent law - cornerstone of the industrial property rights - referred to objects and technical procedures, which set it aside from the ethical issues.

With the evolution of the times patent law suffered the brunt of the market, which today allows, without attracting the attention, the incorporation of ethical dilemmas and concerns. The unusual extension of their domains to ever imagined themes demands this consideration. The patentability of living beings, of biological processes, genetic information, cells and cell lines, seeds, microorganisms and even of mammals, can not and should not be studied without warning the ethical impact that it causes. In this setting the traditional idea that the industrial property and ethics were in different and distant lanes, is overwhelmed by the facts.

The report produced by the French State Council on the reform of the laws on bioethics, stressed the need to consider relevant ethical aspects. It was oblivious to reality to locate the industrial property and ethics in watertight compartments, which would only justify the abuses involving the industrial property rights presently [1]. Today is unquestionable the ethical approach in this matter, especially when we talk about patents related to human beings.

A tangible proof of this is that the European Directive 98/44/C regarding protection of biotechnological innovations - the most complete instrument developed in this field - initially did not contain ethical provisions. In the long way that required its approval - almost a decade - regulations were added in relation to this subject and finally about the eighteen articles which compose it, seven contemplate ethical aspects. The issue that we believe is given from the beginning of the Human Genome Project. More than two decades ago, when settled the chair of Law and Human Genome at the University of Deusto, on the initiative of Carlos María Romeo Casabona, an important international event was held in which - among other matters - were discussed the ethical issues that were already predicted on the patentability of human genes.

Since then, the exponential growth of the patents granted in this field prompted a hard debate over its ethical and legal backgrounds, which has not be terminated. In the United States courts justified the patentability with various arguments, but increasing pressure from scientists and civil society sectors led the theme to podiums in the Supreme Court. The decision, long-awaited by the prestige and influence this Court has in the world, is daunting since it confirms in substance the policies held up to that time.

Such background motivated me to comment on this decision which - at first sight - seem to turn the tide, but in a deeper analysis lead to reiterate it once again.

## Background

It is interesting to examine the case background to appreciate in full extent what was at stake. Disputes raised both in the United States and the European Union against Myriad Genetics had as the center patents granted on two genes of predisposition to breast and ovarian cancer: the BCRA1 and the BCRA2. In healthy people, both genes are suppressor of tumours that help to regulate cell division. It is believed that the mutated forms of these genes are responsible for half of inherited breast cancer cases, especially of those which arise in young women. Women with mutations in any of these two genes have a higher risk of developing breast and ovarian cancer than women with "normal" genes versions [2].

The first of these two genes was located on chromosome 17 by researchers of the University of Berkley in December 1990. Warning about the economic implications that finding would have, Mark Skolnick founded the Myriad Genetics Society, which formalized an alliance with the pharmaceutical company Eli Lilly in order to continue with the researches directed toward the commercial exploitation of the discovery, which led to clone and patent the gene. A second gene implicated in breast cancer was identified in 1995 by a consortium of Canadian, US, and European public laboratories led by British researchers of the London Cancer Research Institute and the Sanger Genome Centre at Cambridge. This finding triggered the request of several patents by North American universities in order to economically valorize the knowledge gained; as well as by researchers of the European Consortium that aimed to ensure free access to genetic information.

A federation of aid for research on cancer offered its collaboration to British laboratories of the Cancer Research Company, which asked the second gene BRCA2 patents in 1995 and; obtained, it granted a license for commercial use to Oncormed,

competitor of Myriad Genetics, to contain the monopolistic intentions already expressed of this. The situation caused by the coexistence of patents relating to the BRCA1 and BRCA2 genes among competing firms concluded in 1998 with the merger of both gene patents held by Myriad Genetics [3].

With another eight patents related to the aforementioned genes, Myriad Genetics provided a much extended monopoly on knowledge and application of genes predisposing to breast cancer. It should be noted here that granted patents are very extended as to cover any reproduction of the DNA sequence and all products derived from it (probes, antibodies, transgenic animals carriers of altered alleles, etc..) and all diagnostic method predisposition to breast cancer, just as much as applications for therapeutic purposes or "screening". The claims contain no limitations regarding techniques used in order to show a mutation of the sequence of the genes involved [3].

At the same time Myriad Genetics requested and obtained from the European Patent Office similar titles. Held by a portfolio of patents related to these genes, oriented its activities in two directions: the therapeutic use - more complex issue -; and utilization for diagnostic use, less complex and more profitable issue [4]. The rights for therapeutic uses were negotiated with pharmaceutical firms and was reserved exclusively the diagnostic area, which provided him substantial profits through the creation of a division dedicated exclusively to hog global provision of such services.

With its patents Myriad Genetics, which had demanded that all diagnostic tests were carried out in its laboratories in Salt Lake City, the world monopoly was ensured, which was considered in the ethical and economic levels as outrageous [5]. The monopolizing use of the exorbitant rights agreed by patents compromised the safeguard of the health of populations, motivating the actions of public institutions to override patents or to limit them on reasonable terms. Francis Collins notes that Myriad has fiercely protected the rights deriving from its patent, denouncing any attempt to offer these laboratory analysis. All other companies that have tried to make this diagnostic test in the United States have been forced to go out of business. Myriad holds an absolute monopoly on a test that nowadays many women are considering with a family history of breast or ovarian cancer. The lack of competition in the market has remained its fairly high price (about $ 3,500), out of reach of many people who would like to have that information [6].

The terms in which it was made the judgment here mentioned allow us to conclude - with the central theme involving the protection of public health - that Myriad's patents are still in force, leading to claim that it may remain the only company authorized to provide genetic testing for breast and ovarian cancer. This threatens to further litigation, while Myriad filed suit for violation of its rights against two companies that had announced that they would begin offering lower-cost tests to detect genes linked to breast and ovarian cancer. This led the President of the Senate Judiciary Committee to urge the National Institutes of Health (NIH) to use march-in rights, rights which are implemented in cases where the research falls within the scope of the Bayh-Dole Law (public funding) and that would lead to require the indicted to grant licenses on "reasonable terms" [7].

In Europe they processed for the invalidity of the patents the National Federation of Centres to Combat Cancer, Hospital Federation of France, the Belgian Society of Human Genetics, the German Society of Genetics and similar Danish, Czech, Swiss, Austrian, Italian, Finnish and British institutions, obtaining a considerable limitation in the granted claims. In the United States indicted for nullity numerous scientific institutions and the Department of Justice presented itself in the process as *amicus curiae,* alleging that the discussed had a great importance to the national economy, medical sciences and public health.

## The debate on the patentability of human genes

In 1988 the offices that handle patents worldwide, USTPO (U.S.), EPO (European Union) and JPO (Japan), issued a joint statement unifying criteria on the central theme of the debate to come, in which laid the following doctrine: *Purified natural products are not considered natural products or simple discoveries, while since they don't exist in nature in isolation* [8]. Put into plain language the simple task of isolating the natural product makes it "appropriated" by way of industrial property rights.

When as a result of the Human Genome Project advancement the battle for dominance of genes took place and thus the genetic information carried, this criterion was imposed: the DNA sequences isolated from their environment are still patentable until it is deemed to constitute an "industrial product" and not merely a natural substance. Clearly the informative character of the genes, resulted in the fact that they are carriers of genetic information, can not lead to its patentability. It is not possible or

reasonable that someone submits to its control any information pertaining to the natural world and that is simply revealed to the alleged "inventor" through the isolation and purification procedures, with no change in the external world.

In this direction, according Tallacchini the isolation and purification have become the legislative scientific criteria for legally presumed that biological materials have become patentable artifacts [9]. Under this approach a patent on a new "chemical product" - the genv - covers all uses, whether or not described by the owner. At the time Barton criticized this stance understanding that it is not clear is wise to apply these legal principles of chemical basis to the genomic context [10]. Kahn - eminent French biologist - marks the specificity of the gene in this field. A gene - he teaches - can be chemically synthesized from their basic constituent, i.e. nucleotides. However, compared with other inert molecules in the biological world, for example enzymes, uric acid, a protein, an albumin etc., genes have a complementary property that makes their specificity: constitutes the support of a genetic program [11].

To make patentability policies viable followed by USTPO and shared by other central offices, it was necessary to define the "invention" of the genetic sequence as the operation consisting of isolating it from its natural environment or reproduce it by technical procedure. This definition - teaches Cassier - widens the scope of the invention, justified by the *human intervention on nature.* This is where finally the "inventor" is located. That is to say, the intervention of man over nature through the isolation of this sequence from a more complex environment to place it in a different environment.

The operation that is to isolate, manipulate and reproduce natural events and natural objects is the very definition of laboratory activity. Therefore, in this way, the distinction between the efforts for discovering a natural substance and the invention of a device disappears: *All laboratory products resulting from the work of discovering will be potentially patentable, in despite of the low level of satisfaction of classical criteria of patentability* [12]. Apart from these considerations and descending to the ethical field, we understand the genes as components of the genome, carriers of genetic information may not be appropriate, as I have sustained for quite a long time[12-15].

The genome - UNESCO has said in one of his brilliant statements - is the basis of the fundamental unity of all members of the human family and the recognition of their inherent dignity and diversity [16]. This is not an empty description of contents or a statement of circumstances; genome characterizes the species. All living beings are subjected to the same genetic code, but the genetic information of each species determines it, making the human species is different from a bird, a microorganism or a walnut. This is given by nature and accompanies each member of the species throughout its life.

Submit such information to the vicissitudes of industrial property rights is absurd. It seems to be very risky to assert that someone holds the genetic information of the species or in particular of that which carry a segment of it (the gene).

## The judicial conflict in the United States

The invalidity of the Myriad´s patents was demanded by a group of several entities, including the American Civil Liberty Union, by the courts of the District of Manhattan in 2009. In March 2010, Judge Robert Sweet accepted the complaint and declared invalid patents arguing that genes are important because of the information they transmit and that an isolated gene is not different from a gene contained in the body actually. Appealed the decision before the Federal Circuit Court, the court ruled on the date of July 29, 2011 revoking all parts of the sentence.

In the decision of the Federal Circuit Court (second instance) substantially two topics were discussed: a) the patentability of genomic DNA; b) the patentability of the cDNA (complementary). Regarding the first point, there was a dissent, as Judges Lourie and Moore were inclined to support its patentability, following the mainstream; while Bryson, in an extensive voted, voted in the negative. The arguments of the majority can be summarized as:

- No human gene has been patented, but something different, an isolated gene differs from the native gene because the extraction process results in changes in their molecular structure (although not in its genetic code);
- The "purified natural products" have different distinguishing features compared to the impure product, resulting in significant potential utility. The isolated DNA sequences have very different properties which are directly responsible for a significant and new use;
- Since the different chemical structure of the isolated DNA is a product of human intervention, this leads to a different and beneficial utility. That is why it is considered that small isolated DNA fragments are patentable subject matter.

The vote of Bryson, dissenting, begins by noting that the essence of Myriad´s argument is that it has not been patented a human gene, but something very different, an *isolated human gene*, which differs from the natural gene since the extraction process results in changes in its molecular structure (although not in its genetic code). In order to isolate the BRCA gene is required to break the chemical bonds that hold the gene in place on the body, but the sequential genetic code that is the subject of each of the claims of the BRCA gene remains the same, whether the gene is in the body or separate from it.

If we were to apply the conventional nomenclature of any field to determine whether the DNA claims isolated by Myriad are "new" - notes - it seems to make more sense to look at the genetics that is the language of the claims, rather than chemistry. From the viewpoint of genetic that claim covers a "composition of matter", the BRCA1 gene. The isolated BRCA genes are identical to the BRCA genes found on chromosomes 13 and 17. They have the same sequence, encoding the same protein and represent the same units of heredity.

It is true that molecules claimed were split and they have terminals which differ from those found in genes that are produced naturally. Most - notes - gives a meaning to this fact; but the function of the isolated DNA molecules can be attributed not to the nature of the isolation process or the identity of the terminal bodies in the molecules; the function of the molecules claimed is dictated by the nucleotide sequence of the gene, which appears exactly in the isolated DNA claimed. The only difference between the BRCA genes that are generated naturally and the isolated ones, claimed, is that they have been isolated according to limits predefined by nature. In this regard extracting a gene is similar to cutting a leaf from a tree. Even pulling the sheet before time it would not become a human invention.

From another angle, remember that most of the court gives significant importance to the fact that the encoded segments of natural genes claimed are part of a much larger molecule and the isolated BRCA genes, being smaller molecules extracted from a larger one are man-made inventions. But - refutes Bryson - the argument that the isolated BRCA gene is patentable because their natural environment is part of a much larger structure is no more persuasive than to argue that, nonetheless, an atom can not be patentable, a subatomic particle it is because was formerly part of a larger structure or a tree is not patentable, but a branch it is when it is removed from the tree.

Finally stresses that the split of covalent bonds that affect the insulation, in itself is not an invention, and the fact that separate molecules have terminal groups that differ from the nucleotide sequences that occur naturally, adds no inventive character to the molecules claimed. The functional portion of the composition - the nucleotide sequence - remains identical to the gene that nature produces. Recorded Bryson´s arguments are very strong dissipating any doubts about genomic genes claimed by the processed are not patentable. Regarding the second question, the patentability of the cDNA, the three members agreed to endorse it.

## The decision that raised this comment

Appealed the judgment on the date of March 20, 2013, the Supreme Court issued the ruling that we comment. In its decision the Court ruled unanimously accepting the claim regarding the non-patentability of genomic genes, and rejected the arguments of the actors in the case of cDNA.

*After referring to the backgrounds of the case, the Court entered fully into the first subject (patentability of genomic genes merely on the ground of locate, isolate and sequence them).*

It is indisputable - the Court points out - that Myriad did not create or alter the genetic information encoded in the genes BRCA1 and BRCA2. The location and order of nucleotides existed in nature before Myriad found them. Myriad did not create or alter the genetic structure of DNA. In contrast, Myriad's main contribution was to discover the exact location and the genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13. The question is whether this makes genes are patentable.

Myriad recognized that the decision of the Court in the Chakrabarty case is central to this inquiry. In Chakrabarty the scientists added four plasmids from bacteria, allowing to degrade components of crude oil. The court then held that the modified bacterium was patentable. The court expressed that the claim for the patent was not for an unknown natural phenomenon, but for a non-natural product or composition of matter - a product of human ingenuity - which has name, own characteristics and distinctive use.

Chakrabarty´s bacteria was new with markedly different characteristics of any other in nature, due to the plasmids added and the resulting ability to degrade oil. In this case - the court said - by contrast, Myriad has not created anything. Definitely found

an important and useful gene, but separate the gene from its genetic or surrounding material is not an act of invention. The revolutionary discovery - innovator and even brilliant itself - does not satisfy the requirements of Article 101.

He also recalls the earlier decision of the Court in the judgment of Frank Brothers Seed Co. v.. Kalo Inoculant Co., in the case where was intended to patent a composition of bacteria without any alteration. He argued at the time that the composition was not patentable because the applicant did not alter any bacteria. Therefore the application fell squarely into the exception of natural product. The same - he adds - happens to Myriad true. Myriad found the location of the BRCA1 and 2 genes but that discovery by itself does not make the aforementioned genes a composition of matter patent eligible. It explained that the location of the gene was unknown until he found among the approximately 8 million nucleotides contained in a portion of chromosome 17.

Many of the descriptions of Myriad's patent simply detailing the "interactive" step of the discovery by which Myriad reduced potential places for sequences he wanted. Myriad attempted to link these great research efforts to cases of patentability of Article 101. But - the Court added - just hard work is not enough to meet the demands of such a requirement. Myriad´s claims - adds - are not sufficient in the fact that the isolation of DNA from the human genome breaks chemical bonds and thus creates a natural molecule Simply claims are not expressed in terms of chemical composition, nor in any way rely on the chemical changes that result from the isolation of a particular section of DNA.

Instead claims are focused on the encoded genetic information of the BRCA1 and BRCA2 genes. In additional note, after transcribing the first part of the claims of the processed, the Court concludes its opinion on this matter: *However, the repeated use of the term present invention by Myriad derives from the text of the patent that the various findings are the invention* [17]. The arguments of the Court on the non-patentability of genomic genes are indisputable as supplementing and reaffirming what Bryson expressed in the minority vote in the Federal Circuit Court.

## The patentability of the cDNA

This part of the judgment is, in my opinion, the most important, since in a few lines the Court seeks to support the patentability of the cDNA. CDNA (complementary) is a DNA type molecule recomposed from the RNA molecule "produced" by the gene. The gene actually contains in addition to the encoding of constituent amino acids of the protein, information concerning the regulation of transcription; information that cause the gene to be operative [18]. About the subject says the court:

*The cDNA does not have the same obstacles to patentability than isolated segments of natural DNA. As explained above, creating a cDNA sequence from the mRNA results in a molecule of only exons, which is not naturally occurring. The petitioners admit that the cDNA differs from natural DNA in that the non-coding regions have been removed. They argue, however, that cDNA is not patentable because the nucleotide sequence of the cDNA is dictated by nature and not by the laboratory technician. It may be so, but the lab technician certainly creates something new when done cDNA. CDNA conserves exons from natural DNA but is different from DNA which is derived. As a result, the cDNA is not a "product of nature" and is patentable under Art. 101* [17].

The analysis of the question asked leads us to review some basic concepts of biology. DNA is a composed *informative* macromolecule, into which can be distinguished a number of sub-elements known as sequences or regions to which are assigned specific functions [19]. Presented as a concept of molecular genetics, genetic information is defined as the set of heritable messages contained in the coding genetic material for all structures and operation [20]. From the evolutionary point of view to make something (a source) contains or carries *information* there must be precisely some kind of receiver that reacts to that source and interpret it. As a result of such a reaction and interpretation the functional state of the receptor is modified in a way that is related to the shape and organization of the source [21].

The expression of genetic information allows an organism to replicate according pre-established norms. In the cell the information needed for it is encoded in a molecule known as deoxyribonucleic acid - DNA - which is transferred to a molecule of messenger ribonucleic acid (mRNA) by a process known as DNA transcription. MRNA transcribed are translated into specific proteins [22].

The *information units* are known as genes, located inside chromosome and are controlled in their expression by regulatory proteins that bind to specific preexisting sites in regions near the coding

regions. In eukaryotes (complex organisms including human) genes are composed of large DNA coding regions (exons) separate from long noncoding DNA regions (introns). This was discovered not long ago, in 1977, showing that in the genes of eukaryotes did not form contiguous blocks of coding sequences of proteins, but mosaics of exons (DNA sequences which encode fragments of proteins) and interspersed with "introns" (DNA intercalated often external that is not encoded in proteins) [23].

Most of the human genome is transcribed into RNA, but only 1.5% determines proteins, which teaches that the human genome is packed with useless transcription or those uncoded RNA fulfill some unknown function. Unlike DNA, RNA is a single-stranded molecule, which is predominantly present in cells as a single strand. Depending on the role, there are three major classes of RNA. One is the mRNA (messenger), carrier of the sequences of bases encoding the amino acid sequence of one or more polypeptides specified in a gene or set of genes. MRNA molecules serve as a template for protein synthesis.

When started the Human Genome Project, one of the two major groups of research, led by C. Venter, pointed out to the sequencing in large-scale of human cDNA, it is to isolate mRNA produced in various cell types and obtained from they the reverse transcribed of cDNA, that obviously correspond to exons of genes expressed in said cell [24]. Scientists who want to get a clean copy of the gene can intercept the mRNA transcript and determine its sequence. They can even use the mRNA to produce cDNA that have the same sequence. The cDNA - Jeff Guo teaches - would look like the DNA if it were purged of all introns. It does not exist naturally because our body wants to maintain the DNA protected. Thus the cDNA is an artificial composition despite containing the same data (coding sequences of bases) than mRNA, which is a natural creation [25].

Consequently, the difference between "genomic" DNA and "complementary" DNA is that in one case we have a compound "raw" and in the other a compound "clean"; but both contain exactly the same genetic information. The "lab technician" that mentions the judgment of the Court, who won the cDNA has not created anything. As complicated as it may be the process leading to its realization and as long as it may took, has simply done a non-creative laboratory work. From there to a "creation" that leads to the existence of a "patentable invention" there is an unbridgeable gap.

Note that what was an issue in the case decided by the Court was not the procedure used - it is on the other hand in the public domain - but the product or composition of matter (the gene). Well, no one is unaware that in both cases the product is the same: the coding sequence of bases and the genomic gene. So what is the "invention"? Nobody can explain it rationally.

Jeff-Guo rightly points that genes are basically information and *information can not be patented*. The body has its own code, which is a natural source and the body naturally handles the code, making copies, edits and deletes. Molecules that provide such information, either DNA or RNA, if naturally exist is completely irrelevant [25]. The Court states in a complementary note on the analysis of the second point: we don´t *express an opinion on whether the cDNA satisfies the other requirements for patentability* [17]. This does not reflect the importance of the issues discussed. At least the Court should have incontrovertibly established in the existence of a "patentable invention" and consequently the requirements that must fulfill: novelty, inventive step and industrial utility.

In less than half a page sought to prove the patentability of the cDNA, in my opinion without success. Three central arguments put forward to justify the patentability of the cDNA: a) the lab technician creates something new when he gets cDNA; b) cDNA conserves native DNA exons; but differs from the DNA from which it derives and; c) as a result the cDNA is not a product of nature and is patentable under Article 101. Let's see now the consistency of this reasoning.

In first place, argue that the lab technician created something new when producing cDNA is very weak. If they are separated in a gene the exons and introns, and from such cleavage arises a molecule consisted only of the coding elements, what has made the "lab technician" is - despite all the time and every effort employees - a laboratory work. If you could describe as "creation" to all debugging work, as segmentation, as purification, the "lab technicians" and even "industrial workers" would make a very creative task, since by the end of the day they would have a credit because of the creation of various products or compositions of patentable matter.

Also, note that the cDNA is different from DNA which is derived, it is a very weak reflection. It could also be argued that a peeled orange retains the wedges of a natural orange, but is different from which it came. Any change in the external world, no matter how small, leads in this scheme to differentiate the original product from new. This, in order to sustain a patent right, sounds very strange.

Finally, to argue that the cDNA is not a product of nature and therefore patentable, does not seem very meritorious. What expresses the aforementioned reasoning is that everything which has the human seal is patentable, because we move away from the natural world, which summarizes what is excluded from patent protection. With this approach the field of patentable widens to absurd limits.

Apart from the above, we can not overlook that in court it had been brought into question the concept of "patentable invention" and strangely the judgment is silent on this issue, which deprived it of a test that- in consideration of the terms in which the debate was set - it was essential.. The *invention* does not express an indefinite concept that can be applied to "anything under the sun" to justify the granting of a patent. The substantial difference between an *invention* and a *discovery* can not be overlooked. Only a gross misunderstanding of law can lead to enlarge unjustifiably the field of patentable. To enter in this field must exist a human creation, an intellectual development with technical means to solve a technical problem.

Even though the patent laws do not generally define the invention, this should not authorize the entry into its territory of any product of human activity. The patent for invention is something exceptional that in the economic field challenges the general principle of free competition, and in science the free use of current *stock* of knowledge for the continuous progress of science. Invention and discovery (including here natural laws or basic science contributions) are located on opposing fields. The technical creation faces the knowledge that according to Stiglitz is a global public good.

It is clear that in the case of obtaining cDNA did not exist "human creation" that justifies the claim to a patent. It should be noted that not all intellectual effort deserves protection. The law has organized the private rights and has subordinated the benefit to certain conditions: e.g. novelty, inventive step and industrial character on patents for invention, originality in literary and artistic property. The creation that does not meet the legal requirements are said to be in the public domain, meaning that is available to all [26]. Apart from that, this case does not meet the universally known requirements, objectives of patentability: novelty, inventive step and industrial applicability or utility:

The ruling, in a footnote, says that *we do not express any opinion on whether the cDNA satisfies the other requirements for patentability* [17]. Precisely in this case was necessary to mention what the inventiveness is of a person who, using existing knowledge in the public domain, obtains cDNA. In this regard, the Nuffield Council on Bioethics states: the hypothesis of isolation and cloning of genes involved in the discovery of new molecules of a type not produced by man are questionable. The fact that genes are essentially genetic information makes the issue of patentability is very different from the one that involves the isolation of other chemicals component [27].

In the specific case of "inventions" of human genes is about intermediate products, i.e. products that not only lack of direct industrial application, but also are research tools of products capable of industrial application. Genes and information concerning them (their structure, biological function, mode of regulation) will serve as a "raw material" for other researches that will lead to other drugs susceptible to phase of industrial production. The industrial application of genes occurs only in the case of medication gene involved in gene therapy [28]. In most cases the gene will act as element of a manufacturing process of a medical protein or as a means of better understanding the objective on which the therapeutic molecules should act or even the genes upon themselves.

## Final considerations

The Supreme Court of the United States had a wonderful opportunity to offer to the world an example of fairness and correctness in a gravitating issue not only in the legal field but also in social and fundamentally in ethics. Unfortunately it wasted it and opted for continuing a line based in the protection of economic interests committed. in fact patent right is geared decidedly toward goals inconceivable until not long ago.

In the aforesaid conference that took place at the University of Deusto, Alberto Bercovitz Rodriguez Cano, leading expert and author of the Spanish law of patents, in his presentation he highlighted: *you don't make a mistake, the patent law is not a law in which the legal principles prevail mainly, but those are the economic interests prevail; it would be sufficient that there is a lobby strong enough, that involved investments that are billions of dollars, are sufficiently important to change the principles that have governed it for centuries* [29]. The mercantilist view only directed by the accumulation of income, not only affects the patent law, but the dissemination of knowledge.

On this matter Coriat and Orsi acutely observed that the transformation of knowledge into a commodity (in the form of marketable industrial

property and guarantor of future income) has created the right conditions to allow the entry of financial capital in the production of knowledge [30]. In the background - teaches Gaudrat - Patent is a commodity. We are in the logic of investment [31].

In this scene is not difficult to understand why industrial property is at the center of negotiations of the World Trade Organization (WTO) and why exerts much pressure - reaching the limits of intimidation - on international bodies and states to pursue the generalization of an intangible property (we can not say intellectual anymore) attributable to investors [31]. Naively we expected a change, but unfortunately in this field sectoral interests are superior to the legal principles or ethical grounds.

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