Patenting Human Genes in Europe:

Is it possible to set an ethical *minimum* based on common values?

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Dr. Leandros K. Lefakis

Abstract

Dealing with the issue of patents on human genes has proved to be quite challenging and complex due to a variety of factors. Firstly, many different interests are involved in patenting. For instance, interests of legal, financial, diagnostic, therapeutic and ethical nature. Secondly, the patent law allows room for various interpretations. Often, the debate on human gene patents is so complicated that it is not easy to reach a *consensus* on what is actually being discussed. Thirdly, the connection between law and ethics in this area is another obstacle as it makes matters more complicated. Is it ethical to patent human genes and gene sequences? As with many questions regarding what is ethically permissible, this query has more specific issues of complexity, which include fundamental questions about what should be patentable from an ethical perspective, as well as what is patentable under existing patent legislation in Europe. Legal practice has proved that although current patent laws can be interpreted to allow gene patenting, this may always pose an ethical challenge. And even if –contrary to expectations- it is feasible to reach a common understanding in the wording, the practical implementation of the values would still be disputed, leaving only a set of "common values" to apply as an ethical *minimum*. This might possibly initiate a dialogue about the formulation and implementation of ethical principles on human gene patents.

Key words: genes, patent law, ethics, common values

1. Introduction

The short definition of the gene is that it is a functional unit of the genome. In other words, a gene is a unit of heredity in a living organism. It is a name given to some stretches of DNA (Deoxyribonucleic acid) and RNA (Ribonucleic acid) that code for a type of protein or for an RNA chain that has a function in the organism. It is estimated that there are between 20,000 and 25,000 human protein-

coding genes, although it must be pointed out that the estimate of the number of human genes has been repeatedly revised as genome sequence quality and gene finding methods have improved. Earlier predictions estimated that human cells consisted of as many as 2,000,000 genes.

Patenting human genes is generally perceived as ethically controversial. The ethical scruples partly stem from the question of whether it is at all acceptable to patent human genes and partly from the consequences such patenting can have for diagnosis, treatment of illness and disease and research. The most significant question is whether a common understanding on ethical issues can be reached. As a matter of fact, the need to consider moral concerns is pressing in the European patent law. Indeed, the patent law, contrary to other laws, traditionally excludes from patentability inventions which would be contrary to "public order or morality". These two matters of exclusion are mentioned in the existing law, as well as in Article 53 (a) of the European Patent Convention and the national laws of members - states. Any proposal forwarded should take into account this moral concern, which aims to adapt to the specific case human gene patents which, as based on elements of human origin, involve the issue of fundamental human rights.

This paper wishes to contribute to the general discussion about the ethical defensibility of taking out patents on human genes. Additionally, it wishes to propose some recommendations to the rules in force and to the current practice of granting human gene patents regarding best practices to safeguard ethical considerations in the process.

2. Patenting human genes in Europe

2.1. EU regulations

The legal basis for granting patents at the European Patent Office (EPO) for inventions concerning living organisms, stem-cells and DNA has three elements. The first is the European Patent Convention (EPC), which sets out the general legal principles for granting patents in all technical fields. In addition, biotechnology is to date the only field to have its own special provisions. These are derived from the European Union Directive 98/44/EC on the legal protection of biotechnological inventions, enacted in 1998 by vote of the European Parliament following a ten – year debate between all interested parties. Finally, the national patent laws of each European Union (EU) member - state govern European patents after grant.

The EU “Biotechnology Directive” (98/44/EC) aims to harmonize and define how inventions in the field of biotechnology are to be patented. It affirms that living organisms, cells and gene sequences are patentable and enhances the ethical aspects to be considered when granting patents for biotechnological inventions. The EPO implemented the relevant provisions of the EU Directive into the EPC in 1999. However, a legal challenge against the directive commenced, but finally was rejected by the European Court of Justice in 2001. The Court found

that the Directive had been correctly put in place and that it contained sufficient ethical limitations to the patentability of biotechnology. To date, the Directive has been implemented in national laws by the majority of the EU's member states, including Greece. However, patenting biotechnology remains controversial in respect of the evaluation of important ethical principles such as the respect of human dignity, the adequate protection of the human embryo, the prohibition of financial profit from the human body and body parts, as well as the respect of individual autonomy and the protection of public health. The main problem in applying these principles is that it is often difficult to detect their influence on the patent system. For example, how is human dignity related to patent system? The basic objection to patents on human genes is that they may threaten the individual autonomy, the fundamental principle that everyone should be master of himself, and, in particular of our own bodies, so that one person cannot legitimately acquire control over another person's body or some part of it. The thought behind this claim is often phrased in terms of "human dignity". Human dignity is our inherent status as embodied humans. That implies that control over one person's body cannot be lawfully exercised by another person. Therefore, the important issue is whether individual autonomy really does conflict with patents involving human genes.

2.2. The EPO and the EU Directive practice

Like other patent offices, the EPO has been granting patents in the fields of genes for some time. It first granted a patent for a human gene, namely that encoding alpha-interferon, in 1984, and granted another patent for the DNA encoding erythropoietin in 1990. The EU Directive confirmed this long – standing practice by stating in Article 5 that while neither the human body in its natural state nor the mere discovery of one of its elements is patentable, an isolated human element, including a gene sequence, may be patentable, even if it is identical to the natural elements. These two sentences are often regarded as contradictory and merely a creatively worded ploy to enable patents to be granted. Certainly, the underlying purpose is the desire to enable the grant of patents to encourage research in the exciting and promising field of biotechnology. Without patents biotechnology companies have little incentive to make the heavy investment in research and clinical trials required to bring a product in market.

2.3. The current practice

It may come as a surprise that patents for genes and gene sequences are today still the subject of such a huge controversy. Patents for so-called "first generation DNA", i.e. DNA which has been discovered and for which a function has been detected, almost belong to the past. At some point, all genes of interest have been subject to this type of "right investing activity". It is also surprising to see scientists, organizations or ethical groups persisting in the discussion that patents should not be granted for genes or gene sequences, since they are discoveries and not inventions. Irrespective of the fact that such reasoning is based

on an incorrect understanding of the principles of patent law, it is also an argument which has lost *momentum* in all respect. The relevant patents sought now are patents for new applications and functions. Discovering these new functions and applications can hardly be considered not to be patentable subject – matter. But it should be clear that in the case of present day patents for genes related inventions, emphasis should be placed more on the scope of protection of the inventions claimed, than on the very issue of patentability.

3. Discovery or invention?

A discovery has to do with any material or phenomenon that exists in nature, including the chemical properties of materials. To be an invention a discovery must also include an intervention that makes use of the material or its properties in a novel way and so provides some new process or product. Discovering a pre-existing aspect of the natural world is not an invention, but applying some innovative step to that new discovery may be. One of the original principles for patents is that "discoveries" of items that already exist in nature cannot be patented, for these previously existed ("products of nature theory") and are the common property of all. It was stated that the patenting of a gene found in nature is similar to claiming copyright and performance royalties for the song of a bird transcribed into standard musical notation. It was also stated that gene sequences, and the amino - acid sequences in the proteins encoded by nucleic acids, are obviously not inventions if that sequence is found in nature.

The distinction between discovery and invention lies in that a patentable invention has always a practical and technical character, in contrast to a discovery. For example, a natural substance –such as an antibiotic- which has presumably existed for a long time is a discovery in patent terms. However, it could be considered novel if it had not been available to the public before the filing of a patent application. Subject - matter which was previously hidden is not regarded as having been available. Similarly, a human element, such as a gene or a gene sequence, isolated from its natural surroundings is regarded as novel, since it was not available in that form previously. An isolated gene lacks its surrounding DNA, which may influence the expression of the gene. In any case, the novelty of the gene sequences for which patents are filed is a rule beyond doubt, since what is isolated is, in the vast majority of cases, not a gene found in the body, but rather a copy DNA (cDNA) which does not occur in nature. As reflected by the wording of Article 5 of the EU directive, an isolated human element neither is nor regarded as a discovery, since its isolation involves a technical process that adds value to what was known beforehand.

The European Group of Ethics in opinion No 8 on the "Ethical Aspects of Patenting Inventions Involving Elements of Human Origin" stated that the traditional distinction between discovery (not patentable) and invention (patentable) involves, in the field of biotechnology, a particular ethical dimension. What follows from this distinction is that knowledge related to the human body or its elements is relevant to scientific discovery and cannot be patented. It has to be

clearly specified that the simple knowledge of the complete or partial structure of a gene cannot be patented.

When patent authorities award patents on genes and gene sequences, it is done on the basis of the criteria of novelty and inventive step. That is to say that the patentholder must in some way have invested some effort to warrant the description of the genuine invention. However, that effort should be confined to creating, with the aid of synthesizing techniques, an artificial molecule in such a way that it contains the same genetic information as the natural gene. However, technological developments have made it possible to map DNA sequences as a matter of routine. As previously, mentioned, however, it is not sufficient to create a synthetic copy to obtain a patent on a gene. The applicant must also be able to substantiate that the gene sequence can be used industrially in a way that the gene sequence can be used industrially in a way that has novelty value. Therefore, the patent system rests on the assumption that the patented item constitutes an invention, although some will refute the view that human genes could constitute inventions.

The assertion that patents on genes are patents on discoveries, however, is further complicated by the fact that human genetic material can be modified. For instance, when manufacturing a synthetic gene, a researcher can modify it, so that it is no longer identical with the naturally occurring gene. According to some parties it is arguable whether such a modified gene is an invention or discovery. Our opinion is that it is not even debatable to describe a synthetic gene as a discovery, due to the fact that it has been substantially changed in comparison to the occurring gene.

4. What is being patented?

4.1. General issues

It is often contended that genes should not be patented, since this practice leads to commercialization of the human body. However, patenting cannot be equated with commercialization –many not patented products are sold. The sale of all medicaments is tightly controlled by regulation. Furthermore, the commercialization of elements of the human body is generally accepted and indeed desirable to a certain extent (i.e. insulin, human growth hormone and blood proteins). Moreover, it is often considered inappropriate to grant absolute product protection for a gene or a DNA. Since the number of genes is limited, many genes may be multifunctional. It is feared that research may be hindered by granting protection for all functions and uses. However, this argument applies equally well to all organic chemicals. Not only genes but also many pharmaceutically active molecules possess several often widely different activities. A well-known example is aspirin, which was initially uses as a pain – killer but much later was found to help prevent heart attacks as well. This situation is so commonplace that a specially – worded type of patent claim was developed to enable these further medical uses of known products to be patented. The owners of these patents may be dependent on the proprietor of the broad patent and will thus have to obtain a license from the latter in order to practice their inventions. Pharmaceutical

companies usually come to cross - licensing agreement, so that a market is seldom blocked by a dominant patent.

As far as DNA is concerned, the argument that DNA should not be patented, as it is a product existing in nature (and is as such a discovery and not an invention) is not entirely convincing. It is based on a reasoning which does not take into account all "intricacies" of the technology and the patent system. First of all, when a gene or a gene sequence is patented, it is not just merely a matter of patenting a "product of nature". There is isolation and in some way also purification, as the coding parts of the DNA (exons) are separated from the non-coding parts (introns). It was a very complicated technological task to arrive at such scientific result. Secondly, in most cases it is not the DNA as such which is patented but a cDNA which does not exist in nature, but is synthesized.

4.2. Actual genes and synthetic copies

In legal terms, the thing on which a patent is taken out is not the naturally occurring gene, but a synthetic copy, which may nevertheless be "identical to that of a natural element". From a legal point of view, this is an important point but the question is whether it is also important seen from an ethical viewpoint. Another important issue to be noted is that gene patents deal with the information that can be extracted from working with the genes. For this reason the question of who owns the individual human being's concrete genes can, according to a number of debaters, be dismissed as impertinent question.

Since the issuance of a patent that deals with human genetic material, a lot of groups and organizations have become fond of asking the question of who "owns" a person's genes. However, this is not the right question. A more appropriate question would be who owns the intellectual property associated with human genes? Newly discovered genetic material can be patented as long as it is isolated from its natural environment and purified, so as to separate it from extraneous material. In other words, the existence of a patent issued by the EPO owned by companies as "Myriad Genetics" or "Amgen" on purified genes does not mean that these companies own human genes derived from a human body. These human genes are neither "purified" nor "isolated". Consequently, these companies' patents do not cover human genes *per se* and that settles any relevant ethical concern.

4.3. Patenting practice for genes

Biotechnology patenting practice for genes derives from that applied to other organic chemicals, in particular small molecules such as pharmaceuticals. The isolation of small organic molecules is in itself seldom inventive. What makes a chemical inventive is its non – obvious activity. If inventive step is acknowledged, a patent for the product is given. By analogy to the above, the isolation of genes is nowadays a routine and seldom requires inventive skill.

However, if a surprising or unexpected activity or function of the gene (or the protein it encodes) is disclosed by the inventor, the gene is held to be inventive and may be patented. While additional data supporting the claimed activity may be provided later on, the function must be disclosed initially in the application as filed. Any kind of function is acceptable; it may be of medical use (of the encoded protein), of medical use as a drug target or it may be useful for the diagnosis of a disease. A gene or a gene sequence for which no specific function is described is not regarded as inventive and will not be patented.

It is of significant importance to note that at present filing patents for DNA with only primary functions (i.e. that it codes for a protein) almost belongs to the past, for the simple reason that most genes of interest have already been subject to patent applications. Current and future applications will focus on further applications: genes can be claimed as diagnostic tools, DNA coding for specific proteins, whereby a recombinant vector is produced containing DNA with a specific sequence, genes which control biological pathways, such as in receptors which can then be useful in drug discovery and development, DNA as a promoter, enhancer, polymorphisms, expressed sequence tags (EST's).

5. The BRCA genes

BRCA is a human tumor suppressor gene that produces a protein called breast cancer type 1 and type 2 susceptibility protein. It originally constituted for the University of Berkeley at California, as primary evidence for the existence of the gene was provided by the King laboratory at UC Berkeley in 1990. Both genes were later cloned by scientists at "Myriad Genetics". In the United States, methods to isolate and detect BRCA1 and BRCA2 were granted a patent by the United States Patent and Trademark Office (USPTO). On March 29, 2010, a coalition led by the American Civil Liberties Union successfully challenged the basis of Myriad's patents in New York District Court. Patents have been invalidated, but the decision is being appealed.

In Europe Article 53(a) was invoked by several parties who opposed the patent "for methods of diagnosing a predisposition to breast cancer by screening for mutations in the BRCA 1 gene". The main reason for the controversy surrounding this patent is the alleged overcharging of the patent proprietor and whose refusal to grant licences under the patent to third parties wishing to perform tests. The patent was revoked in 2003 for technical reasons, in particular for lack of "inventive step". However, the Opposition Division rejected the objection under Article 53(a) against the patent. The above division referred to a decision (G 1/98) of the EPO's Enlarged Board of Appeal (the highest instance of the EPO), which held that the EPO had not been vested with the task of considering the economic effects of a patent and limiting the claims accordingly. The sole criterion for objecting under Article 53(a) was whether the exploitation of the invention was contrary to ethics or not.

The BRCA patents, in particular, shook the scientific community. In these patents, a plethora of tests were claimed, all to determine whether a patent had a

specific mutation in a gene, which might cause breast cancer in the future. Besides the fact that the patents had very broad claims, there was another reason why these patents caused the turmoil they did. The patent holder ("Myriad Genetics") had decided to pursue a rather aggressive licensing strategy relating to these patents. Myriad granted only exclusive licences, implying that only a very limited number of licensees over the world were allowed to use the technology in the patent and to perform these tests. Such an exclusive licensing system had another adverse effect, a rise in on price, made it rather expensive for research institutions to carry out these tests or to pay the licensee the fee to carry out these tests. In addition, Myriad did not allow local screening, but required the samples be sent to the US.

6. Ethical issues

6.1. Guiding principle

The guiding principle regarding the ethics of patenting DNA is whether the level of protection that is being awarded to inventors by granting gene patents is commensurate -within reason- with the contribution that they have made. In general, patents are defensible and the patent system has to work towards the people's benefit. However, two questions have to be answered. Do patents for these human genes meet the legal criteria? And, is the overall effect of allowing these uses to be claimed in patents beneficial in terms of public interest?

We believe that, as a point of departure, an overall ethical evaluation of the patent system in respect of gene patents is needed. In patent law emphasis has to be laid on the distinction between the original genes and the synthetic copies of the genes. This distinction is hardly of great importance regarding the ethical evaluation of the patent system. An essential aspect of the genes is their content of information, being common to mankind for the most part, and at the same time containing a small part that is unique to every individual. This information content is identical in naturally occurring genes and synthetic copies, thus giving rise to ethical concerns. For example, a broad patent claim on particular genes (whether it is the original gene or a synthetic copy) can prevent scientists -other than the patentholder- from carrying out diagnostic examinations on the gene under consideration. Accordingly, the practical consequences are the same.

Another important distinction in patent law lies between discovery and invention. It is true that in genetics many so-called inventions are actually speaking discoveries and that the current practice of granting patents to these discoveries is dubious. So, it might be seen as a violation of common morality that private interests can secure rights over phenomena or processes that were discovered by nature long before mankind was capable of identifying them. Man's genetic material should be regarded as a common property as it contains information which is common to mankind. Therefore, everyone should have a share in that knowledge and the therapeutic options developed on the basis that should be available for everyone, which also implies that it could not be blocked

by broad patents. Moreover, it is widely supported that health services should not be allocated purely on the basis of financial resources.

The special *status* of genes as carriers of information about the individual as well as all living beings does mean that patenting needs to be done with greater consideration for both the individual and the common good than when patenting traditional materials. The possible advantages of patenting genes, particularly the development of new knowledge and new therapeutic opportunities, must be weighed up against the undesirable consequences of the commercialization and, especially, the monopolization of diagnostic and therapeutic options and the risk of research environments becoming more exclusive.

6.2. Recommendations

On the condition that human gene patents will continue to be granted in the future all legal criteria should be met (new, novel, industrial applicability). Moreover, a number of more specific recommendations concerning the regulation of the patent field should be made. Specifically:

- It should not be possible to award broad gene patents where the patentholder is given sole rights over several possible applications of a particular gene as this may have an negative effect on the development of new treatment and diagnoses. Only narrow patent claims with a precise, detailed description should be issued. Broad patents can have an outright inhibiting effect on the development of new treatments and diagnoses. In addition, the benefit which the intended use is expected to provide must also be specified to ensure that only new inventions of substantial general beneficial value could result in a patent.
- More emphasis should be given to granting compulsory licences in order to prevent anyone from enforcing its patent in a way that unreasonably prevents others from developing new diagnoses and therapies. A compulsory licence can be considered if a company enforces its patent in a way that unreasonably prevents others from developing new diagnoses and therapies. It must be pointed out that the possibility of a compulsory licence is rarely exploited, but this route has to be taken more often in cases where enforcement of a patent is at odds with the interest of the public interest.
- The patent rules should be formulated so as not to prevent research. Furthermore, researchers should not be under an obligation to patent results in the area of basic research. People whose genes are used in research that leads to applications for patents should give their written consent to the research activities and this should also include consent to the possible result of the research activity being patented.
- The present rules on human gene patents are both very obscure and complex, which creates both a fairness issue and a practical problem. It has been suggested that a possible tool which would eliminate these problems would be to set up independent bodies (both at national and European

level) to undertake an ethical and legal evaluation of specific patent applications relating to genes and gene sequences.

- Other means outside the patent system, such as price regulation, could also be instrumental in counteracting the possibly "deleterious effects" of broad patents for science and the right of freedom of research.
- Significant ethical principles such as respect of human dignity and individual autonomy, the prohibition of financial profit from the human body, the protection of public health should be the landmarks for any issue regarding patents that deal human genes or cells.
- The collection or sampling of elements from a human being relies on the consent, cooperation and generosity of the person collaborating in the research. This collection or sampling may raise ethical concerns regarding the information provided to the donor, his consent concerning the future use of the elements, whether it is used for research or commercial purposes, and the compensation he may claim.
- The ethical principle of informed and free consent of the person, from whom retrievals are performed, must be respected. This principle includes that the person in question should be completely and specifically informed, in particular on the potential patent application of the invention which could be made from the use of this element. Any invention based on the use of elements of human origin, which have been retrieved without respecting the principle of consent will not fulfill the ethical requirements.

6.3 In search of "common values"

It is not a *utopia* to commence a discussion on whether the values stated in international conventions should serve as an expression of common and shared values on a European level. European governments have signed the 1950 European Convention on Human Rights, the Council of Europe's 1997 Convention on Human Rights and Biomedicine, the European Charter of Fundamental Rights and UNESCO's 1997 Universal Declaration on the Human Genome and Human Rights. The problem in applying these values is that it is often difficult to detect their influence on the patent system. For example, how is human dignity related to the patent system? Moreover, in many cases these values and rights have to be balanced against each other and this is, for instance, highlighted in Article 2 of the Council of Europe's Convention on Human Rights and Biomedicine, according to which "the interest and welfare of the individual shall prevail over the sole interest of society and science".

It is suggested that all common values could be redefined by means of social research. However, a much more pragmatic view should be heard by examining an unresolved conflict between ethical philosophy or research and certain impatience with theorizing. Religious and cultural frameworks vary very widely across Europe. If we try to establish a "common value system", it has to be based on a scientific understanding of human life. This means not to look for some abstract ethical concepts and theories, but at practical questions in respect of issues such as scientific progress, health or human suffering.

The reality is that EPO has to grant patents and ethics is part of the evaluation. Therefore, a kind of common notion on how we interpret ethics has to be reached. However, the main issue is that even if we could agree on some ethical values or approaches, how could we incorporate them in the patent system? European patent law framework already incorporates ethical concerns, but it is a matter of assessment to examine whether further regulation is needed. The idea of an independent body to perform ethical evaluation has been proposed, as a practical solution to all the above issues. We believe that Europe may not be large enough for a full debate and overview of the ethics of patenting human genes. We are obliged to discuss about the reality on a global level. Without a global discussion about ethical patenting it would be very difficult to establish a rational legal framework regarding the enforcement of these patents.

7. Conclusion

It is true that patents had been granted on genes according to the rules of the existing patent system, before scientists acquired an in-depth knowledge of the function of human genes. Moreover, no one could deny that genes differ from the traditional materials for which the patent rules were designed. This is the reason why we believe that it is time to re-embark on a thorough ethical discussion of the problems and advantages of permitting patents on human DNA.

Even though values set in international conventions and charters could be seen as an expression of shared European values, the content of these values may vary among countries and cultures. However, it might be possible to detect shared European values, e.g. by way of surveys into how people actually feel about which values should be used to regulate different sorts of technology. Additionally, a more case - oriented approach might be a good way to identify possible common values at European level. Even if it might not be possible to distinguish important common values, such as informed consent or human dignity, it could be achievable to identify values of a more procedural kind, such as transparency, honesty and willingness to respect different points of view. Finally, as for the question of how the common values -given that they can be established- can be incorporated in the patent system, it is suggested that on a national level ethical concerns should be incorporated in the general rules of the patent system. On a EU level it would be a huge step forward if an ethical advisory board were set up to perform ethical evaluations of specific patent applications for the EPO. Concerning the inventions deriving from the knowledge of a human gene or a partial human gene sequence, the granting of a patent is acceptable only if the identification of the function attached to a human gene, or a partial human gene sequence allows new possibilities (for instance the production of new drugs), on the one hand and, on the other hand, if the intended use of the patent is sufficiently specified and identified. The complexity and sensitivity of the issues raised by patenting in the field of human gene patents require us to make every effort to inform citizens of the technical, scientific and social as well as ethical aspects of those issues. The affirmation of the citizens' rights in the EU implies that the

economical advantages derived from biotechnological developments should in no way affect the respect of ethics.

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