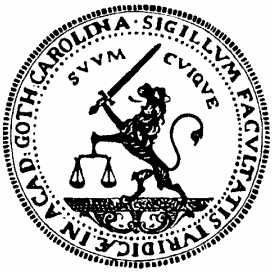

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The European Patent Law and Biotechnology: Ethical, Legal and Economic Aspects of Human Genes Patentability.

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Abstract

This thesis analyses the debate around the patents on human genes from three most important angles: ethical, legal and economic. In the ethical context, patents on gene-related inventions are often seen as inappropriate because of the alleged special status of human DNA. The special status stems from their alleged responsibility for everything from diseases to social propensities and personal traits. If so, patents could be seen as ethically undesirable because they would grant monopoly power over the very determinant of humanness. Yet, despite the fascination of the scientific community with DNA, the special status does not find any foundation in science. The formation of either a disease or personal traits is not determined solely by genes but rather by a complex interplay between different participants of cell reproduction process and the environment. Therefore, since DNA seems not to have any special status, patent protection cannot be denied because of the violation of it. Ethics provide also an additional argument on the basis of which patents could be rejected: the threat of commodification or even enslavement of people. Genes occur in each and every individual, therefore they should belong to everybody constituting the common heritage of mankind. Patents however grant monopoly rights (understood often as ownership rights) over the protected inventions. It implies that these exclusivity rights are granted to a single person or entity entailing in the popular understanding the restrictions on the use or right to dispose over one's own body by all the other individuals. This has been often perceived as a form of a contemporary enslavement. This logic however overlooks one important element: patent protection has not been granted on the genes being still a part of human body but their isolated and substantially modified copies. Therefore, patents cannot entail enslavement of people because they do not apply to their own body parts. The other argument advanced by the patent-opposing voices posits that patents lead to commodification of people. Patents apply market rhetoric to the objects they protect thereby subordinating human genes to market terms or market exchange. The major concern is here that the perception of some body parts (i.e., genes) as a marketable good will expands to cover the entire human. Interestingly, such concerns are not voiced in relation to other body elements such as hormones, blood or bone marrow, which are similarly researched on and often rendered into patentable inventions. Therefore, the unease about the commodificating consequences of particularly patents on human genes is to be traced back to the special meaning ascribed to them. However, since the special status-argument does not stand the critics, also the assertion that patents will eventually lead to commodification of people does not seem persuasive. Overall, the only meaning human genes may be ascribes is a symbolic one. But it is not sufficient to justify the denial of patents on gene-related inventions.

In the legal context, genes are often seen as a product of nature rather than a patent eligible invention. This view however does not see the differentiation between genes occurring in nature and those, which have been isolated, purified and modified for the purposes of a particular

industrial application. This distinction still upholds the dividing line between product of nature and product of human ingenuity: the naturally occurring genes cannot be patented as opposed to those isolated and purified ones. It has to be noted however that genes indeed pose a challenge to the existing patent regime. Therefore, each of the requirements of patentability must be reviewed again to sketch an exact scope, which is to be fulfilled by gene-based inventions. The dividing lines between the patentable and not patentable genetic material appear however still obscure.

Also the economic efficiency of the patent protection on gene-based inventions is questionable. Contrary to the expectations standing behind the decision to protect gene-related inventions by patents, the recent developments are frightening: there is an impasse in the research and development process in the biotechnological and pharmaceutical fields reflected by the inability of the industry to conduct post-invention research. The main reason for this impasse is the excessive proliferation of property rights coupled with the grant of too wide patent protection. As a consequence, the downstream research is completely impossible, too expensive or not profitable. It follows that the development of new therapies and pharmaceuticals is not only not promoted by patents but rather impeded by them. What would be the best solution to the current deadlock? Most frequently three ways are proposed: narrower utility requirement, patent pools and compulsory licensing. The last one seems to be the most comprehensive and persuasive.

I. Introduction

Biotechnology and more specifically gene technology has become popular over the last ten years sparking emotional discussions in the scientific and non-scientific circles. Biotechnological advancements are truly amazing: Mapping and sequencing of human genome sketches a map of the entire human DNA sequence. Such a map raises hope for the development of new therapies and cures for the most intractable and devastating diseases: it guides the paths of biotechnological research, which were up till now determined mostly by chance. This accelerates the search for the molecular causes of particular ailments what is essential to discovering new therapeutic targets.[1] As a consequence, new generation of medicines and therapies may be developed. This new class of medical tools based on human genes, antibodies or proteins promises medical benefits going far beyond those of conventional drugs. As William A. Haseltine, the Chairman of the Board of Directors and Chief Executive Officer of the Human Genome Sciences, observes, "[h]uman molecules pose fewer toxicity hazards, and for that reason alone may be easier to shepherd through clinical trials. It is also easier to identify and test a selection of candidate human-derived drugs in the laboratory than it is to test a range of small-molecule drugs, because far less medicinal chemistry is needed. This will help to eliminate expensive testing of drugs that will ultimately fail in patients and healthy volunteers."[2] Moreover, whereas conventional medicines compensate for a deficiency only for as long as the drug is present, gene-linked pharmaceuticals hold the potential to regenerate tissues that have been damaged by age, disease, or trauma on a long-term basis.[3] "The power of genomics (i.e., the use of large collections of human genes to answer biological questions) is that we are beginning to understand how the body's manifold components communicate. We are learning how to activate and manipulate the body's own systems for repairing and restoring itself. We can do this because we know the signals the body uses to tell cells to move, differentiate, or die."[4] Therefore, "the sequencing of the human genome marks a watershed in mankind's development."[5]

Yet, no matter how the biotechnological and genetic achievements were desired by medicine, they cause a great ethical unease. On the one hand, biotechnology undeniably has the ability to change the nature what may entail unpredictable consequences. On the other, trying to find new ways to cure diseases, it tampers with parts of human body thereby affecting their subjective value inferred from the inheritable connection with humans

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[1] "Convergence, The Biotechnology Industry Report", 2000, Ernst & Young Millennium Edition of the Annual Reports on Biotechnology Industry, p. 14.
[2] Supra no. 2.
[3] Supra no. 2.
[4] Supra no. 1, p. 7.
[5] "The European Life Sciences Boom: Looking Back and Ahead", available at: http://www.ey.com/GLOBAL/content.nsf/International/Eighth_Annual_European_Life_Sciences_Report_2001_continued; being an excerpt from "Integration: Ernst &Young's Eighth Annual European Life Sciences Report 2001".

and rendering them a mere object of research, patents and commodification. As a consequence, the contemporary social and ethical order may be threatened. As Laurie Zoloth puts it, "at stake is not only the rules of play, and not only the consequences of action … but the question raised by James Keenan (1999): Who are we and what we become when we do this thing?".[6]

The debate concerning biotechnology evokes inevitably the question of necessity and desirability of patents on human genes. Patents are needed to foster the pharmaceutical industry. Without them the investment in the biotechnological field would be substantially lower meaning less inventions and slower research and development path leading to the reduced development of pharmaceuticals. In other words, patent protection stimulates the biotechnological developments. However, given that these developments are often controversial, the question arises, whether the fostering of gene technology by human gene's patentability is ethically desirable. Or conversely, does ethics have persuasive arguments to bar the patentability and/or medical application of human genes?

The patents on inventions based on human genes raise some doubts also from the legal perspective. The existing patent regime emerged in the nineteenth century as an upshot of the Industrial Revolution. This particular historical context, seeking to protect mostly mechanical devices, shaped the requirements of the regime drawing a clear borderline between patentable and unpatentable subject matter. The recognition of the living matter as eligible of patent protection has however blurred the dividing line. Do genes, being rather discovered than invented, fit into the patent regime? In which form can they fulfil the requirements of novelty, inventive step, the susceptibility of industrial application?

Finally, the arguments opposing patents on genes are often refuted with a counter thesis positing that patent protection, despite of all its deficiencies, secures the development of pharmaceuticals therefore needs to be granted. The empirical evidence shows however that patents can also entail excessive proliferation of property rights. The current situation in the genetic field presents a deadlock in research and development process caused by the extreme fragmentation of rights and resources. As a consequence, the pharmaceuticals either cannot be developed or are unduly expensive, which suggests that patents on genetic material (at least in the existing scope) restrict rather than promote access to innovative health care. How to redress the balance between the protection and stimulation to innovate leading to efficient research and development process?

This thesis tries to answer all the above questions. It commences with an analysis of the background accounting for the decision to grant patent protection for genes (Chapter II). Chapter III explores the ethical debate around the patents on human genes and is concluded by an analysis of the interplay between gene technology and human rights. Chapter IV concerns the problematic legal requirement, i.e., the fulfilment of patentability requirements by gene-based inventions. Chapter V addresses the economic efficiency of the existing patent regime in the genetic field.

[6] Zoloth, "Jordan's Banks, A View from the First Years of Human Embryonic Stem Cell Research", in "Stem Cell Research: A Target Article Collection", The American Journal of Bioethics 2002, p. 7.

II. Need of patents

Biotechnology is a branch of science, whose achievements are of primary importance for human health. Its developments in form of medical products or therapeutic methods hold an immense curative potential what implies their significant commercial value. Yet biotechnology has also its drawbacks. The major concern connected with biotechnological research and development (R&D) process is the uncertainty in the art. The uncertainty is caused by the high start-up costs of the biotechnological R&D coupled with the risk involved in producing a successful end product and the hazards of free-riding activity.

A. Uncertainty in biotechnological and pharmaceutical industries

On the one hand, the biotechnological R&D process is marked by a high rate of failure. As Qin Zhang notes, "what may be a theoretically feasible procedure may not, in reality, bring the desired result. The complexity of the working materials and numerous surrounding factors result in uncertain success rates for any new experiment."[7] The empirical experience proves this observation true: Out of a total of about 10,000 substances synthesised by a research laboratory with a theoretical potential to be developed into marketable products, patent filings will be sought for only selected few hundred, out of which only one or two will be actually placed on the market (for the process of pharmaceutical research and development see Appendix).[8]

The high rate of failure is logically accompanied by time and cost intensity. It takes 10 to 12 years to develop a newly synthesised active substance into a marketable medicine.[9] The length and complexity of the biotechnological R&D require accordingly huge investments. The costs, which need to be recouped, include the cost of carrying out clinical trials of novel medicines, the regulatory requirements regarding safety and the costs of investments in research and development which do not succeed in producing a new product.[10] The expenditure on biotechnological R&D is covered in a major part by the private sector. Yet, the proportion between the outlays on R&D and the incomes from the marketed products does not look encouraging. The U.S. biotechnology industry lost $4.1 billion dollars

[7] Zhang, "Patent Law and Biotechnology: A Proposed Global Solution for the Public and the Biotechnology Industry", Southwestern Journal of Law and Trade in Americas 2002-2003, p.195.

[8] Kon/Schaeffer, "Parallel Imports of Pharmaceutical Products: A New Realism or Back to Basics", European Competition Law Review 1997, p. 124.

[9] Vicién, Why Parallel Imports of Pharmaceutical Products Should be Forbidden", European Competition Law Review 1996, p.220.

[10] Nuffield Council on Bioethics, "The Ethics of Patenting DNA – A Discussion Paper" July 2002, p. 14.

in the fiscal year 1993-94 and $3.6 billion in the 1992-93 fiscal years.[11] The R&D costs have substantially increased in the last years (see the figure below).

Source: http://www.nefarma.nl/upload/website/jaarverslag/FBENG.htm

The second aspect of the biotechnological uncertainty concerns the simplicity with which the successfully marketed products can be copied. As the European Commission's Report, "Innovation Policy in a Knowledge Based Economy", puts it, "in information-based industries such as pharmaceuticals … and biotechnology there is an enormous gap between the costs of discovering or developing a new innovation and the ease with which they can be copied".[12] This constitutes a significant threat for both researchers' and investors' side. Copying impedes the commercial value of a product developed. As Rebecca Eisenberg observes, "if successful inventions are quickly imitated by free riders, competition will drive the prices down to a point where the inventor receives no return on the original investment in the research and development. As a result, the original may be unable to appropriate enough of the social value of the invention to justify the initial research and development expenditures".[13] This, in turn, may result in under-investment. To avoid such an outcome, the patent protection system has been brought on the scene.

B. Patent protection

Patents are one of the most important incentives to engage in biotechnological R&D. They stimulate the commercial enterprises to undertake research and development by allowing them to enjoy returns on the generation and application of knowledge.[14] The key advantages of patents are the stimulation of inventing and promotion of disclosure, which enables other inventors to learn about them and to develop improvements and alternatives.[15]

[11] Supra no. 1.
[12] European Commission Report, "Innovation Policy in a Knowledge Based Economy", available at www.irc-irene.org/do-organisation.html.
[13] Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use", University of Chicago Law Review 1989, p.1017.
[14] Supra no. 10.
[15] Supra no. 10.

Patents serve as an incentive to invent. They accord monopoly rights for twenty years over an invention, which fulfils the requirements of inventiveness, novelty and susceptibility of industrial application,[16] enabling the patent holder to make, use or sell it.[17] Therefore, they reward the efforts of an inventor and, by allocating benefits directly to the companies making the investments, serve as an incentive to invent in the production and application of knowledge.[18]

They counteract also the-free riding activity. Preventing any unauthorised uses, they eliminate the threat of unauthorised copying thus securing the profitability of the investment in the biotechnological research. Therefore, the second aspect of biotechnological uncertainty may no longer play a role.

Patents contribute also to dissemination of new knowledge and increase efficiency of the research through the requirement of disclosure of invention. Such a disclosure is, on the one hand, desired by the scientific community, because the advancements of knowledge are achieved most rapidly through interchange of ideas between the researchers. It is also congruent with the traditions of the community, since one of the most significant rewards for a scientist is recognition of the successful result of his research by the scientific environment.[19] It has also a positive impact from an economic perspective. Disclosing informs other researchers about the current stance of knowledge thus allowing them to avoid duplicative research. This enables also the industry to direct its resources into unexplored areas thus to be saved from wasteful investments since there usually will not be any commercial incentive in inventing the same creation multiple times.

Patent protection serves also as a viable alternative to trade or actual secrecy[20], which would be probably resorted to if patents were not available.[21] The protection through secrecy is perceived as a less beneficial means than the patent protection. Its major aim is to prevent pervading the information enclosed in an invention to both the public and the scientific community. This forecloses scientific recognition and is disruptive of scientific communication. But paradoxically it does not offer much in exchange. Under the realm of secret protection may fall only inventions, which would not generally be known or readily ascertainable by proper methods. This creates considerable practical difficulties to maintain a secret making it at the same time costly foiled easily. Furthermore, the scope of the

[16] European Patent Convention of 5 October 1973, Article 52 (1); Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, Article 3 (1).
[17] WIPO Intellectual Property Handbook 2001, p.17.
[18] Supra no. 10.
[19] Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research", Yale Law Review 1987, p.177.
[20] Rebecca Eisenberg distinguishes between these two kinds of secrecy explaining that legal trade secrecy "affords a remedy in tort to persons who disclose certain kinds of information in confidence against those who breach this confidence or otherwise misappropriate the information" whereas actual secrecy "is a practical, nonlegal strategy for protection that may be effective in circumstances where not all of the requirements for trade secrecy protection have been satisfied." See supra no. 19.
[21] Supra no. 19.

protection conferred is limited. As Rebecca Eisenberg observes, "this requirement insulates from liability anyone who derives the trade secret through independent research, reverse engineering, or information obtained from publicly available sources. Once the secret becomes generally known to other scientists through independent discovery, the first discoverer loses protection." Thus the protection through undisclosed information seems fragile and easily violable.

Overall, patents reconcile the incentive to invent with the incentive to invest. As Barbara Looney puts it, "genome researchers need the incentive that a patent provides… [because] … investors simply will not invest in genome research without the guarantee of patent protection and its corresponding commercial reward."[22] Similarly, the Nuffield Council argues that patents do play a significant role for the pharmaceutical and biotechnological industries: "while patents may not always increase innovation, when they do, it is usually in the pharmaceutical and biotechnology sectors."[23] Of particular importance are patents especially for small companies: "The possession of patents helps to attract financing, especially support from venture capital, and assists in the establishment of alliances, enabling companies to share the costs of research and development, or in providing support when a product is put on the market. Some biotechnology companies do not in fact manufacture products, but engage in research with the aim of funding their work and of making profits by licensing their patents and databases."[24] Therefore, the Council comes to the conclusion that: "[i]t is in general in the public interest that there be a patent system which promotes inventions such as new medicines and other medical products by providing an incentive in the form of limited monopolies. … [W]ithout patent protection, some novel medicines might never be invented."[25]

III. Ethical concerns

Yet, the stimulation of commercial incentives in the field of biotechnology has raised significant concerns as to its impact on the moral values and principles on which human society is built. The commercial perspective introduces a simple cost-benefit analysis as a major factor in deciding whether to commence, continue or drop the research. Yet, biotechnology exceeds the pure economic logic and challenges the fundamental values on the ethical level, making the biotechnological patents highly controversial.

The inventions in biotechnology are closely connected with humans. They often deal with or consist of human genes, germ cells, and proteins.

[22] She bases her statement on an interview with Dale Hoscheit, an international patent lawyer in Washington D.C.; see: Looney, "Should Genes Be Patented? The Gene Patenting Controversy: Legal, Ethical, And Policy Foundations of an International Agreement", Law ans Policy In International Business, Fall 1994, p. 231.
[23] Supra no. 10.
[24] Supra no. 10.
[25] Supra no. 10.

Patents, on the other hand, are often connected with market values. Indeed, they confer property rights over a patented creation. This is where the controversy between patents and ethics begins. Bestowing exclusive property rights over parts of the human body (seen by many simply as "patents on humans"), i.e., something perceived by many as sacred and untouchable because inherently connected with human personality may imply an altered perception of self or humanness in general.

The controversy-prone interplay between economics and ethics is best reflected by the conflicting emotions evoked by biotechnological advancements and their patentability. Biotechnology has been welcomed and promoted since it gives hope to conquer contemporarily incurable diseases. But at the same time, it has become a cause of fear because it holds the potential to intervene at a greatest thus known scale into the human body and human development.

The scale and potential of the biotechnological intervention into humans raise questions about its future outcomes and implications. Being just at the dawn of the biotechnological evolution (the famous Dolly the Ship was cloned in 1996), the scientific community is still in the process of learning about the complex world of genetics, thus cannot answer the crucial question where will the changes, modifications and improvements ultimately lead. As long as the picture of all ramifications is not completed, there remains uncertainty about the future outcomes substantiating the fear.

A. The ethics of DNA patenting

Although the promises the genetic technology seems to give are indeed close to miracles and thus generally welcomed, they are also a cause of a great unease. Much of the controversy arises out of the confusion the genetic or biological terms spark in the non-scientific spheres. This may easily turn into a pure speculation as to the scope and the abilities of the technology taking a fearful dimension of a branch of science holding power to transform the human race into Nietsche's "Über-" or "Untermenschen", or the "conditioned" society of Huxley's "Brave New World". But even understanding the real potential of the genetic technology, its rapid advancements may give rise to significant concerns.

Let us focus the analysis on human genes, the basic element, by the means of which the gene technology may proceed into any of its further applications. Does DNA have a special ethical status, which would be infringed by gene's patentability? Does it fit into the patent regime, requiring novel, inventive and industrially applicable inventions? And lastly, is the patentability of genes and genetic inventions not detrimental to health care?

1. The achievements and promises of biotechnology

What is the difference between DNA, genome or genes? To avoid confusion about the different elements falling under the common notion of "genetic material", I shall commence with an explanatory note concerning the relation between the above terms.

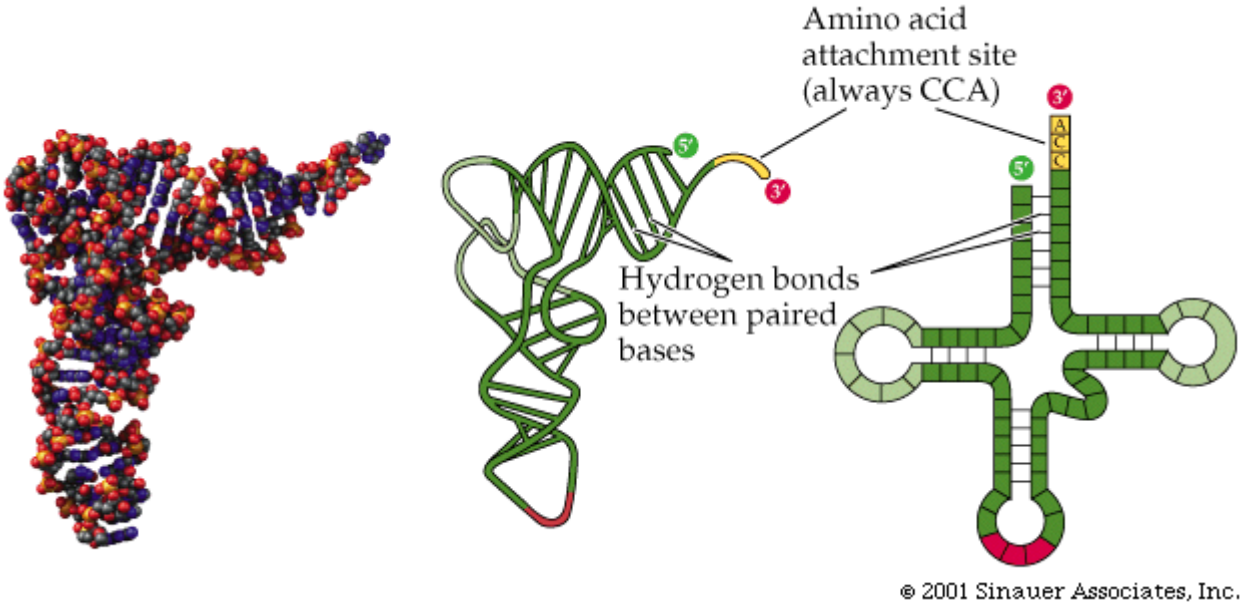
a) Human genome

The entirety of all human hereditary material is known as human genome. The hereditary material is contained in each human cell, i.e., in its nucleus, in the form of forty-six chromosomes organised in twenty-three pairs (except the reproductive cells containing the half of it). Each chromosome constitutes a molecule of DNA.[26] The whole set of chromosomes (i.e., twenty-three pairs) is present in each of the cells in the same form, constituting the genome.

b) DNA

DNA (i.e., deoxyribonucleic acid) is organised as a double-stranded and twisted chain built up from nucleotide sub-units. They consist of four bases, adenine (A), thymine (T), guanine (G), and cytosine (C), which are arranged correspondingly on each of the strands (A always forms a pair with T, G with C). Always three bases (ATC for example) constitute a codon, an entity coding for particular amino acids. The amino acids are building blocks of proteins, which provide structure to and mediate chemical reactions within the cell.[27]

[26] Ridley, "Genome" 1999, p. 6.
[27] Curtis/Barnes, "Invitation to Biology", 1994, p. 254-267.



c) Human genes

Gene is a fragment of DNA, which through the particular sequence of codons contains information about the particular sequence of amino acids thus the function and structure of a protein built by them. Thus, coding for production of particular kind of protein, genes determine the characteristics of cells, what in turn collectively determine the characteristics of the individual.[28]

2. Status of DNA

Why is there any debate over the patenting of genes? Why should the genetic patents be perceived antithetical to ethical or moral values?

It all originates from the controversy over the status of human DNA. The core question is, is human DNA just a chemical compound, which can be patented like other chemicals? Or is it something more than just a chemical, whose patentability undermines our humanness and poses a threat to human dignity?

While the industry sees DNA as a pure chemical compound, by the means of which new and more effective medicines and therapies may be developed, the scientists, media and universities tend to ascribe a special status to human genes.[29] Both attitudes may have somewhat opportunistic background. Minimising the significance of DNA could be underpinned by the hope to minimise the possible moral offence that could ensue the patent

[28] Curley/Caperna, "The Brave New World Is Here: Privacy Issues and the Human Genome Project", Defense Counsel Journal 2003, p. 22.
[29] Morse, "Searching for the Holy Grail: The Human Genome Project and Its Implications", Journal of Law and Health 1999, p. 219.

practise.[30] On the other hand, propounding the significance of DNA above the meaning of the other body compounds may serve as a useful way for attracting capital investment for the research, or capturing the attention of the public. Who is then tantalising? Let us consider arguments as well as the professed implications of the gene technology of both sides.

a) Genes in the viewpoint of society

Francis Crick, one of the discoverers of the double-helix nature of DNA wrote: "You, your joys and your sorrows, your memories and your ambitions, your sense of personal identity and free will, are in fact no more than the genetically determined behaviour of a vast assembly of nerve cells and their associated molecules."[31] Similarly, his co-discoverer, James Watson: "we used to think our fate was in our stars. Now we know, in large measure, out fate is in our genes."[32] Both men of authority seem to suggest that everything that defines us, what shapes our personality, and constitutes the unique individuality of each of the humans, rely in fact on the genetic information contained in each of our cells. In other words, we are a product or perhaps an expression of the information written in our genetic material. It follows that human genes are the sole and decisive factor in deciding who we are and what we will become.

The link between genes and human personality signalised by the prominent representatives of the scientific community has revolutionised the way the rest of the society looks at human genes. For example, the anthropologist Kaja Finkler writes: "[E]verything about an organism's existence is predetermined and genetically programmed, including its variation, although geneticists recognise that the program may be affected by unknown and external factors in the environment, chance or human manipulation. The sequence of our DNA reveals to us who and what we are; that is what it means to be human."[33]

The genetic revolution has not only contributed to the increase of importance attributed to the role played by genes by laypersons, but also deeply impacted the moral and religious values. If genes shape our personality, there is no place for God, fate or destiny. And indeed, our time has been described as a world of "gene hegemony"[34], where DNA has replaced the concept of human soul, being perceived throughout the centuries as the focal point in understanding and defining humanity. As Dorothy Nelkin and M. Susan Lindee observe, "[t]he gene has become a way to talk about the boundaries of personhood, the nature of immorality, the sacred meaning of life in ways that parallel theological narratives. Just

[30] "Religious Voices in Biotechnology: the Case of Gene Parenting", The Hastings Center Report 1997, p. 4.
[31] Crick, "The Astonishing Hypothesis: the Scientific Search for the Soul" 1994, p.3.
[32] Watson, quoted in Curley/Caperna, "The Brave New World Is Here: Privacy Issues and the Human Genome Project", Defense Councel Journal 2003, p.22.
[33] Finkler, "Experiencing the New Genetics: Family and Kinship on the Medical Frontier" 2000, p. 48.
[34] Supra no. 33.

as the Christian soul has provided an archetypal concept through which to understand the person and the continuity of self, so DNA appears in popular culture as a soul-like entity, a holy and immoral relic, a forbidden territory. … DNA has taken on the social and cultural functions of the soul. It is the essential entity – the location of the true self – in the narratives of biological determinism."[35]

While DNA has been ascribed such a significant role, the fear inspired by every genetic modification and the outrage caused by the successful attempts to patent human genes become understandable. If DNA is to be equalised with the very essence of man, it becomes sacred and untouchable, like the Christian soul has been seen as sacred and untouchable for ages. It implies further that tampering or even patenting DNA violates its sacredness and truly puts human scientists in the position of playing God rising at the same time significant ethical concerns. [36]

Yet, alone the assertion that genes shape human personality cannot cause an ethical condemnation of gene's patentability. Gene technology and its patentability can be ethically rejected only when it factually holds the potential to interfere with ethical values. In other words, only when the science confirms that genes are indeed responsible for the shape of human personality their patenting or research on them can possibly be seen as ethically inappropriate.

b) The attitude of scientific community to human DNA

The recent years have brought revolutionary changes in the way of medical thinking. As the advancements in genetic knowledge progressed, many diseases have been linked to a dysfunction or a disorder of particular genes. Therefore, it has become a priority to acquire the widest insight possible into the location, structure and functioning of human genes.

The major source of knowledge about the structure and functions of DNA has been the results of so-called Human Genome Project (HGP). The HGP has been an international effort, which has aimed at identifying the full set of genetic instructions contained inside human cells and to translate the complete text written in the language of the hereditary chemical DNA.[37] It began in 1988 and since then has attracted researchers from twenty-six countries, inter alia the United States, the United Kingdom, Germany, Japan, China and France.[38] Europe (taken as a whole) participates in the costs of the HGP in a proportion of 30 – 40 per cent.[39]

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[35] Nelkin/Lindee, "The DNA Mystique: The Gene as a Cultural Icon" 1995, p. 41-42.
[36] Supra no. 30.
[37] Knoppers/Hirtle/Lormeau, "Ethical Issues in International Collaborative Research on the Human Genome: The HGP and the HGDP", Genomics 1996, p. 272.
[38] Sturges, "Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind", American University International Law Review 1999, p. 219.
[39] Piazza, "The Human Genome Project and the Genetists' Responsibility", in: Mazzoni, "Ethics and Law in Biological Research" 2002, p. 21.

The major goal of the HGP has been the mapping and sequencing of the complete human genome. Mapping means assigning genes to specific chromosomes and locating them on DNA chain.[40] Sequencing – translating genes into their basic bases structure.[41] The knowledge acquired should serve to analyse the genomic variability what may help in the study of human evolution, and of diseases whose origin or predisposition are genetically controlled. It may also be a precious marker for the study of complex diseases such as cancer, diabetes, cardiovascular and mental diseases, to whose risk several genes contribute each in reduced measure.[42] The information from the HGP should contribute to further development of functional genomics concerned with the interaction between each individual genome and its environment under normal conditions and in contact with other organisms. The HGP has also been partly devoted to study of non-human genomes, what has been aimed at comparing them with those of humans in the quest for universal biological mechanisms possibly explaining more complex genetic functions.[43] Overall, the HGP has been seen as foundation to a "book for biomedical science in the next [i.e., already current] century".[44]

In June 2000 a "working draft" of the human genome was announced as accomplished, claiming to represent ninety percent of genetic composition of chromosomes. This led to a declaration on February 12, 2001 that the very first readable draft of the "Book of Men" has been produced.[45]

On April 14, 2003 the sequencing of the human genome was completed, covering about 99 percent of the human genome's gene containing regions, at the accuracy rate of 99.9 percent.[46] "The completion of the Human Genome Project is a truly momentous occasion for every human being around the globe"[47] commented Nobel Laureate James D. Watson. Yet it "should not be viewed as an end in itself. Rather, it marks the start of an exciting new era – the era of the genome in medicine and health"[48] adds Fancis S. Collins, the Director of the National Human Genome Research Institute, one of the two leaders of the HGP for the United States.

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[40] Costa, "Genetic Testing: International Strategies to Prevent Potential Discrimination in Insurance Risk Classification", Suffolk Transnational Law Review 1996, p. 109.
[41] Supra no. 28.
[42] Supra no. 39.
[43] Supra no. 39.
[44] Supra no. 37.
[45] Supra no. 28.
[46] Human Genome Project Information Webside, available at www.ornl.gov/TechResources/Human_Genome/project/50yr.html (visited on 11.08.2003).
[47] International Consortium Completes Human Genome Project, Bethasda, Maryland, April 14, 2003, Press Release, available at www.ornl.gov/TechResources/Human_Genome/project/50yr/press4_2003.htm.
[48] Supra no. 47.

c) The fascination with master molecule

The proclamations in the kind of "the Book of Men" seem indeed to suggest that the HGP, by researching on and acquiring knowledge of the human genetic material is the first step to unravel the secret determinants of humanness. Indeed, the scientific community seems to be truly fascinated by the opening world of genetics what accounts for the tendency to treat human DNA as a "master molecule".[49]

The first and contemporary foremost dimension of this fascination concerns the medical utility of genetic material. As Alison Morse observes, "[t]he wide adoption of DNA as master molecule, which can 'control' manifested traits from disease to personality, is seen in the scientific community in the incredible explosion of trials for differing gene therapies".[50] The "personal" or mental dimension (i.e., the role of genes for human personality) appears faintly in background but does not play a primarily role. Possibly however, the understanding of the role of genes for the development of diseases is the first step on the path leading to unravel their role in shaping human personality: if genes independently of all other factors cause in the process of formation of the entire organism a development of a disease, they might also play a similarly master role for the development of personal traits. In other words, if DNA is indeed to be seen as a master molecule, which controls the cellular processes and thereby is responsible for the shape and functioning of the entire human body, it is highly probable that it also endows people with particular personal characteristics. Let us then look at the role of genes in the cellular processes scrutinised in the course of development of genetic therapies.

d) Genes and development of certain diseases

The scientists have been indeed experimenting with gene therapies basing on the premise that some diseases are exclusively determined by genetic factors. This assumption implies that a discovery of a defected gene will lead to an effective gene therapy, which intervening in the altered spot, will cure or prevent the disease. But is the discovery of the link between a gene and a disease really sufficient to improve nature?

Some say it is. "A significant number of genetic disorders, approximately 1,050 as of 1995, have been correlated with specific chromosomes or even particular genes".[51] Diseases like cystic fibrosis, Tay - Sachs disease, Down Syndrome, Thalassaemia, Huntington's chorea, amyotrophic lateral sclerosis, and colon cancer (to name just few) are

[49] Supra no. 29.
[50] Supra no. 29.
[51] Iles, "The Human Genome Project: A Challenge to the Human Rights Framework", Harvard Human Rights Journal 1996, p. 27.

claimed to be genetically determined.[52] Thus, "the promise [of the research on the human genes] is great … [because] to identify the causes of human disorders is the first step toward their prevention or cure".[53] Interestingly, guided probably by similar considerations, "[t]he [American] National Institute of Health is spending an estimated $200 million a year to develop and test tools and techniques for gene therapy. Private companies have raised hundred of millions of dollars to enter the field and are now sponsoring most of the clinical trials. Many academic centres have created gene-therapy programs and joined the jockeying for a piece of action".[54]

Yet, there are also strong opposing voices. Anne Lawton contends that the scientific knowledge acquired in the course of genetic research is limited. Even if a particular disease is related to a genetic defect, genes do not operate in a vacuum. Therefore, the assumption that a detection of a genetic defect lays just a small step from developing a curative gene therapy seems to have been made too quickly.[55]

Let's consider the scientific facts. Diseases related to a genetic defect occur in basically three forms. There are single (or monogenic) genetic disorders, which result from the dysfunction of a single gene.[56] There are also multigenic (or polygenic) genetic disorders, which are based on an interaction involving many genes.[57] And there are multifactorial disorders, which are caused by malfunctioning genes in conjunction with other factors. Some genetic disorders may be both polygenic and multifactorial.[58] Against this background, gene therapies may be an effective cure only in case of a dysfunction of a single gene, which may be substituted in the course of such a therapy by its properly functioning equivalent. Yet the single gene disorders are the exception, not the rule. Most common disorders are multigenic.[59] In the case of multigenic and multifactorial disorders the gene therapies will probably prove ineffective. Maurizio Salvi provides an example. On 14 September 1990 a gene therapy was performed on a patient, who, born with a rare genetic disease, lacked a healthy immune system. The therapy has not however achieved the expected scientific goal. The patient died on 17 September 1999. [60] The author observes, "[t]he multiple relationship among genes, disease proteins and the immune system (only to quote some factors) have shown the impossibility of reducing genetic diseases to simple causative factors to be simply 'substituted' by non-defective corresponding nucleid acid sequence."[61]

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[52] Kirby, "The Human Genome Project – Promise And Problems", Journal of Contemporary Law and Policy 1994, p. 6.
[53] Supra no. 52.
[54] Marshall, "Gene Therapy's Growing Paints", Science 25.08.1995, p. 1050.
[55] Lawton, "Regulating Genetic Destiny: A Comparative Study of Legal Constrains in Europe and the United States", Emory International Law Review 1997, p. 365.
[56] Supra no. 55.
[57] Supra no. 55.
[58] Supra no. 55.
[59] Supra no. 55.
[60] Salvi, "Genetics' dreams in the post genomics era", Medicine, Health Care and Philosophy 2002, p. 73.
[61] Supra no. 60.

The complexity of genetic disorders is also highly dependent on the external influences and the environment. It means, that the existence of a genetic defect may not mean anything. The genetic mutation will turn into a factual predisposition only if it is associated with unfavourable external factors.[62] Therefore, as Alberto Piazza, Professor of Human Genetics at the University of Turin, observes that the polygenic and multifactorial pathologies should not even be called "diseases", precisely because they are conditioned by the presence of environmental factors.[63]

Furthermore, the emphasis on genes as the exclusive determinant of human diseases may lead to negligent treatment of other causative factors, what could result in deteriorating of human health care. As professor Jonathan King of the Massachusetts Institute of Technology and member of the board of Council for Responsible Genetics, , observes, "[w]e are concerned that the emphasis on gene sequences will be used to imply that genes are the basis of a variety of human disease and conditions, when in fact the great body of evidence establishes that the majority of human ill health is not inherited but is due to external insult including pollution, infection, inadequate or inappropriate diet, physical accident, excess stress or social disruption such as wars. Preventing damage to human genes from carcinogens is a far more effective public health strategy than allowing the disease to develop and then attempting gene therapy."[64]

Thus it seems that the link between genes and diseases is too simplistic, what implies that the hope for a soon curative gene therapies appears pretty naive. Undeniably, detection of genetic disorders may be an important informative source, but the stance of current knowledge does not suffice to control and cure complex gene-related diseases. Therefore, the therapeutic capacity of genetics "stands out in perspective where technological innovation still needs very advanced research".[65]

The above analysis has shown that DNA should not be seen as a sole and decisive determinant of genetically linked ailments. Undeniably, genes play a role for the development of certain diseases by endowing an individual with a potential to fall ill. Therefore, they can help medicine to acquire information about the propensity to them and possibly in the future contribute to cure them. Their role however cannot be overestimated. In the case of most genetically linked ailments genes are only one of the factors contributing to a development of an illness. Without an interaction with other factors such as immune system or external influences a disease may never occur. They are thus but a small part in a very complex process, whose each element is equally important. That undermines the perception of DNA as a master molecule and questions their role in shaping human personality.

[62] Supra no. 55.
[63] Supra no. 39.
[64] Brashear, "Evolving Biotechnology Patent Laws in the United States and Europe: Are They Inhibiting Disease Research?", Indiana International and Comparative Law Review 2001, p. 183.
[65] Supra no. 39.

3. Lack of justification for the special status?

a) Biology and "master molecule"

As has been indicated above, biological genes are only one of the components of a process of cellular reproduction, which as a whole is exposed to a strong influence of external factors. Roger Hoedemaekers and Wim Dekkers (2001) pursue an even deeper analysis. The authors try to find a justification for the special status of DNA in its natural, biological characteristics. Yet, they come to the conclusion that genes, similarly like the other components (cytoplasm, ribosomes and mitochondria), are present in every body cell; similarly like the structure of proteins and enzymes, their structure may serve as a source of information about the sequence of chemical subunits it consists of.[66] Therefore, if anything should deserve a special status, "[t]here is more reason to term the whole process of cell reproduction unique than to single out one particular component of this process. … For cell reproduction, the other cell components are as essential as DNA. Why should only the genome be perceived as a unique substance? A distinction between genes as carriers of information and the cell as carrier of information seems arbitrary given the complex character of cell reproduction."[67]

Should DNA be awarded a special status because it plays an important role in the production of amino acids and thus proteins, which determine the characteristics of the individual? Yet, as it has been discussed earlier, there are a number of factors, which contribute to organism's development. Thus, "[i]t is not so much the functioning of particular genes, but the interaction of the total human genome with the environment, that produces the human body and its typical properties".[68] If there should be any special status, it should be assigned to all the contributing factors equally.

Should DNA be termed special because, as David B. Resnik proposed, genes occur in humans? The author argues, "[t]he most reasonable view on this distinction [between genes as such and human genes] is to say that biological context determines the humanness of genes: a gene is a human gene if and only if it contributes to the structure and functions of human being".[69] The humanness of genes is then the factor deciding about their special moral status. Yet, 98 percent of "human" genes occur also in non-human species.[70] This implies, that the genes, which contribute to the structure and functions of humans similarly contribute to the structure and function of other species. It would be illogical to treat the same gene differently depending on the organisms it occurs in.

Thus it seems that the perception of DNA as the master molecule is scientifically not justified. Genes alone are neither responsible for human

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[66] Hoedemaekers/Dekkers, "Is there a Unique Moral Status of Human DNA That Prevents Patenting?", Kennedy Institute of Ethics Journal 2001, p. 366.
[67] Supra no. 66.
[68] Supra no. 66.
[69] Resnik, "The Morality of Human Gene Patents", Kennedy Institute of Ethics Journal 1997, p. 44.
[70] Supra no. 66.

body properties nor for development of most of diseases. What about their role in the formation of human personality?

b) Genes and human personality

The analysis of the role of genetic factors in the development of human personality must necessarily commence with a clarification of what is understood under the notion "person" and what are the determinants of or personality or personhood. What is the relationship between body and person (mind or soul)? Does a body make a person?

The traditional philosophical approaches differ on this issue. Thomistic tradition, originating in Aristotle and found in Kant, postulates a close relationship between body and soul, the soul is being present in every body part.[71] The Cartesian tradition on the other hand posits a dichotomy between a material body and an immaterial soul.[72] Yet, to analyse whether DNA is endowed with a special status, is must be assumed that there is a strong connection between a person and a body, i.e., human body, if not seen as an inalienable part or expression of personality, is at least of particular importance for it. Otherwise it would be illogical to examine the role of something material (DNA) for something immaterial (personality).[73]

Roger Hoedemaekers and Wim Dekkers (2001) contend that personhood is not exclusively biologically determined but rather constitutes a social concept. It means that personality is not a result of a particular set of genes but it arises from and within social interactions, which assign specific rights and responsibilities to an individual.[74] The social context implies that the personhood expressed in each of the personalities of every human is formed by the interaction between individual and society modified through the cultural and/or religious contexts in the presence of particular biological predisposition. However, it is extremely difficult to discern the role of biology, i.e., the genes, from other environmental, social, cultural or religious factors contributing to the development properties thought to be characteristics of a "person". Therefore, the assignment of the entire responsibility for the formation of human personality to genes seems too far-fetched. They rather "constitute a necessary determinant for the development of *biological potential* for properties characteristic of persons".[75] A potential, which similarly like the cultural, social or religious potential to influence, is there or it is not and may possibly never leave its stamp on one's personality.

[71] Hoedemaekers/Dekkers, "The Ontological Status of Human DNA: Is It Not Fist and Foremost A Biological "File Self?", Theoretical Medicine 2002, p. 381.
[72] Supra no. 71.
[73] Supra no. 66.
[74] Supra no. 66.
[75] Supra no. 66.

4. Reasons underlying myths around genes

Undeniably, genes do play a role in the development of certain diseases as well as they do contribute to the shape of human personality. Their role however is not extraordinary. DNA is not a master molecule, which according to information inherited inevitably causes and supervises the processes of formation of human personality, body, or most of the diseases. Rather, being subjected to a variety of environmental influences, genes simply participate in them like all other relevant factors. Therefore, human genes do not deserve any special status.
Why is there then a myth about their role created by those, who should know the best, the scientists?

a) Scientific reductionism

As Professor of Zoology, Ernst Mayr contends, one of the reasons underlying the genetic myth is the tendency to scientific reductionism. The reductionist framework is based on the premise that by discovering the smallest component of an object, the explanatory cause for the thing concerned will be found.[76] This approach has been proven successful in the field of physical sciences, which were able to produce a vast amount of energy from splitting the atom.[77] The reductionist logic has become very popular. "Our society rewards people who discover tangible things. This perpetuates the perspective of linear cause and effect as the only paradigm in which to explain our world and to get scientific recognition. Moreover, an easy cause-and-effect relationship fits nicely into a news sound bite."[78] Yet, what has indeed explained some natural phenomena is inadequate to explain others. Living organisms are too complex to be understood from the perspective of one of its elements. As the author observes, "the claim that every attribute of complex living systems can be explained through the study of the lowest components (molecules, genes, or whatever) struck me absurd. Living organisms form a hierarchy of ever more complex systems, from molecules, cells and tissues, through the whole organisms, populations and species. In each higher system, characteristics emerge that could not have been predicted from a knowledge of the components."[79] The critic of reductionist thinking in the context of genetics appears justified. As has been shown above, neither diseases nor personality or behaviour are exclusively caused by genes, but rather they evolve and are modified by the interaction between multiple factors. Thus, application of the reductionism to the role of genetics in explaining the functioning of the whole organism leads to false assumptions, which give rise to the exaggeration of the role of genes expressed in the view of DNA as a master molecule or the very essence of human.

[76] Mayr, "This is biology", 1997, p. 17.
[77] Hubbard/Wald, "Exploring the Gene Myth", 1997, p. 55.
[78] Supra no. 29.
[79] Supra no. 76.

b) Pursuit of own interests

Additionally, the amplification of the role of genes prioritises the research in the genetic field as opposed to other scientific areas, whose importance decreases because they do not deal with molecules "equally important for all humans". Thus, the genetic exaggeration serves the interests of many groups engaged to a smaller or larger extent in genetic R&D. On the one hand, the description of DNA as the master molecule, the very essence of human or book of men "grants power and prestige to the scientists who work with such material and may be rhetorically useful for attracting capital investment in their work."[80] On the other, due to the popularity of genetic research, the biotechnological companies "will be the recipients of funding for new technological breakthroughs in isolating genes and will profit from the marketing of DNA tests to doctors, employers and genetic counsellors."[81] Also the traditionally not commercial research institutes may have an incentive to foster the genetic myth. "Universities also benefit from the continued belief in this deterministic model, gaining access to substantial funds poured into this long-term project [the HGP], as well as the subsequent research projects that hopefully will make the half-billion dollars spent on the map of genome meaningful."[82] These funds ensure the interests of individuals who choose to research in the biotechnological field by securing the constant financial support required to conduct research. As Allison Morse predicts, "[t]his will eventually result in a substantially larger tenure track for scholars in this field as opposed to other medical or biological models and will perpetuate the stake research institutions have in this deterministic explanation for human behaviour."[83] Moreover, "the geneticist not only gains from this model through academic recognition, but also through financial gain. Most established molecular biologists are not only paid to map the genetic sequence, but many also have a financial stake in bio-technology enterprises, either as shareholders or as employees."[84]

Interestingly, also the media benefit from the genetic myth by gaining easy publicity by highlighting not always correct genetic sensations. Titles like "Mapping genes for human personality"[85], "Can you be born as criminal?"[86], "Do your genes drive you to drink?: Genes and alcoholism – Does it run the family?"[87] sound revolutionary. Therefore, they easily attract the attention of the public and thereby contribute to an economic success of the particular mass-medium. Worryingly, the accuracy of the information

[80] Supra no. 30.
[81] Supra no. 29.
[82] Supra no. 29.
[83] Supra no. 29.
[84] Supra no. 29.
[85] The title of an article in National Genetics, from 12th January 1996, p. 3-4.
[86] The title of the BBC's programmes called "Talking Point" from 6th August 2002, 14:31 GMT 15:31 UK.
[87] The title of an article in The Science Museum, London 2000, available at http://www.sciencemuseum.org.uk/on-line/genetics/society.asp (visited at 18.08.2003)

publicised often does not count. As Professor Amos Shapira notes, "[m]ore often than not, journalistic treatment has been superficial, ignorant sensational, manipulative, damaging, and exaggerated both in trumpeting unrealistic expected utility or benefits and in portraying an inflated picture of the risks and dangers, allegedly involved in certain technological developments."[88] Similarly Allison Morse, observes that "the fact that virtually all these links [between genes and certain behaviours such as schizophrenia, alcoholism, and homosexuality] have been denounced by further experiments do not garner the same kind of media exposure."[89]

c) Conclusion

The above suggests that reasons justifying the statements founding and promoting the special status of human genes are rather not to be found in science. The main problem spurring the controversy concerning patents on human genes lies therefore not in the consequences of tampering around human genes, which, similarly like other research on human body, does not seem ethically inappropriate, but in the exaggeration of facts, which leads people believe that human DNA deserves a special status. As Allison Morse puts it, "it is not the facts that are discovered by science that are the problem, but *the interpretation* of these facts, the meaning our culture places on them."[90] Therefore, the cause of the unease surrounding the research and patentability of human genes takes its origin in the genetic myth rather than in the real threat of contemporary ethical or moral values. Therefore, the lack of scientific justification for a special DNA status introduces the conclusion that there are no valuable ethical obstacles leading to a denial of patents on human genes.

B. Common heritage of humanity

Apart of the special status of human DNA, there is also another argument opposing the patentability of human genes. The Universal Declaration on the Human Genome and Human Rights[91] lays down that the human genome constitutes the common heritage of mankind. Article 1 of the Declaration states that,

> "The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their dignity and

[88] Shapira, "Biomedical Law: The Aims and Limits of Regulating Biomedical Science and Technology", in: Mazzoni, "Ethics and Law in Biological Research" 2002, p. 77.
[89] Supra no. 29.
[90] Supra no. 29.
[91] Universal Declaration on the Human Genome and Human Rights, adopted on 11 November 1997 by the General Conference of the United Nations Educational, Scientific and Cultural Organisation and endorsed by General Assembly resolution 53/152 of 9 December 1998.

diversity. *In a symbolic sense, it is the heritage of humanity.*"[92] [Emphasis added]

The principle of the heritage of humanity (called also the principle of the common heritage of mankind) is a traditional concept of international law, which has been applied by the international community to, inter alia, the Moon, deep seabed, or Antarctica.[93] It means that the rights and responsibilities of the objects belonging to the common heritage should be shared by all nations. The principle has led some authors to the conclusion that the entire genome as well as its parts (i.e., genes) should be owned by the whole humankind, i.e., confer rights and obligations over the human genome/genes on each and every member of the human family.[94] This understanding excludes any private property interests over genes because they seem contradictory to the concept of common property of them. The edge of the sword is here pointed out at the patentability of genes. "Recognition of the human genome as the common heritage of mankind means that the international community has to assure that the genome is not appropriated or disposed of by any individual or collective. It means that the genome should be regarded as 'owned' by humankind. Consequently, its uses and benefits must be available for all human beings. The human genome's proclamation as common heritage of mankind, therefore, seems to conflict with the recognition of human genes as subject matter of patent protection."[95]

Yet, the major question is, does the recognition of the genome as a common property equal the common property of genes? In other words, has the assumption that genes should be unpatentable because they form part of human genome belonging to the common heritage not been made too quickly?

The Declaration alludes solely to the entire genome. Human genome may indeed be treated as something special because in its entirety it distinguishes the human race from other species. The patentability of the entire genome would also lead to an inequitable outcome. Its patent owner would obtain exclusive rights to all human genes thereby being entitled to exclude all other humans from researching or working on any of them without its authorisation. Therefore, it is indeed hardly thinkable that the entire human genome would belong to a single patent owner. This logic seems to be consistent with the rationale of the Declaration, which always speaks of genome but never of genes: It is the human genome, which in a symbolic sense constitutes the heritage of humanity.[96] It is the genome, which "in its natural state shall not give rise to any financial gains."[97] Likewise, research on an individual's genome requires prior, free and

[92] Supra no. 91.
[93] Supra no. 38.
[94] See for example: Cahill, "Genetics, Commodification, and Social Justice in the Globalisation Era", Kennedy Institute of Ethics Journal 2001, p.229; supra no . 38.
[95] Pridan-Frank, "Human – Genomics: A Challenge to the Rules of the Game of International Law", Columbia Journal of Transnational Law 2002, p. 619.
[96] Supra no. 91, Article 1.
[97] Supra no. 91, Article 4.

informed consent[98] and shall not be conducted to the detriment of human rights, fundamental rights and freedoms and human dignity of individuals.[99] There is no mention about the patentability or unpatentability of genes. This suggests that the interpretation asserting the prohibition of their patentability is rather arbitrary.

Moreover, the language of the Declaration seems to be consistent with the current stand of patent law in Europe. Neither the European Patent Convention[100] nor the 1998 EC Directive on the legal protection of biotechnological inventions[101] (the Directive) recognises the patentability of the human genome. Included into the realm of patent protection are exclusively genes and even they are subjected to limitations. Article 5 of the Directive states that,

> "1. The human body, at the various stages of development, and the simple discovery of one of its elements, *including the sequence or partial sequence of a gene, cannot* constitute patentable inventions.
> 2. An element *isolated from the human body* or otherwise produced *by means of a technical process*, including the sequence or partial sequence of a gene, *may constitute a patentable invention*, even if the structure of that element is identical to that of a natural element."[102] [Emphasis added]

Recital no. 20 further explains,

> "[I]t should be made clear that an invention based on an element isolated from human body … is not excluded from patentability … *given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment*."[103] [Emphasis added]

The human genome is thus unpatentable. Furthermore, the Directive clearly codifies the unpatentability of any part of human's organism, including genes, in their natural state. It seems thus that the European patent regime is in line with the Declaration on the Human Genome and Human Rights. Even if the application of the common heritage principle should be expanded to genes, the Declaration states that "[t]he human genome *in its natural state* shall not give rise to any financial gains." By the way of deduction, the commercial exploitation of the human genome *not in its natural state* is not prohibited. Thereby, even if the silence of the Declaration on the Human Genome and Human Rights on genes were to be read as an implicit opposition to their patentability, the prohibition of their patentability applies exclusively to genes in natural state. This implies that

[98] Supra no. 91, Article 5.
[99] Supra no. 91, Article 10.
[100] European Patent Convention of 5 October 1973.
[101] Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30/07/1998.
[102] The Directive supra no. 101, Article 5.
[103] The Directive supra no. 101, Recital 20.

both documents, the Declaration and the Directive, set the same standard. Therefore, the contemporary European patent law does not violate the principles of the Declaration.

Yet, the discussion about the scope of application of the common heritage principle brings the question of the implications of exclusive rights conferred by gene patents. Do they grant an ownership over a part of human body and thus lead to commodification of people, violation of the right to privacy, enslavement?

1. Ownership

The objection of ownership is based on the assumption that patents, granting exclusive property rights over human genes, grant in a sense monopoly rights in part of another human being. Protected through patent regime, a patent holder acquires the right to preclude everyone who produces the protected biochemical material from transferring or commercialising it to third parties possibly even for non-commercial purposes.[104] Thereby, the argument goes, patents limit an individual in its self-autonomy and create a modern form of slavery.

Yet, it is questionable whether the above logic is correct. Firstly, patents do not in fact grant ownership rights.[105] The rights accorded by patents are more limited than the proper ownership rights. Whereas the ownership entitles to possess, use, dispose of, or alienate (through sale or donation for example) the owned object can be limited only by pertinent regulations, "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 or commercial purposes…."[106] Thus, patents entitle only the right to prevent others from unauthorised use being at the same time subjected to possible restrictions of exploitation by the patent holder. Therefore, the scope of the rights granted in the case of ownership and patent protection differs significantly. It implies that from the legal perspective patent protection cannot be equated with ownership.

The second objection refers to the claimed violation of the right to self-autonomy and enslavement. Rogeer Hoedemaekers and Wim Dekkers (2002) provide an illuminating analysis[107] hereto. They argue that it is generally inappropriate to use the notion "ownership" or "to own" to the relation between body and person. Property rights as such cannot be attached to a body in a sense that a person holds an ownership over the body similarly like one may own a thing. The relationship between body and person is "special and unique" and has rather an immaterial nature. It consists in "subjective experience" of one's body, by which it becomes a "metaphysical ownership"; not an owned thing but a personified self.

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[104] Demaine/Fellmeth, "Reinventing the Double Helix: A Novel and Nonobvious Reconceptualisation of the Biotechnology Patents", Stanford Law Review 2002, p. 303.
[105] Crepi, "Patenting and Ethics – A Dubious Connection", Journal of the Patent and Trademark Office Society 2003, p. 31.
[106] Recital 14 of the Biotech Directive, supra no. 101.
[107] Supra no. 77.

Yet, when body material is separated from the body, the special relation between person and body ceases. The body material becomes a thing, over which property rights can be conferred. The authors suggest that a distinction should be made between "naturally occurring DNA in cells forming still part of the body or in body samples separated from the body, and DNA which has been removed from the cell, fragmented and cloned [a usual practise commencing any genetic research]. These cloned parts of these complementary (or copy) genes are identical to the original fragments, but properly speaking the cloned DNA cannot be said to have belonged to the body".[108]

The analysis clearly states that the notion "to own" can come into question first after the separation of body material thereby giving rise first at this stage to possible objection to patents. Yet, the right to own one's body material after its separation from the body does not belong any longer to the sphere of self-autonomy. Isolated and purified sequences (as has been mentioned earlier only those are eligible of patent protection), being usually copies of the ones originally extracted, cannot be equalised with an individual they have been taken from. This logic is present in the opinion of European Council and Parliament to the patentability of biotechnological inventions. "[E]lements obtained by a technical process from the human body in such a way that they are no longer directly linked to a specific individual may not be excluded from patentability because of the human origin of these elements".[109] Thus patent protection neither creates a modern form of enslavement nor infringes one's right to self-autonomy.

Yet, in spite of denunciation of the above arguments against gene patens, the notion of ownership read in another, symbolic meaning could still remain ethically significant. The ownership itself does not have to be defined in the strict legal terms. "[T]here are greater and lesser bundles of rights that still constitute ownership, and precise boundaries of the concept are difficult to determine."[110] The term "ownership" in relation to patent rights does not have to be inconsistent with a general understanding of the notion ownership. It implies that even if patents do not factually confer ownership in the legal understanding, people may intuitively feel that certain things by their nature should not be subjected to any kind of property rights including patents.[111] Thus the notion of ownership may in fact serve to emphasise the opposition to apply any proprietary rhetoric to the symbolically meaningful DNA.

2. Commodification

Let us depart for a moment from the above analysis and focus on the notion of commodification through gene patents.

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[108] Supra no. 77.
[109] Ibarreta/Thumm, "Ethical Aspects of Biotechnological Patenting Revisited", available at http://www.jrc.es/iptsreport/vol65/english/BIO1E656.html.
[110] Supra no. 30.
[111] Supra no. 30.

Commodification of humans is a notion used to define a reduction of humans or human's life to the pure commercial value and marketability. Professor Margaret Jane Radin distinguishes between two forms of commodification:[112] Commodification in a narrower sense, which means actual buying or selling marketable goods and economic services. And commodification in a broader sense ascribing a market value to an object thus perceiving it purely through market terms without an actual market exchange. The second type of commodification (i.e., the commodifiaction in the broader sense) may contribute to what Radin calls "universal commodification" as a conceptual scheme of the world. "From the perspective of universal commodification, all things desired or valued – from personal attributed to good government – are commodities. Anything that people are willing to sell and others are willing to buy can and should be in principle the subject of free market exchange."[113] Radin observes also that there are different degrees of commodification. There are complete commodities, whose value is entirely assessed from the market perspective. And there are incomplete commodities, which are valuable from both the market and non-market perspective. Furthermore, the classification as complete or incomplete commodity is not constant. A continued application of market terms to an incomplete commodity may foster the process of devaluation of other values, rendering it eventually in a complete commodity.

The major objection to gene patents in this context posits that patents apply market rhetoric to human genes thereby contributing to the process of commodification of people.

Can patents entail the commodification in the narrower sense? It seems unlikely, for patents do not involve in actual market exchange. Additionally, the process of selling and buying requires legal ownership, which as has been analysed above patents do not confer. The only link between patents and commodification in the narrower sense may be to see patents as a prerequisite for market transactions and the acquisition of profits that result from products that patent enables.[114]

Yet, patents seem to resemble rather the broader notion of commodification. In a sense, by granting monopoly rights and a title to an exclusive exploitation (thus a source of profits) to biotechnological companies, patents apply market rhetoric to human genes without actual trade. Therefore genes may already be classified as an incomplete commodity. The major fear is that the process of commodification will advance. "[T]he reason people are troubled by 'mere' market rhetoric, when applied in ways they think it will be 'contagious' and will lead to literal commodification."[115] Thus, there may be a reasonable suspicion that a continued patentability may provoke a change in values attached to DNA transforming it into a purely marketable thing. Yet, even if genes became complete commodities, would it necessarily entail the commodification of human?

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[112] Radin, "Contested Commodities", 1996, p. 13.
[113] Supra no. 112.
[114] Supra no. 30.
[115] Supra no. 112.

Interestingly, patents on other molecules occurring in human body such as proteins, hydrocarbons, hormones, and lipids have been widely accepted.[116] Also the patentability of other biotechnologies, for example technologies for transplanting, growing, analysing or bone marrow, is morally acceptable.[117] Even the marketability of some body elements such as blood, kidneys, and eggs also do not fuel a similarly furious discussion.[118] Why should the patenting of genes be treated differently? Here we come back to the final thought of the analysis of patents and ownership, the symbolic meaning, which DNA may intuitively have been granted.

Over the years of amplification of the responsibility of DNA for human personality, behaviour, and susceptibility to diseases, human genes seem to have acquired a symbolic meaning, propounding it over every other body part. This symbolic meaning and not so much some objectively scrutinised scientific or ethical concerns has contributed to the major extent to the unease with which gene patents are viewed. In this context the observation of Lindee and Nelkin that DNA has become a cultural icon, or a substitute for the concept of Christian soul appears very accurate.

Yet, the attachment of a symbolic meaning to DNA may in fact be very dangerous to people or human relationships. It facilitates the exaggeration of the role of genes what leads to simplistic reductionism seeing in our genes a predetermined and unavoidable cause for every unusual, negative or positive characteristic of a given individual. This leads to an unjustified discrimination on the one hand, and rejection of gene technology on the other. And although gene technology objectively resembles other technologies falling under the realm of biotechnology, when ascribed God's-like capabilities, it seems to pose more threats to the contemporary social order or ethical hierarchy of humankind.

As has been shown above, the special status of DNA, although existent in a symbolic sense, does not have any objective scientific justification. In their status, human genes do not differ from other body elements, thus they should not be treated in any special way. Yet, similarly like the special symbolic status of human heart or brain, whose symbolic still functions in human culture although a passage of years of its scientific denunciation, also the symbolic meaning of genes will probably not cease to exist after their real role and capabilities will have been thoroughly explored and widely understood. But can the purely symbolic meaning be seen as a sufficient justification for the prohibition of gene's patentability (what entails the stifling of the progress of technology capable to significantly improve medical knowledge and thus human health care)? In the world where widely different and divergent ethical principles coexist the idea of giving a universal answer seems too ambitious. But logic and objectivity suggest that rather not.

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[116] Resnik, "DNA Patents and Human Dignity", Journal of Law, Medicine and Ethics 2001, p. 152.
[117] Supra no. 69.
[118] Radin, "Response: Persistent Perplexities", Kennedy Institute of Ethics Journal 2001, p. 309-310.

C. The contribution of Human Rights to gene technology

Genetic technology, although not ethically inappropriate because of the subject of research (human genes), causes societal anxiety about the scope and speed of its new developments. The genetic developments open up wide-ranging possibilities, which go beyond the attempts to understand the functioning of human genes and patent gene related inventions. The most controversial advancements concern techniques like cloning or human embryo research.[119] Therefore, there is an increasingly growing conviction that the potential of gene technology as well as its ramifications are still unknown followed by the anxiety that the powerful technology is exceeding the reach of the societal control, leaving the society with no say in how its discoveries and inventions are to be deployed. Therefore, the need for a normative framework controlling and directing the biotechnological developments has increasingly been voiced.[120]

The role of the biotechnological guardian has been entrusted to human rights: The scientists, philosophers, lawyers have turned to human rights in the quest of finding there ethical limits of biotechnological progress, which would allow controlling the current and future advancements and their implications, thus partly transferring the burden of responsibility for them from the hands of scientific community on the non-scientific communities and the society as a whole.

1. Human dignity

Human rights pose serious demands of biotechnology. "All human beings are born free and equal in dignity and in rights" proclaims Article 1 of the first and basic human rights document, the 1948 Universal Declaration of Human Rights.[121] Thus, the core value, which constitutes the bedrock of human rights and ultimately shapes their scope, is the concept of human dignity.

To date, as the framework of human rights has developed and specified over the time, the value of the notion of human dignity has not diminished. Quite to the contrary, the role played by human dignity has become crucial when assessing the ethics of biotechnological research and its applications. "As a right is widely recognised as intangible and inviolable, and that suffers no exemptions, human dignity is the very bedrock of bioethics

[119] The problematic of cloning and embryonic stem cells research goes beyond the scope of this Paper and therefore will not be analysed.

[120] See supra no.22; Maher, "The International Framework for Biotechnological Regulation", New York International Law Review, 1993, p.98; Tauer, "International protection of Genetic Information: The Progression of the Human Genome Project and the Current Framework for Human Rights Doctrines", Denver Journal of International Law and Policy, 2001, p.209.

[121] The Universal Declaration of Human Rights, adopted and proclaimed by General Assembly resolution 217 A (III) of 10, December 1948.

law."[122]As one of the most prominent documents pertaining to biotechnology, the Universal Declaration on the Human Genome and Human Rights,[123] states,

> "[the] research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and humankind as a whole, but … such research should fully respect human dignity, freedom and human rights…".[124]

In other words, the pursuit of technology, however desired and justified its goals were, cannot omit or affect the importance of human dignity. The improvements in health care and respect for human dignity become then two equally important objectives, what implies that the first one cannot be achieved at the expense of the other. Article 10 further specifies that,

> "[n]o research or research applications concerning the human genome, in particular in the field of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individual or, where applicable groups of people."

Thus, the aims of science and technology may not reign over the rights and interests of an individual.

Similar principles are reflected in the first international convention on human rights and biomedicine, the Council's of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.[125] Article 1 states that,

> "[p]arties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. …"

Thus, human dignity and identity shall be preserved indiscriminately in any application of biotechnology or biomedicine. Article 2 adds that,

> "[t]he interests and welfare of the human being shall prevail over the sole interest of society or science".

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[122] Lenoir, "Universal Declaration on the Human Genome and Human Rights: the First Legal and Ethical Framework at the Global Level", Columbia Human Rights Law Review 1999, p. 537.

[123] Universal Declaration on the Human Genome and Human Rights, adopted on 11 November 1997 by the General Conference of the United Nations Educational, Scientific and Cultural Organisation and endorsed by General Assembly resolution 53/152 of 9 December 1998.

[124] Preamble of Universal Declaration on the Human Genome and Human Rights.

[125] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997, ETS. No. 164.

The respect for the rights and values attached to the individual shall take prevalence over the other incentives pushing for further research and its promotion. In other words, neither the economic efficiency nor the scientific progress should prevail over the interests of the individual, when the use of genetic information proves detrimental to them.[126]

Thus, it appears that the first and prevailing principle safeguarded by human rights, the non-violability of human dignity, constitutes an overriding value, which cannot be infringed in the pursuit of any biotechnological or economical goals. The respect for human dignity should prevail over the interests of society, i.e., the welfare of society cannot justify any infringement of it. It should also serve as guidance sketching the scope of any technological or scientific developments. The human dignity has then become the limit sought to restrict the biotechnology to the dimension ethically acceptable. As Noelle Lenoir puts it, "the unique value of dignity [is] the only principle that can enable a society to protect itself in a sustainable and human fashion."[127] In other words, all the biotechnological advancements are welcome and should be promoted (through patent protection for example) as long as they do not contravene the respect of the dignity of an individual.

2. Human rights and gene related patents

How does, however, the relation between human rights and gene related patents look like? In other words, what are the possible threats to human dignity posed by biotechnology and what impact do the biotechnological patents have on it?

Interestingly, the human rights documents do not say much about the desirability or inappropriateness of patents in the field of biotechnology. The Preamble of the Universal Declaration on the Human Genome and Human Rights states merely that the Declaration shall be "without prejudice to the international instruments which could have a bearing on the applications of genetics in the field of intellectual property…". And Article 14 seems to allude implicitly to them by saying that,

> "[s]tates should take appropriate measures to foster the intellectual and material conditions favourable to freedom in the conduct of research on the human genome and to consider the ethical, legal, social and economic implications of such research, on the basis of the principles set out in this Declaration."

Thus, the patentability of biotechnological inventions has not been condemned or rejected, which implies that biotechnological patents do not as such contravene the respect of human dignity. However, the decisive factors in deciding about the patentability have been widened: not only

[126] Supra no. 55.
[127] Supra no. 122.

economic and legal but also ethical and social considerations should be taken into account when deciding about a grant or a denial of a patent protection.

Overall, the language of the above-mentioned principles is pretty vague, what implies that it needs to be clarified in more detail, where and when the human rights' principles should find a concrete application.

3. Human Rights and gene tests

One of the most widely discussed fields, where the application of human rights values is increasingly needed, concerns the treatment and protection of the information achieved by gene tests.

Gene tests, directed at screening the genetic make-up of the tested individual, are often held to be capable of revealing highly valuable and sometimes very delicate information about the tested individual. As Bartha Maria Knoppers writes, "rapid advances in genetic research will ultimately result in affordable and more pervasive testing. Indeed, not only have we moved from tests for the rare, monogenic conditions to the discovery of genetic factors in common multifactorial diseases, but the development of 'DNA biochips' will allow testing for hundreds of conditions at a time. With the standardisation of this technology, a single sample of DNA (found in every cell in the body) will provide information on the present and future health of a person and thus, necessarily, that of fellow family members."[128]

Other scholars contend that the scope of information obtained from gene tests can be even wider. For example, Jennifer Krumm observes, "[b]y 1992 genetic tests were already beginning to link genes not only to physical ailments, but also to mental illnesses and personality traits … including homosexuality, aggressiveness, shyness, stress and exhibitionism."[129] The tests are also claimed to be capable of supplying predictive and socially usable information, such as:

1. "Individual propensities to contract diseases, with varying degrees of medical therapy available to moderate or overcome any such diseases,
2. An individual's status as a carrier of harmful or defective genes, even though not personally affected,
3. An individual's propensity to engage in antisocial behaviour, based on theories of inherited characteristics having effects independent of nature or environment,
4. An individual's likelihood of having various exceptional abilities based on theories of superior inherited mental or artistic talents."[130]

[128] Knoppers, "Who Should Have Access to Genetic Information?", in Burley, "The Genetic Revolution and Human Rights", 1998, p. 40.
[129] Krumm, Genetic Discrimination", Journal of Legal Medicine 2002, p. 491.
[130] Westin, "Privacy and Genetic Information: A Socio-political Analysis", The Genetic Frontier: Ethics, Law and Policy 1994, p. 66.

The scope of information, which can be achieved through genetic testing shall presumably, (similarly like the view that DNA is a master molecule, which can do and say almost anything), be treated with a bit of caution. However, gene tests do provide some information about an individual. Human rights' task consists in codifying rules, which secure their adequate transmission to the person concerned and to his or hers environment.

a) Value of the results of gene testing

Let me commence however with denouncing the capabilities of gene testing which seem rather not probable.

It has been asserted that the insight into genetic make-up shall detect one's social or criminal propensities. Such a link suggests however that human behaviour is entirely dependent on genetic make-up, depriving it from any cultural or social influences. It also leaves no space for human ability to free reasoning – the foundation of the ability to decide whether or not to act or behave in a certain way. Yet, what pushes an individual to behave in a certain way, is not his genes, but the aggregate of all elements of his or hers life, the conditions he or she lives in, the experiences gathered, and how the individual combines these elements into the manner of acting.[131] As Professor Gerald Dworkin wrote, "[w]hat makes an individual the particular person he is, is his life plan, his projects. In pursuing autonomy, one shapes ones life, one constructs its meaning."[132] It is therefore an oversimplification to reduce human behaviour to the pure expression of genetic structure. Human behaviour is something far more complex than the pure genetic make-up. It involves an interaction between genetics, culture, society melted and modified by the ability to free reasoning. Genetics therefore cannot claim to give ultimate answers as to the reasons of human behaviour or the occurrence of certain propensities. "Humans … are complex organisms leading complex lives, and our experiences and our biology interact in unpredictable ways. Neither genetics nor molecular biology can tell us all that much about people. They can only tell us about our genes."[133] In other words, the real role played by the genes sketches the limits of the predictive value of the information obtained by gene tests. Gene tests will possibly be able to show the potential to develop certain diseases or behaviours but rather not the very reasons for one's criminal or homosexual propensity.

However, even predictive ability of gene tests in the case of diseases is limited. As genes constitute only one of the relevant factors, which may be causative to the development of a disease, the results of gene tests will never be comprehensive and ultimate. Therefore, one of the main deficiencies of genetic testing is their inability to show the role played by other factors, especially the environment. As Rogeer Hoedemaekers and Wim Dekkers (2001) write, "the environment cannot be disregarded. Isolated genes or

[131] Supra no. 29.
[132] Dworkin, "The Theory and Practice of Autonomy", 1988, p. 31.
[133] Supra no. 77.

gene segments are inert; they can function only within a cell or organism."[134] Additionally, gene tests show only the state of an organism in the moment of testing and not the ongoing changes and processes, which take place in the organism. Rogeer Hoedemaekers and Wim Dekkers observe that even where genetic dysfunction appears, "there are repair or compensation mechanisms in a cell or organism that may annihilate the effects of a specific gene mutation."[135] It means that a discovered genetic defect may "disappear" naturally in the course the organism's development proving any test inaccurate. Thus, "[e]ven assuming technology continues to rapidly advance, 'it seems highly unlikely that any one test or series of tests' will ever 'be able to incorporate the numerous factors that influence the development of … illness.'"[136] Therefore, the information achieved by the way of gene's screening is "unreliable and inconclusive"[137] because it will never provide a complete and ultimate picture of one's health or social behaviour.[138]

b) Possible harm to individual because of the lack of adequate counselling

Due to the popularity of the myth positing the special role of human genes, it should be ensured that the individuals tested are adequately counselled that genetic diagnosis does not constitute an ultimate judgement about their health but is rather an indication what may but not necessarily will happen in the future. Without an adequate explanation the patients are likely to be confused about the factual predictive capability of the tests what may result in a psychological harm: the person concerned might expect with certainty or high probability to fall victim to the disease and thus subordinating his or hers entire way of life to the future disease. The information about the existence of some kind of genetic defect could also affect the maternity choices. A person convinced to develop a serious disease in the course of his or her life, could decide not to have children. Or, a child showing a genetic defect already in the pre-birth stages of its development might more easily be aborted, regardless if it would later on develop the disease or not.[139]

It should also be ensured that the society in general acquires an adequate knowledge about the factual predictive value of tests. Otherwise, if the information leaked or were otherwise made publicly available, the person concerned might be exposed to social stigmatisation possibly similar to that,

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[134] Supra no. 66.
[135] Supra no. 66.
[136] Weaver, "Genetic Screening and the Right Not to Know", quoted in Krumm, surpa. no. 129.
[137] Kaufmann, "Genetic Discrimination in the Workplace: An Overview of Existing Protections", Loyola University Chicago Law Journal 1999, p. 393.
[138] Supra no. 55, 60, 39, 29.
[139] Koller, "Human Genome Technology from the Viewpoint of Efficiency and Justice", in: Mazzoni, "Ethics and Law in Biological Research", p. 47.

which has initially followed the statement "HIV positive".[140] Moreover, the unfavourable result of gene test could complicate the relations with employers or insurers, both willing to avoid the negative consequences of their employee or person insured contracting a disease.[141]

c) Protection of valuable information

The above are the negative outcomes arising from the exaggeration that our future is written in our genes, i.e., the genetic tests hold the potential to predict out inevitable future of health or behaviour. Yet how should the factual information be provided by gene testing treated? The question is not easy to answer.

Genetic information usually applies not only to a single individual but also to other family members who could have inherited the same genetic defect. Even if the genetic tests have a purely informative nature, which may or may not give rise to a concrete disease in the future, have they the right to be informed about the existence of such risk? Should the genetic information be treated as a familial property, because "[the] shared biological risks create special interests and moral obligations … that may outweigh individual wishes"[142]? This would necessarily involve the break of the patient – doctor confidentiality if the person concerned were not willing to disclose the result to himor herself.

Unlike the proceeding issue, the human rights documents are not quite silent on this problem. The Convention on Human Rights and Medicine states in Article 10 (2) that,

> "Everyone is entitled to know any information collected about his or her health.
> …."[143]

For this provision forms a part of the Chapter entitled "Private life and right to information", it should rather be read as applicable solely to the person directly concerned, whose DNA sample has been tested, than all other relatives that may also carry the same mutation, because it would otherwise run counter to the very right to privacy. Therefore, it seems that the confidentiality of the patient – doctor relationship prevails even where significant interests of other family members are at stake. Similar conclusion can be drawn from Article 7 of the Declaration. It says,

> "Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law."[144]

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[140] Gatter, "Genetic Information and the Importance of Context: Implications for the Social Meaning of Genetic Information and Individual Identity", Saint Louis University Law Journal 2003, p. 423.
[141] Supra no. 128.
[142] Supra no. 128.
[143] Supra no. 125.

It remains to be seen, how this issue will be dealt with in the future.

d) Justified claim by employers and insurers?

The other controversy related to gene tests concerns the availability of the genetic information to the insurers and employers. Both groups have legitimate interests supporting their potential demand for genetic testing or a disclosure of the results to them. As Bartha Maria Knoppers observes, the insurers "could not maintain business by selling large insurance policies to individuals who recently have learned that they carried, for example, the gene for Huntington's disease [i.e., one of the rare occurring single-gene pathologies] or similar lethal, late-onset disorders. Unless the insurers have access to the same information as the applicant, they are at a disadvantage."[145] As to the employers, "[t]he interest in healthy, productive workers is legitimate, because unhealthy workers cost a company money in lost time, insurance, and retraining. Physical and medical conditions often cause an increase in absenteeism and turnover, higher accident and workers' compensation rates, decreased productivity and related problems. Conversely, healthy employees are better able to perform physical and mental tasks."[146] Moreover, the author contends further that "[i]n fact, employers have the right to select the most productive applicants within the twin constrains of human rights and unfair labour practices."[147] Yet, these interests, however legitimate they were, can entail very negative consequences.

The gene tests, whose popularity within companies is rapidly growing,[148] may provide the employers or insurers with a quite strong reason (or sometimes pretext) to discriminate. The American Journal of Human Genetics revealed already in 1992 forty-two instances in which individuals have been discriminated against on the basis of genetics. For example one of the airlines grounded all black employees with the sickle cell trait in the 70-ties fearing a "sickling attack if the plane depressurised".[149] This tendency may be expected to have only aggravated throughout the years. As a consequence, if people were fired or never employed or insured because of their unfavourable genetic characteristics (regardless whether they show symptoms of the illness or not), it could lead to establishment of a "new special underclass".[150] Employment and

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[144] Supra no. 91.
[145] Supra no. 128.
[146] Supra no. 129, 137.
[147] Supra no. 128.
[148] Gostin, "Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers", American Journal of Law and Medicine 1991, p. 109.
[149] Billings et al., "Discrimination as a Consequence of Genetic Testing", American Journal of Human Genetics 1992, p. 476.
[150] Supra no. 128.

insurance are necessary economic goods for obtaining other goods such as the access to health care and other basic means of subsistence (for example home, food, and car). If persons showing genetic defects were deprived of them, what would they have left? As a mean of prevention to such an outcome, leaving the demand for genetic information on the side of employers and insurers untouched, could serve anti-discriminatory legislation including the concerned group of people to the category of persons disabled or handicapped. Yet, such a decision, though possibly neutralising the discriminatory policy of the would-be insurers or employers, might on the other hand contribute to further entrenching of social stigmatisation of these people, ultimately categorising unfavourably genetic traits as "abnormalities".[151]

Yet, even if the insurers or employers were allowed to have access to the genetic information, how should the tests be conducted? Should they be voluntary? Given the already negative experiences with discriminatory behaviour of the insurers and employers aggravated by the spectre of potential social stigmatisation, it appears highly unlikely that many would agree to participate in them. Indeed, a survey conducted in 1997 in the United States shows that two-thirds of the respondents would refuse to participate in a genetic test if employers or insurers could see the results.[152] Should they be mandatory then? Taking into account that they do provide information about the potential risks, which may probably and seriously affect one's health, an obligation to undergo gene testing would violate the right to privacy and the right not to know. The human rights documents are quite clear on this issue. They require voluntary decision-making accompanied with an informed and free and necessarily prior consent. Article 5 of the Declaration states,

> "a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law.
>
> b) In all cases, the *prior, free* and *informed consent* of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorisation shall be obtained in the manner prescribed by law, guided by the person's best interest.
>
> c) The right of each individual to decide *whether or not to be informed* of the results of genetic examination and the resulting consequences *should be respected*." [Emphasis added]

Similarly, Article 5 of the Convention on Human Rights and Biomedicine,

> "An intervention in the health field may only be carried out after the person concerned has given *free* and *informed consent* to it.

[151] Supra no. 128.
[152] Miller, "Genetic Discrimination in the Workplace", Journal of Law, Medicine and Ethics 1998, p. 189.

> This person shall *beforehand* be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.
> The person concerned may freely *withdraw consent at any time*." [Emphasis added]

And Article 10 of the Convention on Human Rights and Biomedicine,

> "1. Everyone has the right to *respect for private life* in relation to information about his or her health.
> 2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals *not to be so informed* shall be observed.
> 3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient." [Emphasis added]

These provisions expressly exclude any obligatory gene testing. Instead, they require respect for the right to privacy what involves the right not to be informed. Both documents also oppose any discrimination. Article 2 of the Declaration says,

> "a) Everyone has a right to *respect for their dignity* and for their rights *regardless* of their *genetic characteristics*.
> b) That dignity makes it imperative *not to reduce individuals to their genetic characteristics* and to respect their uniqueness and diversity." [Emphasis added]

Article 6 stipulates further,

> "*No one* shall *be subjected to discrimination* based on *genetic characteristics* that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity." [Emphasis added]

Likewise, Article 11 of the Convention on Human rights and Biomedicine,

> "*Any form of discrimination* against a person on ground of his or her *genetic heritage* is prohibited." [Emphasis added]

And Article 12,

> "Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed *only for health purposes* or for *scientific research linked to heath purposes*, and subject to appropriate genetic counselling." [Emphasis added]

The above quoted provisions remind the fundamental principle of the respect for human dignity and allow gene testing solely for the health purposes guided by the best interests of the individual concerned. Read together with the previously cited principle that the interests of individual should prevail over the interests of society or science, they in fact reject any demand on the side of the employers or insurers for the disclosure of genetic information or mandatory gene testing, unless made available voluntarily by the person concerned. This at least averts the spectre of genetic discrimination and sketches the path, which should be taken by national law.

IV. Genes and Patent Regime

Leaving the ethical side of the debate around the patentability of genes, let us proceed with a legal one. Gene patents have encountered considerable opposition on grounds that they are claimed not to fit within the patent regime.

Patent regime emerged in the nineteenth century as an upshot of the Industrial Revolution. It was primarily tailored for mechanical inventions. This particular subject mater, lifeless technical inventions, sketched the three main requirements of patentability: novelty, inventiveness and susceptibility of an industrial application.

The first great challenge to the mechanical devices-anticipated patent regime came with the development and progress of the chemical industry. As an answer to it, the scope of eligible inventions expanded to encompass chemical molecules. To date, the patent regime is faced with a next challenge, biotechnology.

A. Products of nature

One of the arguments opposing the patentability of genes posits that genes cannot be eligible of patent protection because they, unlike the mechanical devices, consist of living matter and are not products of human ingenuity. This argument posits further that genes have been created and developed by nature; thereby they had existed before people acquired knowledge about them. Human intervention consisted solely in their discovery.

The European Patent Conventions clearly prohibits patenting of discoveries,[153] what implies that, according to the product-of-nature doctrine, genes should not be patented. Yet, this is only partly true. The 1998 EU Directive on the legal protection of biotechnological inventions draws a line distinguishing between two forms of genes. Article 5 states that the simple discovery of one of the elements of the human body, including the sequence or partial sequence of a gene, is not patentable.[154] Yet, an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, is eligible of patent protection even if its structure is identical to that of a natural element.[155] In other words, genes in their natural state are treated as a discovery and are therefore not patentable. Yet, genes, which were isolated and purified constitute an invention eligible of patent protection. patentable and not patentable genes. In this way, the traditional distinction between patentable inventions and not patentable discoveries has been upheld. The same say the EPO guidelines:

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[153] Article 52 (2) a EPC.
[154] Article 5 (1) EU Directive.
[155] Article 5 (2) EU Directive.

> "an element isolated from human body or otherwise produced by means of a technical process, which is susceptible of industrial application, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of this element is identical to that of a natural element. Such an element is not a priori excluded from patentability since it is, for example, the result of technical process used to identify, purify and classify it and to produce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing itself."[156]

The guidelines provide thus a justification for the differentiation between natural and isolated and purified genes. Human intervention, which consists in isolating and modifying amolecule found in nature, transforms it into a patentable invention: It modifies the molecule concerned for the purposes of a particular application thereby conducting processes, which could not be carried out by nature alone. This is therefore human ingenuity, which transforms genetic discovery into a genetic invention.

The same logic is advanced also in the literature. Rebecca Eisenberg (2002) observes, "[o]ne cannot get a patent on a DNA sequence that would be infringed by someone who lives in a state of nature on Walden Pond, whose DNA continues to do the same thing it has done for generations on nature. But one can get a patent on DNA sequences in forms that only exist through the intervention of modern biotechnology."[157] The author notices also that such logic is consistent with the long-standing practise because the same distinction has been applied to chemical products: Patents have been issued on isolated and purified chemicals that already had existed in nature but only in an impure state. The human intervention has made them available in a new form that is capable of meeting human purposes.[158] Likewise, the same should apply to genetic inventions. The isolation and purification "prevents the issuance of patents that take away from the public things that they were previously using (such as the DNA that resides in their [human] cells), while allowing patents to issue on new human manipulations of nature",[159] which being the result of human ingenuity are worth rewarding.

However, although the above theory seems persuasive, the differentiating between a genetic invention and a genetic discovery is much more complex in practise. In reality, in order to be discovered, all genes must be isolated by various technical means first.[160] As Denis Schertenleib explains, "[t]his is because genes exist within cells in chromosomes. In order to discover them, a scientist must first separate them and finally

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[156] Guidelines for the Examination in the European Patent Office, October 2001, Part C Chapter IV, p. 54a.
[157] Eisenberg, "How Can You Patent Genes?", The American Journal of Bioethics 2002, p. 4.
[158] Supra no. 157.
[159] Supra no. 157.
[160] Schertenleib, "The Patentability and Protection of DNA-based Inventions in the EPO and the European Union", European Intellectual Property Law Review 2003, p. 127.

isolate them. The same applies to cell cultures."[161] Therefore, the genetic invention and discovery merge into one, rendering the requirement of isolation and purification as a distinction between an invention and a discovery in fact legally ineffective.

1. Industrial application as a determinant of an invention

The requirement of isolation and purification may however be effective if read in conjunction with an additional element: susceptibility of industrial application. Recital no. 20 states,

> "it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, *which is susceptible of industrial application*, is not excluded from patentability …."[162] [Emphasis added]

It seems thus that genes, which have been isolated and are additionally industrially applicable (as opposed to the only isolated ones), shall be defined as inventions. This is presumably the logic of the EPO guidelines,

> "[t]o find a previously unrecognised substance occurring in nature is … 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 gene which is discovered to exist in nature [and] may be patentable if a technical effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy."[163]

Thus, the capability of a later industrial application renders an isolated and purified gene into an invention. Conversely, a gene, which cannot show any usefulness in the applied art, will be seen as a discovery even after its isolation and purification.

Interestingly, the EPO clarified lately the question of patentability of human embryos. In September 2004 the Office rejected two involving human embryonic stem cells and partially blocked a third. The main ground of the refusal was that the EPC prohibits the industrial or commercial use of human embryos.[164]

[161] Supra no. 160.
[162] Recital no. 20 of the Directive, supra no. 101.
[163] Supra no. EPO 156.at C Chapter IV, p. 51
[164] Vogel**, "**Stem Cell Claims Face Legal Hurdles", Science 2004, Vol. 305, p. 1887ff.

2. Lax utility requirement

Yet, although the determinants of the notion "genetic invention" are discernible, the standard remains still far from being clear. How concrete should the assertion of the future utility be? This question is particularly difficult in the complex world of genetics.

When the first gene's patents were granted, in 1970-ties and 1980-ties, they easily passed the utility criterion,[165] because the method used to discern them departed from a known protein and went back to the gene encoding it. Thereby the scientists knew exactly, which protein the discovered gene codes for, making the assertion of the future gene's application highly plausible. Today however, a reverse method prevails. Employing computerised homologous sequencing techniques, they presume the function of a gene through similarities. As Denis Schertenleib explains, "[a]s the sequence of DNA specifies the sequence of amino acids in a protein, it is possible to predict the amino acid sequence of a protein coded by cDNA. If two proteins share similar sequences across regions then it is likely that they will have similar structure and properties."[166] In other words, the scientists depart from a gene sequence discovered and determine the kind of protein it may code for. Yet, neither does it shows the complete range of processes the gene is responsible for, nor does it say much about the functions of the protein concerned. Therefore, the computer homology assigns genes to a very broad class of functions but does not show their real cellular tasks.[167] The homologous sequencing techniques resemble rather guessing than a thorough scientific analysis, rendering the utility asserted highly vulnerable to failure.

The other difficulty when analysing the requirement of susceptibility of industrial application concerns gene fragments known as expressed sequence tags (EST's). The EST's are used to identify the full-length genes or as probes to ascertain the expression level of genes.[168] They are thus merely research tools, which implies that they cannot be useful in the applied art. Yet, patent applications have been filed for them. The question arises then whether the utility in research alone is sufficient to meet the requirement of susceptibility of industrial application.

As to the contemporary European legal standard, the Article 57 of the EPC states,

> "An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture."

It does not help much in dealing with the difficulties with the gene-related patents. The 1998 Directive is here more specific. Recital 23 states,

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[165] Gitter, "International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and A Fair-Use Exemption", New York University Law Review 2001, p. 1623.
[166] Supra no. 160, p. 126.
[167] Supra no. 160, p. 126
[168] Supra no. 160, p. 128

> "[A] mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention."

And Recital 24 specifies,

> "[I]n order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify *which protein* or part of a protein is produced or *what function* it performs." [Emphasis added]

The Directive seems to rule out the patentability of EST's. Their mere capability to trace other genes appears not to be capable of meeting the industrial applicability threshold. On the other hand, the gene sequences, whose functions are determined by homologous sequencing techniques, are patentable. They can be assigned to proteins, whose functions may be guessed. Thereby they meet the requirement of protein's specification and indication of the protein's function. The Directive does not set any standard concerning the credibility of an assertion based on similarities.

A more detailed standard has been set by EPO in the course of Trilateral Projects between the European Patent Office, the United States Patent and Trademark Office and the Japanese Patent Office. The EPO announced that it requires a utility that is plausible,[169] specific,[170] and credible beyond mere speculation.[171] More specifically, the genes, whose functions have been discerned on the basis of similarity, meet the threshold of susceptibility of industrial application where the homology exceeds fifty-five per cent.[172] The EST's, on the other hand, will pass the industrial applicability test if, being used as probes, enable diagnosis of a known disease,[173] or enable obtainment of a gene sequence, which has specific utility.[174] Enabling to locate any sequence is not sufficient.

B. Inventiveness

Let us look at the other requirements of patentability. Another, except the susceptibility of industrial application, threshold to meet is the inventive step. Article 56 of EPC defines this notion.

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[169] Trilateral Project 24.1 at 2.1.
[170] Trilateral Project B3b: Comparative study on biotechnology patent practices; Theme: Patentability of DNA fragments. Available at: www.epo.co.at.
[171] Supra no. 169 at B3b.
[172] Supra no. 169 at B3b.
[173] Supra no. 169 at B3b, cases D and E.
[174] Supra no. 169 at B3b, cases B and F.

> "An invention shall be considered as involving inventive step if, having regard to the state of art, it is not obvious to a person skilled in the art."

The House of Lords in the United Kingdom has given a good definition of the inventiveness in the case Biogen Inc v Medeva plc.[175] Although this decision is not binding on the European level, it may nevertheless indicate the scope of the requirement concerned also for the EPO, since the UK Patent Act exactly mirrors the wording of the European Patent Convention. The House of Lords said,

> "[w]henever anything inventive is done for the first time it is the result of the addition of a new idea to the existing stock of knowledge. Sometimes, it is the idea of using established techniques to do something, which no one had previously thought of doing. In that case the inventive idea will be doing the new thing. Sometimes it is finding a way of doing something which people had wanted to do but could not think how. The inventive idea would be the way of achieving the goal. In yet other cases, many people may have a general idea of how they might achieve a goal but not know how to solve a particular problem, which stands in their way. If someone devises a way of solving the problem, his inventive step will be that solution, but not the goal itself or the general method of achieving it."

The EPO in the course of the established practise developed so-called "problem and solution approach" when analysing this requirement. It consists of three steps:

> 1. An objective assessment of the technical result achieved, accompanied by an analysis what constitutes its closest prior art against which the assessment is to be made;
>
> 2. Determination of the technical problem, which is to be solved and an analysis of the features of the invention;
>
> 3. Analysis whether the technical result achieved would have been obvious to the person skilled in the art.[176]

The degree of skill and ability are here of utmost importance. The EPO guidelines explain that "[t]he person skilled in the art should be presumed to be an ordinary practitioner aware of what was common general knowledge in the art at the relevant date. He should be presumed to have had access to everything in the 'state of art', in particular the documents cited in the search report, and to have had at his disposal the normal means and capacity for the routine work and experimentation. If the problem prompts the person skilled in the art to seek its solution in another technical field, the specialist

[175] Biogen Inc v Medeva plc, [1997] R.P.C. 1.
[176] Triazole case, T939/92, OJ EPO 1996, 309.

in the field is the person qualified to solve the problem."[177] In the field of genetics, the degree of skill must be generally assumed as high, because a high skill level is a basic to entry into the field.[178]

The case law specified the notion of inventiveness further. The case T2/83[179] stated that the requirement of inventive step would be met if a practitioner found the particular solution when confronted with the technical problem, not whether he generally could solve it by chance. There must be thus a "reasonable expectation of success" on the part of an ordinary practitioner. The Biogen case[180] defines the "reasonable expectation of success" as different from the hope of succeeding. Emphasis is here put on the fact that the ordinary practitioner must reasonably predict already from the beginning that he would be able to solve the technical problem, not that he merely hopes to solve it.

The Genentech case[181] specifies the requirement of inventive step to the transfer of technology. Inventive step would not be met when an ordinary practitioner working in one field of genetic engineering would regard transfer of technical knowledge applied in his field to another neighbouring area of genetics as easy and not involving any no-obvious risks. In other words, the usage of genetic engineering technique to a different organism is as such not sufficiently inventive to grant patent protection.

The Unilever case[182] concerns the degree of a technical problem to solve in the field of genetic engineering. The threshold of inventive step would not be met when the problem were straightforward, even if it required a considerable amount of work.

The cases T22/82[183] and Triazole[184] indicate also that the structural originality of a product expressed in a presence of new compounds or new combination of already known compounds does not play any role for assessing inventiveness, unless they present a new technical achievement. On the other hand, if a new product shows an unexpected or surprising technical effect, it will be held to be inventive and will be deemed to have been the goal of the research.[185]

In the field of genetic engineering most of the inventiveness would probably be achieved during the research phase. The inventive step may here consist in any step between state of the art and the invention, i.e., it could constitute a new compound, its technical effects, a process to obtain it, or overcoming the difficulty in obtaining it.[186] The basic criterion would be whether it is obvious to an ordinary practitioner.

On the other hand, the creation of a new product (through isolation or discovery) alone is not deemed to be inventive. Only a new product, which would have a new technical effect, would pass the test of inventiveness.

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[177] Supra no. 156, Part C Chapter IV p. 71.
[178] Cain, "Legal Aspects of Gene Technology", 2003, p. 130.
[179] T2/83, OJ EPO 1984, 265.
[180] Biogen case, T296/93, OJ EPO 1995, 627.
[181] Genentech case, T0455/91, OJ EPO 684.
[182] Unilever case, T386/94, OJ EPO 1996, 658.
[183] T22/82, OJ EPO 1982, 341.
[184] Supra no. 176.
[185] Supra no. 160, p. 131.
[186] Supra no. 160, p. 131

The Trilateral Projects specify the application of the prong of inventiveness to the EST's. DNA fragments, which do not have any specific utility, are not inventive. Also cloned sequences are not inventive, as it is routine in the field of genetic research, unless they have a new technical effect or specific utility. Thereby if the EST's can be used to diagnose a specified disease or they can enable identification of a new sequence with known specific utility, they are held to be inventive because the technical effect would be present.[187]

C. Novelty

The third requirement of patentability concerns the novelty of a product. Article 54 of the EPC states that,

> "(1) An invention shall be considered to be new if it does not form part of the state of the art.
>
> (2) The state of art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application."

In the field of genetics, the massive sequencing and cloning of genes is a source of confusion as to where goes the line between genes, which are still novel and those, which form already a part of the state of the art.

The cases T158/91[188], T479/97[189] and T400/99[190] indicate that to deny a patent on grounds of the lack of novelty a gene must be a subject of a "firm and unambiguous" technical teaching, which must directly lead to what it purports to anticipate. Conversely, where a gene has been sequenced as a part of research routine or in a mass sequencing, it should still be considered as novel because no functions have been ascribed to it and thereby no one would know what technical application it could have.[191]

The Biogen case[192] suggests also that a gene cloned but merely contained in a DNA library, lost among thousands of other genes, is still novel. The criterion of novelty would not be met when a gene was made available to the public.

The Trilateral Projects analysed also a case, where a gene filed for patent protection was isolated but overlaps or is similar in sequence to another gene forming already a part of the state of art. Such a gene shall be nevertheless conferred patent protection. Only if there is a full sequence

[187] Supra no. 169, cases E and D.
[188] T158/91.
[189] T479/97.
[190] T400/99.
[191] Supra no. 160, p. 126.
[192] Supra no. 175.

identity between two cloned and sequenced genes, patent protection for the second claim shall be denied.[193]

Yet, case G2/88[194] indicates that where an already known compound is to be used for a second and different purpose, the patent protection cannot be rejected on grounds of the lack of novelty. It implies that where a gene product is capable of two different uses in two different technical processes, two patents protecting each of these processes could be granted.[195]

D. Disclosure

Apart from the three main requirements of patentability, which determine whether an invention is capable of being patented, the EPC also requires a disclosure of an invention. Article 83 of the EPC states that,

> "The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art."

This is further supplemented by the requirement of clarity of the claims referred to in Article 84 EPC.

The EPO guidelines explain that the disclosure of a biotechnological invention consists of a description and a deposit of the material concerned. Rule 27 a, concerning the nucleotide or amino acid sequences, requires a description in form of a sequence listing. It may also be additionally required that the sequence listing be submitted on a data carrier accompanied by a statement that the information recorded on the data carrier is identical to the written sequence listing.[196] The details of deposition of the biological material are specified in Rule 28.

The disclosure of a gene-related invention may prove particularly problematic because of the variability of the sequences, the difficulties with the reproduction of the molecular techniques and the multiply functions of proteins.[197] The EPO case law has already commenced to deal with this complex problem.

The case T409/91[198] stated that the disclosure must enable the invention to be workable in the whole area claimed. Yet, it requires serious doubts and verifiable facts to find that an invention lacks the enablement.[199]

As to the reproduction process, it shall be conducted without "undue burden"[200] or the use of inventive skills.[201] The standard here is however somewhat unclear. An undue burden would consist in proceeding by trial

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[193] Trilateral Project 24.1: Biotechnology comparative study on biotechnology patent practices, at 2.2; supra no. 160.
[194] G2/88, OJ EPO 93.
[195] Supra no. 178, p.128.
[196] Supra no. 156.
[197] Supra no. 160, p.131.
[198] T409/91, OJ EPO 1994, 653.
[199] T19/90, OJ EPO 1990, 476.
[200] T226/85, OJ EPO 1988, 336.
[201] T931/91.

and error[202] but interestingly not in a "difficult, complex and time consuming" procedure of gene cloning.[203] When the biological material reproduced varies in the starting material, the invention shall still still considered as properly disclosed, as long as the material obtained belongs to the class claimed.[204] Conversely, only where the material obtained belongs to another class than the one claimed the invention should be held as not sufficiently disclosed.

In the case of gene-related patent defined through homology to an already disclosed sequence, the claim should be restricted to the variants of the disclosed sequence, which have the desired property. This should be supported by an easy reproducible test to ascertain that the operation is conducted within the area claimed.[205]

E. Morality exception

Although an invention which is eligible of patent protection still meets the requirements of patentability, and is sufficiently disclosed, it may nevertheless be excluded from patentability. Article 53 of the EPC (mirrored by Article 5 (1) of the 1998 Directive) codifies the rule concerning the exceptions to patentability. It states,

> "European patent shall not be granted in respect of … inventions the publication or exploitation of which would be contrary to 'ordre publique' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;…"

The definition and the scope of morality/ordre publique provision differ throughout Europe because of significant cultural (and sometimes religious) differences between the Member States. It has also been rarely invoked as a ground to deny patentability of an invention. However, the importance of the provision began to increase with the advent of biotechnology. In an attempt to overcome the lack of a universal definition, the EPO has tried to sketch at least general guidelines, on which to base the interpretation of this provision.

"Ordre publique" has been defined as a notion safeguarding the protection of public security and physical integrity of individuals as part of society. It also encompasses the protection of environment.[206]

"Morality" is a concept referring to the belief that some behaviour is right and acceptable whereas other behaviour is wrong. This belief is founded on the totality of the accepted norms, which are deeply rooted in a particular culture. In the European context, it is the culture inherent in European society and civilisation. It follows that the inventions the

[202] T32/85.
[203] T223/92.
[204] T301/87, OJ EPO 1990, 335.
[205] T20/81, OJ EPO 1982, 217; T1/80, OJ EPO 1981, 206; and supra no. 160.
[206] T356/93 OJ EPO 1995, 545.

exploitation of which is not in conformity with the conventionally accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality.[207]

The case law focused on the moral aspect of the patentability of human genes in the Hormone Relaxin case.[208] This case concerned a patent on DNA sequence encoding human relaxin. This particular subject matter gave rise to an opposition claiming inter alia that the grant of patent on human gene offends the morality or ordre publique. Three major arguments advanced by the opposition stated that,

1. In order to put the invention into practice one had to take tissue from a pregnant women what constitutes “an offence against human dignity”;
2. The patenting of human genes “amounts to a form of modern slavery since it involves the dismemberment of women and their piecemeal sale to commercial enterprises”;
3. The patenting of human genes is inherently immoral.

The EPO did not agree with any of the arguments. Answering to the first claim it stated that there cannot be anything immoral in taking human tissue, what constitutes already a standard practise, as long as the donor has consented to it. Dealing with the second claim, the EPO observed that alone the argument “betray a fundamental misunderstanding of the effects of patents”. Patents do not confer any property rights over human beings; therefore they are not tantamount to patenting life. “Patenting of a single human gene has nothing to do with the patenting of human life. Even if every human gene in the human genome were cloned (and possibly patented) it would be impossible to reconstitute a human being from the sum of its genes.” As to the third argument, the EPO could see "no moral distinction" between "the patenting of genes on the one hand and of other human substances on the other especially in view of the fact that only through gene cloning have many important human proteins become available in sufficient amounts to be medically applied". Therefore, the patentability of human genes is as such not immoral which implies that inventions concerning human genes cannot be excluded from patentability.

1. The fragility of the acceptance of patents on human genes

The EPO’s finding that the patents on human genes are not as such immoral has been further confirmed by the adoption of 1998 Directive, which recognises the possibility of human gene patenting. Yet, the European acceptance of human gene patents has proven very fragile. Soon after the Directive was adopted, the Netherlands filed a legal action aimed at annulment of the Directive. Under the guise of technical or legal deficiencies of the Directive, it was factually challenged on ethical

[207] Supra no. 206.
[208] Hormone Relaxin case, T272/95.

grounds.[209] In particular the Netherlands suggested that it was unclear when biotechnological inventions would be ineligible for patent protection on ethical grounds and regarded the possibility of patents over isolated parts of human body including genes as offensive to human dignity.

Both Dutch arguments were dismissed.[210] The European Court of Justice (the ECJ) observed that when assessing the morality provision, the Member States dispose of a "wide scope of manoeuvre". In other words, the Member States have a wide margin of appreciation enabling them to take into account "the particular difficulties to which use of certain patents may give rise in the social and cultural context of each Member State." Interestingly, such a ruling seems to be a setback in comparison with the morality definition formulated by the EPO. The EPO finding suggested that there may exist or at least is emerging a common European standard based on "the culture inherent in European society and civilisation."[211] The ECJ's decision returned to the no-reconcilable European mosaic.

As to the second claim, the ECJ emphasised that the patents may only be granted on genes, which have been isolated and purified which makes them distinct from the human body. The human body as such at the various stages of its formation and development as well as a simple discovery of one of its elements (including genes) cannot be patented. Therefore the Directive guarantees the respect for human dignity. Overall, the consistency of human gene patenting with the morality notion has again been confirmed.

2. The uncertainty remains

Although the Directive has remained in force, the fragility of the acceptance of patenting of human genes is still clearly seen. On 4th October 2001 the European Parliament passed a resolution concerning patents on the breast cancer genes. In the resolution, the Parliament expressed "its dismay at the possible consequences of the granting by the EPO of a patent on human gene" and called "on the EPO to reconsider patenting these genes."[212] In its response, the EPO emphasised that it is only an administrative agency, which "applies and interprets the rules laid down by the legislature,"[213] therefore it cannot change the law the European Parliament itself adopted. Yet, its frustration about the contrary approach of the European Parliament, which as a legislative body set the current standard itself, could clearly be seen.[214]

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[209] Curley/Sharples, "Patenting Biotechnology in Europe: The Ethical Debate Moves On", European Intellectual Property Review 2002, p.566.

[210] R. V. Re Legal Protection of Biotechnological Inventions: The Netherlands v. European parliament and EU Council, case C-377/98.

[211] Supra no. 206.

[212] European Parliament, "European Parliament Resolution on the Patenting of BRCA 1 and BRCA2 ('Breast Cancer') Genes", Texts Adopetd by Parliament, Provisional Ediiton, 04.10.2001, b5-0633, 0641 and 0663/2001.

[213] Supra no. 212.

[214] Moore, "Challenge to the Biotechnology Directive", European Intellectual Property Review 2002, p.149. Not less controversial is the issue of patenting human genes in the United States. In January 30, 2004 the Congress passed a bill forbidding issuing patents on

3. Conclusion

In summary, the patentability of human genes is as such not contrary to the morality provision. It has however remained highly controversial. This controversy has intensified around the morality/ordre publique exception: this provision is the point where the ethical concerns discussed in Chapter III are taken into consideration and exert an influence on the European patent law. And although the concerns and fears connected with human genes patentability have not so far taken prevalence – the patentability of inventions based on human genes has not as such been denied – they have substantially shaken the standard proving the significant meaning the ethical concerns hold. This resulted in blocking any attempt going into direction of European unification of the morality provision and rendered the standard highly uncertain: The definition of morality or ordre publique is still in the margin of appreciation of the Member States which means that each of the States concerned may deny a patent on an invention whose use might entail particular special or cultural difficulties what could factually mean a decision whether to accept or to deny the patentability of human genes.

F. Prohibition of patenting therapies and diagnostic methods

The European patent law also prohibits patenting of therapies and other diagnostic methods. Article 52 (4) EPC states that,

> "Methods for treatment of the human or animal body by surgery or *therapy* and *diagnostic methods* practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application…. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods." [Emphasis added]

This provision was codified to safeguard the free access to medicine, which could be affected, when exposed to profit – guided rationale of patents.[215] It plays an important role for the development and potential protection of gene tests and gene therapies.

Overall, there are three categories of gene patents in Europe.[216]

"human organisms". However, the unclear wording of the act has caused uncertainty as to the term "human organisms", which may imply the prohibition of patenting solely human embryos as well as the prohibition of patenting all human-derived inventions. See: US Congress, "Consolidated Appropriations Act, 2004," HR 2673, Sec. 634, Jan. 30, 2004; to the controversy around ist interpretation see Wilkie, "Stealth Stipulation Shadows Stem Cell Research", The Scientist, March 1, 2004.

[215] Jain, "To Patent or Not to Patent: Gene Therapy in the European Union and the United States", Cardozo Journal of International and Comparative Law 1996, p. 103.

[216] Supra no. 178, p. 121.

1. “Product patent” – covering the gene sequence itself, seen as a product sold as a diagnostic tool to determine whether a particular disease is present. This type of patent can also cover the protein encoded for by the particular gene if this protein could be used as a medicine in the treatment of the disease concerned. The product patent confers rights over all uses of that product.

2. “Process patent” – covering a specified method or process applicable to a gene sequence. This type of patent does not assign rights over the sequence itself, unless the gene or its protein is an element of the process or method concerned but not its product. (It implies that the process or method must be used to produce another product.)

3. “Use patent” – covering the specific use of a gene. This type of patent seems significantly broad. As Nuffield Council on Bioethics observes, “the effect of the patent owner having broad property rights over the diagnostic use of the gene for just one disease, would be that the patent owner has a monopoly over all ways of testing for that disease. This is because, even though the use patent does not include the sequence itself in the patent claims, in practice any other diagnostic test for the disease specified in a use patent would infringe that patent."[217]

Gene tests and gene therapies could fall under either the category “use patent” or the “product patent”. Yet, the prohibition of Article 52 (4) excludes the possibility of granting “use patents” in relation to them: This type of patent protection, if granted, would precisely cover what is prohibited in the Article 52 (4) EPC, i.e., specific use in form of gene therapy or diagnostic methods – gene tests.

Paradoxically however, the grant of “product patents” in relation to genes renders the limitation void. A patent-holder of a product patent on a gene contributing to a disease, although unable to prevent others from an application of a particular method or therapy is nevertheless entitled to exclude all others from the use of the basic element of such a method, the gene contributing to a particular disease. It implies that a product patent-holder may in fact have a monopoly over all the therapies or tests, which involve the usage of the patented gene. In other words, to be able to practise a therapy or diagnosis, the not-patent-holders would be obliged to pay the royalties, which would significantly increase the costs of medical treatment. This is almost tantamount to patent protection for particular methods, since it similarly impedes access to tests and therapies. Thus it seems that although patents on genetic tests and therapies are theoretically prohibited, the product patent-holders may nevertheless undermine the notion of free

[217] Supra no. 10 at 5.24.

medicine in Europe, rendering the provision of Article 52 (4) EPC no longer effective.

G. Conclusion

The European patent law recognised very reluctantly the patentability of human gene-related inventions. Although the standard seems to be harmonised today, such patents can still be denied by each and every Member State voicing the difficulties arising in the "particular social or cultural context."[218] Moreover, gene-based inventions also challenge the patentability requirements. It is still a matter of a heated debate whether and, if the answer proves affirmative, when should the EST's or genes of unknown function be patentable (will be also discussed in the next Chapter). Also the practise concerning the requirements of novelty and inventiveness is rather emerging than well-established. Overall, gene-based inventions constitute a great challenge to the existing European patent regime.

V. The economics of gene related patents

Patent protection has been awarded to gene related inventions in order to foster the progress of science and strengthen the investment incentives in the biotechnological and pharmaceutical industries. A similar policy of granting intellectual property rights proved successful during the industrial revolution and in promoting the developments in the chemical industry. Yet, although patents offer unitary set of rules for inventions in all fields, their impact varies from one industry to another.[219] It implies that schemes that have proven successful in earlier developed fields may have pernicious effects on biotechnological or pharmaceutical industry.

One of the major concerns increasingly voiced during the last years is the observation that patent protection, adversely to its rationale, constitutes a deterrent to biological innovation and accordingly an impediment to the further development of new medical tools. At the heart of the debate lies here the patentability of upstream research results, (i.e., research that is relatively far removed from a commercial end product).[220]

As has been mentioned above, patents are contemporarily being granted on nascent inventions such as isolated genes, gene sequences, or proteins of unknown functions and sometimes pure research tools - EST's. The rationale supporting their patentability emphasises the high R&D costs occurring both in the pre- and post-invention stage. The research path leading from initial discovery of a potentially relevant DNA fragment to a commercially successful downstream marketable product is risky, lengthy

[218] Supra no. 212.
[219] Eisenberg, "Analyse This: A Law and Economics Agenda for the Patent System", Vanderbilt Law Review 2000, p. 2083.
[220] Rai, "Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust", Berkeley Technology Law Journal 2001, p. 814.

and expensive. Moreover, the knowledge acquired in the course of the research may easily be appropriated by competitors without incurring any costs on their side. Therefore, without the protection from competition covering the period of the transition from a discovery to a marketable product, the industry would be deprived of any profit incentives and therefore unwilling to invest in any biotechnological research. This would presumably significantly already decrease the number of discoveries.[221]

The economic and patent literature also provides an additional argument holding that monopolies are conducive to innovation. The economist Joseph Schumpeter contends that monopolies promote innovation and growth more effectively than competition. In the rapidly changing conditions of a capitalist economy investment in innovation requires protection against losses, which is secured by monopolies. Additionally, monopolies enable the developer "to gain the time and space for further developments", allowing further innovation and better appropriation of the surplus of the innovations' investment than in the competitive markets. Monopolies are also susceptible to challenges by new technologies. Therefore those monopolies that become complacent and are not willing to innovate more are likely to be replaced by new monopolies: the prospect of earning more than an ordinary return permeates new innovators to secure financial investment and to bid productive resources away from the current users. Therefore, monopolies increase rather than restrict the use of known technologies.[222]

Edmund Kitch provides a more elaborate analysis of the role of patents for the innovation process. He advocates awarding patent rights for so-called "prospects", i.e., new inventions or discoveries made early in the development process (the notion is synonymous to the "upstream research discoveries" used in relation to biotechnology). Through an early grant of patent rights the potential investors are stimulated to supply financial resources because they do not "fear that the fruits of the investment [would] produce unpatentable information appropriable by competitors". Kitch also argues that patent protection at an early stage of development is likely to effect further research. An immature invention cannot be put on the market. Therefore, a patent owner will be willing to engage in the subsequent R&D, because it renders the invention commercially exploitable thereby securing his profits. Kitch observes also that by creating patent monopolies the patent owners of the early inventions are put in the position of controlling and coordinating post-invention R&D. Thereby, he argues, the duplicative research can be avoided what promotes efficiency of the subsequent developments. The notion of efficiency is also reflected in the proposed scope of patent protection. According to Kitch, the patent rights should be broad encompassing the early immature version of an invention as well as all subsequent refinements made by the patent holder and other researchers within the period of patents' validity. Such broad exclusive rights should induce the other researchers to pursue research on the underlying invention

[221] Eisenberg, "Intellectual Property at the Public - Private Divide: the Case of Large Scale cDNA Sequencing", University of Chicago Law School Roundtable 1996, p. 558.
[222] Schumpeter, "Capitalism, Socialism and Democracy", 1942, p. 81 – 110; "Theory of Economic Development", reprint 1983, p. 61 – 94.

only having agreed for a license with the patent owner. Otherwise, they would be unable to benefit from their work and investment. This broad scope of patents shall further enhance the control of the patent holder over the post-invention R&D facilitating the coordination of the further work and thus promoting greater efficiency.[223]

Both theories support the grant of broad patent rights on gene related upstream inventions. Yet, in spite of the strong arguments in favour of the broad patents, the empirical experience has shown rather negative consequences of such a policy leading ultimately to the under-use of the existing resources.

A. Proliferation of property rights

The basic counterargument directed against patents on upstream biotechnological inventions holds that they have an excessive effect on the proliferation of property rights which creates a serious impediment to the development of downstream products such as pharmaceuticals or diagnostic tests based on genes.

The first element in the complex mosaic of multiple factors and dependencies leading from an early discovery to a marketable medical product concerns the interplay between the sectors directly contributing to the development of medical tools: the biotechnological and pharmaceutical industries.

1. Structure of the relevant industries

In the 1970's and 1980's the pharmaceutical industry worked quite independently from the biotechnological industry. The pharmaceutical companies produced small molecule chemical drug therapies considering only a relatively insignificant number of proteins to be involved in various disease processes. These two types of companies usually did not collaborate at the pre-clinical research stage.[224]

Today however, the distinction between the pharmaceutical and biotechnological industries has been blurred. Almost all pharmaceutical research is based on genetic information, which is owned by biotechnological companies. This prerequisites a high dependency of the pharmaceutical sector on the biotechnological industry. Professor Rai provides persuasive examples hereto. "[A] pharmaceutical company that was interested in developing a drug for Alzheimer's disease would need access to gene fragments or genes relevant to the disease. This 'upstream' research … might be owned by one or more biotechnology firms, thus making it necessary for the pharmaceutical firm to negotiate with the biotechnology firm. Alternatively, a pharmaceutical company that was

[223] Kitch, "The Nature and Function of the Patent System", Journal of Law and Economics 1977, p. 267-278.
[224] Supra no. 220.

interested in developing a 'precision' drug targeted to individuals with a particular genetic subtype of a given phenotypic disease would need information on the slight DNA variations or SNP's that are responsible, or linked to, the subtype. Because much of the SNP's research has been done by biotechnology companies (e.g., CuraGen), the pharmaceutical firm would need to negotiate with the biotechnology firm."[225] Being highly dependent on the biotechnological inventions, the pharmaceutical sector has been trying to facilitate the access to genetic information through a close cooperation with the biotechnological companies.

Interestingly, this cooperation is also partly evoked by the nature of genetic information: Sequencing of human genome is followed by a massive explosion of data in the industry. This accounts for a boom in technology and as a consequence fragmentation of that technology and data among a huge number of organisations such as universities, start up companies and pharmaceutical giants.[226] An upshot of this fragmentation is the fact that no company, however big, can work alone. As Ernst &Young's Eighth Annual European Life Sciences Report 2001 observes, "[t]he only way to survive is through integration with others in the industry. Loners will have no future."[227]

The collaboration takes place on different levels. Horizontally, the pharmaceutical companies are merging creating giant entities which makes their market position more powerful and enables them a more efficient division of work. In the course of the last few years a significant number of prominent pharmaceutical companies like Novartis, GlaxoSmithKline or Aventis are products of horizontal mergers.[228]

Vertically, both the pharmaceutical and biotechnology industries are either going in the direction of a strong integration sharing not only pre-clinical and clinical R&D costs but also the overall profits from the drugs developed. Or, they are expanding their fields of activities: the pharmaceutical companies establish research laboratories (e.g., the pharmaceutical company Novartis has established a research laboratory known as the Genomics Institute conducting independently of the biotechnological companies a substantial number of its research;[229] similarly Pfizer has established a new Global Research and Development Center conducting basic research in drug discovery using genomics tools[230]); conversely, the biotechnological companies move downstream into clinical R&D (e.g., Human Genome Sciences, Millennium, and Abgenix)[231].

The third form of consolidation consists in a mixed horizontal and vertical activity. The already integrated companies such as Millenium or

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[225] Supra no. 220.
[226] Supra no. 5.
[227] Supra no. 5.
[228] Balto/Mongoven, "Antitrust Enforcement in Pharmaceutical Industry Mergers", Food Drug Law Journal 1999, p. 255.
[229] See Genomics Institute of the Novartis Foundation, available at http://www.gnf.org/about.htm
[230] Rosenberg, "Discovery Zone Amid a Reshaping of the Drug Industry; Giant Pfizer Inc. Opens Itself to a New Environment", Boston Globe 17.01.2001, at D4.
[231] Van Brunt, "Grand Ambitions", Signals Magazine 24.02.2001, available at http://www.signalsmag.com

Abgenix that have both upstream and downstream research capabilities have been acquiring upstream companies in order to enhance their vertical strength.[232]

The growing integration of pharmaceutical and biotechnological industries or the increasing strength of the horizontal activities of the pharmaceutical companies may indeed facilitate the access to genetic information on its way down towards the development of downstream marketable medicines. Yet, the worrying feature of such an alliance is the fact that the benefits arising from such integration can be reaped only by the companies within the respective structure, not by the third parties from outside. Therefore, the strong consolidation may be undesirable from the viewpoint of competition law.

However, the vertical and horizontal integration falls short of creating monopolies,[233] what logically weakens the position of firms being outside the integrated structure, i.e., the potential competitors. The consolidation on horizontal and/or vertical levels leads undoubtedly to a creation of a dominant position on the pharmaceutical and biotechnological innovation and product markets. Gaining strength, the emerging monopolies may easily be seen as abusing their market position, since the possession of a dominant market position always resembles balancing on the verge of anti-competitive and therefore unlawful activities. Founding of an abuse of a dominant position infringes the rule of Article 82 of the EC Treaty, thereby inducing the dissolution of the integrated structure. In other words, the consolidation or mergers is quite a risky endeavour, which, if not carefully guided, may end up in the point of departure.

In summary, the tendency to integrate the pharmaceutical and biotechnological industries, if not found anti-competitive and thus unlawful, may at most diminish the number of relevant property rights for the firms working in the close alliances. However, it still does not eliminate the main problem: the proliferation of patent rights commencing already at the level of upstream research discoveries, which effects the inability of biotechnological and thereby pharmaceutical companies to pursue genetic research projects because of too many or too broad patent rights.

2. Deficiencies of upstream patent rights

Let us analyse the grounds accounting for the proliferation of patent rights and its consequences.

a) Proliferation of patent rights

As has been noted above, patent protection is contemporarily being granted for gene fragments such as EST's, not complete gene sequences and other fragmentary genetic material. Such a policy leads inevitably to a

[232] Supra no. 219, 230.
[233] Supra no. 220.

situation where multiple exclusive rights have been granted on different parts of the same gene,[234] what might render any future research attempt on the gene concerned not pursuable. Multiple property claims increase the transaction costs and hamper the conclusion of a licensing agreement.

Where the rights to a gene are held by many persons or entities, any post-invention researcher would need to gather not a single authorisation but a bundle of rights encompassing consent of each of the patent owners. Yet, an agreement between them may prove very difficult to be achieved. Each of the patent holders may have different interests in regard to his invention. A typical example of conflicting goals concerns the diverging interests of the public and private patent owners: whereas the public entities will usually aim at lowering the costs of an invention and promoting the progress of public health, the private companies will typically prioritise the maintenance of lucrative monopolies.[235] Pursuing conflicting goals, each of the patent owners may deploy its rights to block the others, thereby making any licensing agreement unfeasible.[236]

There may also be a potential disagreement about the transaction costs. The rights involved may cover a diverse set of techniques, reagents, fragments of DNA sequence and instruments, which serving different purposes, render the patents concerned not comparable in value. Professors Heller and Eisenberg also observe that the researchers are likely to overestimate the value of their discoveries. "Given the assumption that no owner knows ex ante, which invention will be the key, a rational owner should be willing to sell her patent for the probable value of $200,000. However, if each owner overestimates the likelihood that her patent will be the key, then each will demand more than the probable value, the upstream owners collectively will demand more than the aggregate market value of their inputs, the downstream user will decline the offers, and the new drug will not be developed."[237]

Moreover, the licensing transactions over the early discoveries will presumably occur at the time when the outcome of the project will still be uncertain and the potential gain speculative. Disagreement about the high cost of the royalties relative to the devergent high of the profits expected may also make it very difficult for the negotiating parties to reach an agreement.

The heterogeneous interests of the patent holders mentioned above are very likely to create enduring obstacles on the negotiation path causing an inability of concluding a license agreement. They also account for the difficulty to standardise the biomedical patent negotiations what necessarily leaves the costly case-by-case bases as the only possibility.[238]

Upstream research patent can also generate new proliferation of patent rights. Taking from the public domain basic research discoveries, they restrict the possibilities of access to them for the researchers with

[234] Supra no. 104.
[235] Heller/Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research", Science 1998, p. 698.
[236] Supra no. 235.
[237] Supra no. 235.
[238] Supra no. 235.

limited financial resources. This might induce the latter to agree to give the upstream patent holders the rights in subsequent future downstream products in turn for a lower or deferred license fee. Such an agreement known as reach – through licensing may grant rights in form of a royalty on sales, an exclusive or nonexclusive license on future discoveries, or an option to acquire a license. Such agreements are at the first glance advantageous for both sides: The post-invention researchers may use the patented research tools right away and postpone the payment of license fee until their research yields profitable results. The patent holders may also favour the presumably larger payoffs from sales on downstream products rather than certain but smaller upfront fees.[239] Yet, such agreements lead eventually to exacerbation of the already proliferated property rights. Through the use of reach – through license agreements the upstream patent owner retains a continuing right to be present at the bargaining table as a research project moves downstream toward product development.[240] Consequently, the post – invention researcher may have difficulties conveying clear title to his research results what may in turn discourage the downstream companies interested in developing a marketable product from investing in such a development. As Professor Rai observes, the particularly valuable products' prospects may still attract investment. But less certain or low profits products are unlikely to allure the downstream product developers,[241] leaving the inventions unexplored.

The problem of proliferation of upstream patent rights becomes exacerbated when the research project requires the use of multiple DNA fragments. Unfortunately, most of the commercial products of genetic research require the use of several gene fragments.[242]Accordingly, all the hurdles mentioned above, multiplied by the increased number of parties involved, occur here with greater intensity. Additionally, developing pharmaceutical products, the pharmaceutical firms want to screen potential products against all known members of the relevant receptor families in order to learn as much as possible about the therapeutic effects and side effects of the products concerned. Yet, when these receptors are patented and controlled by different person or entities, gathering the necessary licenses may be very difficult or impossible.[243] Unable to collect a complete set of licenses, the pharmaceutical companies may either be completely prevented in developing a potential medicine and divert resources to less promising projects with fewer licensing obstacles or proceed to animal or clinical testing basing on an incomplete information.[244] Both outcomes may substantially deter human heath care.

[239] Supra no. 235.
[240] Supra no. 235.
[241] Supra no. 220.
[242] Supra no. 165.
[243] Supra no. 235.
[244] Supra no. 235.

b) Excessive scope of patent protection

Research on pharmaceuticals based on genes can also be tied up by too broad patent rights. The main deterrent to further development in this context is granting patents on the basis of homology, i.e., theoretical functions. Theoretical functions do not give the researchers any idea about the potential pharmaceutical products.[245] Quite to the contrary, the upstream genetic inventions require extensive innovation providing a determinate proof of real functions to produce a commercial product.[246] Yet, the uncertainty as to the factual functions can effect in too wide scope of patent protection awarded in relation to upstream research what in turn may have pernicious effects on the further R&D process. Basing patent claim on a hypothesis of future utility, the patent drafter will naturally tend to encompass as broad patent scope as possible, claiming often all possible applications of a particular gene.[247] Such a broad scope of patent implies that the patent holder will have exclusivity claim in relation to all later discovered uses, regardless whether being the result of his or others R&D. Such an outcome leads to an inequitable result, since it deprives the independent working researchers from the benefits of their work and investment rewarding on the other hand the passive patent holder for others fruitful research. As the President of the U.S. National Academy of Science and the President of the Royal Society of London in their joint article put it, "[t]hose who would patent DNA sequences without real knowledge of their utility are stacking claims not only to what little they know at present, but also to everything that might later be discovered about the genes and proteins associated with the sequence. They are, in effect, laying claims to a function that is not yet known or a use that does not yet exist."[248] Sadly, this scenario has already been proven real by the empirical experience.

In 1995 the company named Human Genome Sciences (HGS) filed a patent application in the U.S. for a particular gene (HDGNR10), claiming utility of the invention as "a tool for screening for receptors agonists and antagonists."[249] The claim demonstrated that the gene encoded CCR5 protein, thereby including this protein in the scope of protection sought for, although the utility of the sole protein was neither claimed nor known at that time. The patent encompassing the gene and the CCR5 protein was issued in 2000.[250]

At the same time, the scientists at the Pasteur Institute were conducting research directed at blocking the Human Immunodeficiency Virus (HIV), causing the Acquired Immunodeficiency Syndrome (AIDS). In 1996 the research revealed that the necessary protein for HIV infection was

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[245] Supra no. 165.
[246] Summers, "The Scope of Utility in the Twenty-First Century: New Guidance for Gene-Related Patents", Georgetown Law Journal 2003, p. 476.
[247] Supra no. 165.
[248] Alberts/Klug, "The Human Genome Itself Must Be Freely Available to All Humankind", 404 Nature 2000, p. 325.
[249] Luukkonen, "Gene Patents: How Useful are the New Utility Requirements?", Thomas Jefferson Law Review 2001, p. 353.
[250] Supra no. 246.

CCR5 protein meaning that the failure to express this protein causes immunity to the virus. In other words, the CCR5 receptor has become a basis for downstream research on possible therapies for AIDS.[251] Yet, the one who is entitled to license the receptor thereby getting an adequate share of profits are not the scientists at the Pasteur Institute, but the HGS. Furthermore, to be able to continue their valuable research, the scientists at the Pasteur Institute must negotiate with the HGS for a license on the use of the CCR5 protein. In other words, due to the too wide patent scope, the HGS can capitalise on the research it did not conduct and is entitled to block those who had pursued it from further work.

Such an outcome has spurred frustration in the scientific community. Worryingly, it gives rise to two negative tendencies. On the one hand, the patent holders quickly become complacent with their immature inventions and rests on the basic technology. As bioethics Jon Merz observes, the patent owners "have little incentive to continue to a full characterisation of the gene product – but could claim the rights to the results of other researchers who later did this"[252] without incurring any post – invention R&D costs. On the other hand, the scientists who do not hold patent rights are discouraged to pursue any further research on patented DNA fragments, knowing that their research will be immediately taxed by the patent holder if it was ever fruitful.[253] Indeed, some scientists have already dropped the research because the gene was patented.[254] Both tendencies taken together may stunt the promising new research and leave the upstream genetic discoveries underdeveloped.

Prof. Rai goes a step further in the prediction of likely consequences of the excessive scope of the patent rights. He contends that too broad scope of patent protection on upstream research induces an increased vertical integration of companies.[255] This may further impede the research process because at a stage where only a few vertically integrated firms exist the number of different research paths, which are likely to be pursued, is considerably narrowed.[256] This in turn leads to almost complete stagnation because "[n]ot only is a single vertically integrated firm likely to be relatively large, and hence possibly risk adverse and lacking in creativity, but it is also unlikely to license its upstream research to other developers who may pursue alternative paths."[257]

3. Tragedy of Anticommons

Professors Heller and Eisenberg named the current gene-patenting

[251] Supra no. 246.
[252] Boyce/Coghlan (quoting Jon Merz), "Your Genes In Their Hands", New Scientists 20.05.2000, p. 15.
[253] Supra no. 251.
[254] Foubister, "Gene patent raise concerns for researchers, clinicians", Amednews.com 21.02.2000, available at http://www.ama-assn.org/sci-pubs/amnews/pisk_00/prsb0221.htm (visited on 11.08.2003).
[255] Supra no. 220.
[256] Supra no. 220.
[257] Supra no. 220.

situation as the "tragedy of anticommons". In contrast to the "tragedy of commons", a metaphor introduced by Garrett Hardin thirty years ago in *Science*, which relates to the overuse of the common resources because of the lack of an incentive to conserve; the "tragedy of anticommons" pertains to a situation "when multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use."[258] Heller and Eisenberg acknowledge that patent protection for upstream research may fortify the incentives to undertake risky research; they observe however that "privatisation can go astray when too many owners hold rights in previous discoveries that constitute obstacles to future research."[259]

The metaphor "tragedy of anticommons" reflects precisely the deadlock in the current gene-patenting situation. Granting patents on upstream research discoveries creates a jungle of dependencies which becomes more complex as the product moves down followed by an increasing number of property claims. As the authors conclude "[e]ach upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical research."[260]

4. Blocking patents

It should be noted however, that although patents on upstream research do create a serious impediment of the future research, the downstream development is also marked by pernicious proliferation of property rights.

Overall, upstream inventors should be willing to license their inventions because the subsequent development and commercialisation secures an adequate share of profits, which they would not be able to reap from a nascent and far removed from the commercial path invention. Their main difficulty lies therefore in a conclusion of a license agreement.

On the later stage however, when the invention is already marketed, the willingness to license the product for a subsequent innovation may substantially diminish. The would-be licensee is at the same time a potential improver, which may come out with an improved substitute product effectuating thereby a decrease in the profits reaped from the commercialisation of the first-generation invention. Dr Cho of Stanford University's Centre for Biomedical Ethics published already the evidence of such behaviour in relation to gene testing associated with haemochromatosis, an iron overloaded disorder. "The haemochromatosis patent holders have not been quite as aggressive at preventing researchers from doing research on their own, but they have been fairly aggressive about asking for licenses for clinical testing [necessary to refine and improve the tests]".[261] Myriad Genetics on the other hand, holding the

[258] Supra no. 235.
[259] Supra no. 235.
[260] Supra no. 235.
[261] Salleh (quoting Cho), "Gene Patents May Stunt Research", News in Science 11.11.2002, available at http://www.abc.net.au/science/news/stories/s722384.htm (visited 11.08.2003)

patents on breast cancer genes have limited the number of licensees to a very few.[262]

The other feature of downstream proliferation of the patent rights is the typical blocking patent situation. It occurs when the second-generation inventor comes up with a patentable improvement of the first-generation invention. The second-generation invention, although may be independently patentable, incorporates necessarily the first-generation invention. Thereby the improver must seek a license agreement with the first-generation inventor because otherwise any use of the second-generation invention would infringe on the first inventor's patent.[263] Conversely, first-generation inventor is similarly blocked since his invention cannot be used without an infringement on the second-generation patent.[264] Therefore, both patent holders may block each other unless they come to a licensing agreement entitling both parties to use their own inventions. Yet, as professor Rai observes, it may be very difficult for such a licensing negotiation to go forward. "[I]n the context of blocking patents on cumulative innovation, it is impossible to divide the surplus ex post in a manner that provides adequate incentives for both the initial inventor and the improver: in general, the improver will not receive a sufficient share of surplus. This is especially true where the value of the patented improvement is large relative to that of the initial patented invention. In that case the possibility of strategic bargaining by the inventor is quite high."[265] Yet, when the parties do not come to an agreement and the patents block each other, none of the inventors can take advantage of their respective inventions and the inventions remain unutilised.

5. The concerns of the industry

All the deficiencies of the proliferation of patent rights both in the upstream and in the downstream genetic research are likely to realise fully the prophesied tragedy of anticommons. Too excessive proliferation of property rights leads to an under-use of the existing resources because too many are entitled to dispose of them, whereby they effectively block each

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[262] Supra no. 260; however the patent rights on the genes in question (BRCA1 and BRCA2) held by Myriad Genetics has been revoked in 2004 by the EPO. In Februar 2004 the EPO revoked the Myriad's patent on BRCA2 and granted a Europe-wide patent to the charity Cancer Research UK, because much of the BRCA2 gene was first published by Mike Stratton's group at the Institute of Cancer Research, London, based on work funded by Cancer Research UK. Cancer Research UK announced to the relief of the European scientific community that it will allow publicly owned laboratories to use the gene free of charge. On May 18, 2004 the EPO revoked the Myriad's patent on BRCA1, reasoning that the application was not deemed "inventive". See: EPO Press Release May 18, 2004; Mayor, "Charity wins BRCA2 patent", The Scientist, February 13, 2004; Coghlan, "Europe revokes controversial gene patent", New Scientist, May 19, 2004.

[263] Supra no. 220.

[264] Levang, "Evaluating the Use of Patent Pools for Biotechnology: a Refutation to the USPTO White Paper Concerning Biotechnology Patent Pools", Santa Clara Computer and High Technology Law Journal 2002, p. 330.

[265] Supra no. 220.

other. In such an environment the conduct of any research project prerequisites collecting a bundle of rights, a hurdle intractable either in fact (by lack of an authorisation of one of the patent holders) or through extremely high costs.

Indeed, the proliferation of the patent rights has commenced to affect the industry. Dr. Robert I. Levy called the gene-patenting situation a "minefield", pointing to the difficulty of ascertaining who owns the rights to which genetic sequences and tools accompanied by the high royalty fees, which can amount to twelve to fourteen percent of the cost of a drug.[266] Peter Ringose, the head of R&D at Bristol-Myers Squibb noted recently that there were dozens of project which the company could not pursue because it was unable to conclude the requisite licensing agreements with the upstream research holders.[267] The National Institutes of Health Working Group on Research Tools noted frustration in the biotechnology, pharmaceutical and academic research sectors with high transaction costs of licensing negotiations over research tools.[268] Indeed, forty-eight percent of laboratory physicians surveyed by Jon Merz reported not developing a test because of the fees associated with it.[269] The jungle of property rights becomes even more complex in the international context. As one alarmed U.S. biotechnology lawyer observed: "What if the gene turns out to be linked to another gene that the French have licensed? … I'm not going to invest a million dollars with that kind of uncertainty."[270]

The industry has begun to draw conclusions from the current impasse in the gene-patenting situation. As Francis Collins, director of the Human Genome Project, observed, "nobody wants to travel the road any more. There are so many tools, there are so many complicated patent and licensing agreements, there are so many royalty fees attached, that doing any really interesting experiments, where you may want to draw several discoveries together, and put yourself a little further down the road, just isn't worth any more."[271]

6. Impact on medical care

The impasse in the gene-patenting situation affects however not only the scientific community and the industry. The impossibility to develop certain medical products or the extremely high costs connected with their development has ultimately a harmful effect on the patient care. Patients are eventually those who bear the consequences of the proliferation of patent rights either by being completely blocked from the access to certain medicines or tests or by paying an unreasonably high price for them. As Vida Foubister observes, "[t]he monopolistic nature of patents and their

[266] Pollack (quoting Levy), "Is everything for sale?", New York Times 28.07.2000, at C1.
[267] Pollack, "Bristol-Myers and Athersys Make Deal on Gene Patents", New Yourk Times 08.01.2001, at C2.
[268] Supra no. 220.
[269] Supra no. 104.
[270] Anderson, "US Patent Application Stirs Up Gene Hunters", 353 Nature 1991, p. 485.
[271] Supra no. 264 (qouting Collins).

licensing could … price out many patients, limiting their access to new genetic information about themselves, their children and their future children [what] has the potential to create the haves and the have-nots in terms of genetic information about health."[272] Similarly Dorothy Nelkin, "[p]atent practices may ultimately compromise medical care and undermine trust in the medical profession. A researcher who owns a patent on a gene or DNA sequence can prohibit others from using the gene or charge high licensing fees to researchers who later try to develop related tests or therapies. All other labs may be forbidden from even looking for mutations on the gene unless they pay a royalty to the patent holder. As smaller and smaller sections of genes are patented, licensing becomes more of a constraint. [Ultimately], the patent holder can foreclose testing for a genetic disease or charge licensing fees that raise costs beyond the range of ordinary people."[273] Indeed, the reality confirms those predictions. Myriad Genetics, the patent holder on breast cancer genes, has charged over US$ 2,000 per breast cancer test, what has significantly decreased the accessibility to the product.[274] Similarly, some laboratories testing for Down's syndrome in the prenatal stage have ceased doing the tests because the royalty fees charged by the patentee of the relevant gene exceed the authorised medical reimbursement.[275] Likewise (or even more restrictively), the haemochromatosis patent holders have blocked the licensing for direct patient care.[276]

The tendencies in the current biotechnology and pharmaceutical sectors are indeed worrying. Moreover, the path of development goes in the direction undesirable for all sides. Therefore, there is an increased need to find a reasonable solution, which would factually promote the progress of science and work to the benefit of human health care.

B. Proposed solutions

The literature has provided several solutions to the impasse in the gene-patenting situation. The three most frequently occurring will be discussed below.

1. Narrower utility requirement

One of the proposed solutions postulates a stricter utility requirement. The utility requirement (named formally "the susceptibility of industrial application") should in its origin draw a borderline between not patentable basic research and patentable applied art, meaning in the context

[272] Supra no. 255.
[273] Nelkin, "Patenting Genes and the Public Interest", The American Journal of Bioethics 2002, p. 14.
[274] Supra no. 261.
[275] Nelkin/Andrews, "Homo Economicus: Commercialisation of Body Tissue in the Age of Biotechnology", Hastings Center Report, Sept. – Oct. 1998, p. 30, 37.
[276] Supra no. 261.

of biotechnology between the upstream and downstream R&D.[277] Today however, as the upstream research fall under the realm of patentability, the distinction has been blurred. In consequence, too lax utility requirement is the cause of the too broad scope of patent protection and proliferation of property rights.[278] Thus, it is the source of inequitable outcomes, which can eventually stunt any post-invention research.

The main postulate of this approach is to restore the clear dividing line between basic and applied research thereby counter-fighting too broad scope of patent protection. Professor Rai contends that the stricter utility requirement is the only means to achieve this goal at the disposal of patent law. "In various ways, the doctrinal tools of patent law facilitate drawing the line between patentable and unpatentable inventions. In theory, any of the various patentability requirements – patentable subject matter, utility, nonobviousness, or enablement and written description – could be used. In practise, however, only the utility requirement serves as a particularly good proxy for differentiating upstream from downstream research."[279] Therefore, the susceptibility of industrial application should be narrowed down to inventions, which give a concrete idea about the future utilisation. Basic upstream research or the sequences of unknown functions are rather far remote from a concrete utilisation. As Professor Donna Gitter observes, merely theoretical functions do not furnish determinative proof of real multifaceted role played by a DNA fragment or gene, much less give the researchers new ideas for pharmaceutical products. Excessively lenient application of the utility criterion "hampers biotech research, particularly international collaboration, by permitting patent holders with only a vague notion of a sequence's function to demand exorbitant royalty fees from later researchers."[280] Similarly Teresa Summers, notes "[a] broad utility requirement, which issues patents on basic research tools, is precisely what frustrates collaboration and pre-empts a host of downstream development. When parties to the collaboration pursue opposing intentions, technology sits underdeveloped. Misaligned incentives stagnate innovation."[281]

The proposed stricter utility requirement should encompass only the downstream products and cover their concrete applications, whereas the basic upstream research would remain freely accessible in the public domain. "Traditionally distinct scientific spheres draw a clear dividing line between basic and applied research. Upstream basic research tools remain freely accessible, while downstream innovations are patented and sold to the consumers. For example, a pharmaceutical firm benefits from widespread access of basic research when their proprietary drugs offer added value over the public domain version. The private sector realises greater profits when it builds on the results of publicly funded research and development instead of conducting that research themselves. A narrow utility requirement respects this linear flow of information and accounts for public access and

[277] Supra no. 220.
[278] Supra no. 165.
[279] Supra no. 220.
[280] Supra no. 165.
[281] Supra no. 246.

commercial innovation."[282] Interestingly, Professors Philippe Jacobs and Geertrui Van Overwalle contend that such a clear division – going even a step further and arguing for patents only for medicines not for genes (not even at the stage of downstream research) – would also dismiss the ethical concerns raised by the patentability of human genes.[283]

Some companies have already commenced to follow the proposed path and put in the public domain upstream research. In the mid-1990s, the pharmaceutical company Merck & Co. put into the public domain the results of an EST identification project. The ground for such a decision is the hope "to take advantage of the efforts of those who will use the results to do fundamental research, [believing that] its own comparative advantage lies in using the fundamental research of others to do downstream work directed towards the formulation of particular drugs".[284] More recently, a group of pharmaceutical companies forming a consortium mapping the single nucleotide polymorphisms in the human genome have been placing the information obtained on a quarterly basis.[285] Arthur Holden, chief executive of the consortium, explained that putting the sequences into the public domain what precludes their patentability will "ensure we have the basic alphabet".[286] Similarly, other pharmaceutical companies in conjunction with Affymetrix, a maker of DNA micro arrays, are supporting an effort to sequence the mouse genome and place the results in the public domain.[287]

What is however striking here, given the time the entire sector has had to take similar steps, the companies, which decided to put the valuable information into public domain are rather few against an overwhelming majority still using patent protection. This suggests that the majority of biotechnological or pharmaceutical firms do not consider the free availability of upstream research to be in their best interests. This in turn confirms the fact mentioned already at the outset of this thesis: the pharmaceutical and biotechnological industries rely strongly on patent protection seeing in patents the best form of security against competitors what entails investment and thereby innovation. Therefore, leaving the upstream research in the public domain would presumably have twofold consequences. "[N]arrow patents on upstream research might not provide sufficient incentives for innovation – whether initial invention or subsequent development – especially in cases where the upstream research was expensive and not subsidised by public funding."[288] Consequently, not protected by patents, the basic upstream inventions would possibly never be made or further explored. As a result, the public would never reap the

[282] Supra no. 246.
[283] Jacobs/Van Overwalle, "Gene Patents: A Different Approach", European Intellectual Property Review 2001, p. 505-506.
[284] Rai, "Regulating Scientific Research: intellectual Property Rights and the Norms of Science", Northwestern University Law Review 1999, p. 110.
[285] Supra no. 284.
[286] Supra no. 267 (quoting Holden).
[287] Supra no. 220.
[288] Supra no. 220.

multitude of downstream innovation.[289] Alternatively, firms still willing to pursue the biotechnological research while lacking of patent protection for upstream inventions, would presumably revert to trade secrecy. Any of the outcomes, being a direct aftermath of a stricter utility requirement, would not improve the current genetic R&D situation.

Nuffield Council on Bioethics also observed that the public ownership of gene sequences is likely to lead to waste, mismanagement and a lack of incentive to find and develop new resources, being a foundation for a drift in the direction of another extreme, tragedy of commons. Therefore, the Council argues for the maintenance of the patent protection on gene-related inventions stressing at the same time that the development for profit cannot prevent access to genes. In other words, the central question is how to secure the free and unrestricted access to gene-related inventions. Alone the involvement of private interests and profit-making organisations do not necessarily entail unjustifiable restrictions on it.[290]

The other postulate of this approach – restriction of utility requirement only to concrete application of a given gene – also raises some doubts. The experience has shown that one gene may have a variety of different uses each of which may be discovered by a separate person or entity. In the current situation, the first one gets patent protection thereby blocking or reaping unfair profits from the research of others. Yet, if each of the uses could be separately patented, the inequitable outcomes in the profit share could possibly be avoided, but it would not solve the main problem: the proliferation of property rights. To be able to pursue any research project, the interested researcher or company would have to gather further on a complex bundle of rights, encountering all the problems occurring currently. Therefore, such a solution would perhaps strengthen the incentives for post-invention researchers, but would not solve the current impasse.

2. Patent pools, cross-licensing agreements

The other proposed solution is to foster the formation of patent pools. As Brandley Levang explains, "[a] patent pool is formed when multiple patent holders combine their patents into a single entity that then licenses the bundle of patents to themselves and third parties. Patent pools expand upon the idea of a cross-license, where two parties agree to let the other use their patents, by usually involving more than two parties and creating a system where third parties can buy the right to use the pool of patents."[291]

Patent pools have proven successful inter alia in music and computer industries. In the former one, the American Society of Composers, Authors and Publishers (ASCAP) and Broadcast Music Incorporated (BMI) were founded to facilitate licensing transactions so that broadcasters and other

[289] Maurer, "An Economic Justification for a broad Interpretation of Patentable Subject Matter", Northwestern University Law Review 2001, p. 1061.
[290] Supra no. 10, p. 22 at 3.8
[291] Supra no. 264.

producers readily may obtain permission to play numerous copyrighted works held by different owners.[292] In the computer industry, personal computer manufacturers have pooled their patents to share hundreds of patents held by many different inventors.[293] In 1997 a patent pool was created for MPEG-2 compression technology conserving space and reducing transmission time by compressing information within binary data streams. The pool is administered by an entity called MPEG-LA, which is responsible for royalties and licensing to third parties.[294] Brandley Levang comments that the "patent pools enabled innovation to reach the marketplace that otherwise might have been prevented by blocking or complementary patents."[295]

Indeed, combining numerous patents into a single pool simplifies the process of collecting the rights necessary for a particular project, what in turn helps overcoming the blocking situation and prompts further innovation. Additionally, patent pools reduce transaction costs because they require negotiations only with an entity administering the pool instead of burdensome negotiations separately with each of the patent holders. Moreover, they foster the exchange of information within the pool, what promotes the progress of technology. also and Trademark Office asserts, that patent pools further a more equal distribution of risks since by distributing the royalties to all pool members they ensure profits (or at least a coverage for the costs spent) of the patent holders.[296]

It is doubtful however whether the biotechnological and pharmaceutical companies are likely to form patent pools. The specific features of the biopharmaceutical sector may be the source of serious obstacles: Patents matter in biotechnology and in pharmaceutical sector more than in other industries. Therefore, firms are less likely to be willing to share their exclusivity rights.[297] This holds especially true for the small companies whose only asset are the intellectual property rights. As Iain Cockburn, an economist at Boston University observes, "[t]he nature of the biotech industry is the potential cause of some problems. There are a lot of small, hungry companies out there whose only asset is intellectual property. It's less likely that broad cross-licensing agreements can happen. If you have too many people owing small, overlapping slices of the same pie, there could be a breakdown."[298] Also other scholars contend that patent holders would rather refuse to license their inventions and collect a comprehensive patent portfolio effectively precluding others from working with competing technologies. Additionally, to secure the original market value of their patents, patent holders are likely to attempt precluding others from inventing around the patent, since the development of non-infringing substitutes

[292] Supra no. 246.
[293] Supra no. 165.
[294] Supra no. 264.
[295] Supra no. 264.
[296] Clark, "United State Patent and Trademark Office, Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?" 2000, available at: http://uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf.
[297] Supra no. 235.
[298] Regalado (quoting Cockburn), "The Great Gene Grab" Technical Review 2000, p.50.

would presumably diminish the patent value.[299] It is also worth noting that the leverage of the patent holders is in the field of biotechnology is especially strong because certain biotechnological discoveries do not have substitutes. This may only further aggravate the holdout problems.[300]

Another sort of difficulties, which may arise on the way to forming biotechnological patent pools, concerns the valuation of patents within the pool. Where the patents are granted to the companies, which do not have a definite understanding of the functions of a DNA fragment – thus are uncertain as to the final importance of their patents – it may be difficult to determine the high of a royalty. Taking into account the above discussed tendency to overvalue the patents' significance by the patent holders, the royalty fee is never likely to be agreed upon or be unreasonably high.[301]

The biotechnological would-be pool members would often also pursue disparate goals and thereby take different patent position and attitude toward patents. Although Professor Rai argues that the increased vertical integration in the sector is likely to decrease the heterogeneous interests in the industry,[302] it is still not enough for successful patent pools to be formed. As Brandley Levang observes, "[i]n past patent pooling successes, all of the patents were amassed for one similar product. For instance, the airline patent pool was used to manufacture airlines, or the MPEG patent pool to aid in storing and sending digitised media. Biotechnology patents do not lend themselves so nicely to a mass-produced end product."[303] Therefore, the patent held by one patent holder may be of interest for others on the research stage but not for the development of the single and the same pharmaceutical.

Brandley Levang contends also that the inability of the biotechnological inventions to result in a homogenous mass-production renders the formation of patent pools unprofitable. The formation of a pool is very costly. The MPEG pool members paid the high costs in anticipation of the profits yielded by the mass produces consumer devices such as televisions, DVD players, or cable and satellite services. Yet the biotechnological products have limited uses and applications. Therefore the cost of forming pools is likely to exceed the profits reaped.[304]

The final thought needs to be given to the tension between patent pools and competition law. In the United States, where the pools took their origin, the patent pooling agreements were long seen as anti-competitive and therefore almost completely prohibited. In the recent years however they have increasingly been gaining acceptance.[305] The main concern of the competition law has related to propensity of patent pools to monopoly practices, collusion, price fixing and preservation of the invalid patents.

[299] Supra no. 165.
[300] Supra no. 235.
[301] Supra no. 264, 246, 235.
[302] Supra no. 284.
[303] Supra no. 264.
[304] Supra no. 264.
[305] In 1995 the US PTO issued antitrust guidelines, which allow formation of patent pools provided that the requirements listed in the guidelines are fulfilled. In 2000 the Department of Justice and Trade Commission expressly recognised that patent pooling agreements can have pro-competitive effects.

Indeed, the conclusion of patent pooling agreements involves a risk that the typical competitors, instead of vying with each other for market shares, will combine their patents thereby creating a market monopoly fixing prices and eliminating any competition of the patents from outside the pool. Another risk resulting from creation of patent pools is the increased probability of preserving invalid patents: instead of paying for a costly litigation, the threatened patent holder may choose to form or join a pool as a settlement measure. Thereby, he retains patent rights and royalty streams, which could otherwise disappear if a court invalidated his patent.[306] Professor Rai observes also that patent pools could adversely affect competition through so called grant back clauses, which might reduce the licensee's incentive to engage in R&D and thereby discourage innovation. "[A]nother feature of patent pools that might signal anti-competitive effects would be a grant back requirement, to the effect that members grant licenses to each other for any future technology they developed using the pool license. If pool members were forced to share their successful R&D, incentives to free-ride might diminish innovation. … [T]his problem would be particularly acute if the pooling arrangement included a significant fraction of the R&D in an innovation market."[307]

In Europe the problem of patent pools does not have a long history and is therefore only scarcely regulated. Article 81 (1) of the EC Treaty prohibits the practices, which restrict or distort competition within the common market. There are however exemptions to this prohibition, most important of which is the Regulation No 2659/2000[308] concerning R&D agreements. The regulation states that this research and development agreements shall not be treated as anti-competitive as long as they do not contain restrictions of competition. If the agreement concerns not competing undertakings, the exemption covers the entire R&D time (it is seven years prolonged where they exploit the results jointly). The same period applies to competing undertakings only when at the time the agreement is entered into, the combined market share of the participating undertakings does not exceed 25 % of the relevant market. Overall, patent pools are allowed in Europe only when they fulfil the strict criteria set out in the above Regulation. This implies that unlike the shift in the United States, Europe still puts greater emphasis rather on their anti-competitive than pro-competitive effects.

3. Compulsory licensing

The third proposed solution argues for administratively regulated compulsory licensing. Interestingly, it derives partially from the approaches discussed above and attempts to sketch an improved version of those two: It acknowledges the need for a stricter utility requirement, yet contends that it is not enough to solve the current gene-patenting problem. Patent pools

[306] Supra no. 264.
[307] Supra no. 220.
[308] Commission Regulation (EC) No 2659/2000 of 29 November 2000 on the application of Article 81(3) of the Treaty to categories of research and development agreements.

approach, on the other hand, does touch the core postulate, the licensing and cross-licensing of the patent rights, yet is not effective because the pools, impeded through the specific features of the biotechnology, will not be formed naturally. Therefore the legislative should enact the obligatory licensing of gene-related inventions. As Professor Donna Gitter writes, "a compulsory licensing system … would require an owner of patent rights in a DNA sequence to license that sequence to any and all scientists pursuing commercial research related to that sequence in return for a reasonable fee. The licensing fee would not be established by the individual licensor, but would instead depend on the commercial value of the product developed as a result of the research."[309] The system would, in other words, encourage the potential post-invention developer to invest and pursue further research through its fairness, because the amount of the royalty fee would be tied to the profitability of the product developed. Additionally, the post-invention researchers would not have to request from the patent holder before commencing with the research; a written notice would suffice.[310] The licensor, on the other hand, would also be satisfied because he would receive proportional to the financial success of the product developed by the licensee, adequate compensation. Professor Gitter continues, "[b]y eliminating pre-use license negotiations and up-front payments while still protecting a patentee's rights to a reasonable royalty, this compulsory licensing system will foster innovation."[311] It would also contribute to an increased accessibility to medicines and thereby an improved patient care.

The compulsory licensing solution seems to be the most comprehensive and persuasive one. Although Professor Rai argues that it would be "too radical departure from the existing regime" for the biopharmaceutical sector because this sector relies too heavily on patent protection, taking into account the current number of patent holders together with their different attitudes towards patents, an obligation to license in return for a reasonable royalty seems to be the only feasible way out from the current impasse.

VI. Conclusion

At the heart of the debate over the patents on human genes is the question, how to proceed to improve the state of human medicine in an effective and cautious way, i.e., without impeding the existing social and cultural order. Human genes have proven to be much promising material to develop new generation of medicines whose promises go far beyond the abilities of traditional medicine. Yet, they also do constitute quite an unusual research material, which like nothing before turned out to be of

[309] Supra no. 165.
[310] Mueller, "No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools", Washington Law Review 2001, p. 50.
[311] Supra no. 165.

particular importance for people. Both features of human genes, accounting for contrary interests and attitudes, assign law the conciliatory role consisting in careful balancing between ethics and economics: Ethics shall *condemn* everything which infringes and offends human dignity and thereby brings discredit to the notion of human. As an answer to it, law should *prohibit* everything which infringes human dignity (the role of Human Rights); and award the exclusivity rights in a way securing the efficiency of the protection granted and promoting future development (the role of Patent Regime). Ultimately, economics should serve as an indicator of the efficiency of the existing law and show whether or not the balance between the protection and promotion has been maintained.

This thesis is an application of the above analysis to the human genes problem. It aims at verifying whether contemporary European legal order fulfils its role. Yet, the results achieved are only half-satisfactory.

Since patents on gene-related inventions do not concern living humans or their body parts but rather genetic material derived from it; and genes do not also play any special, "master" role in the development of human body or personality, gene-patents do not give they rise to any scientifically justified ethical opposition. As a consequence, they cannot be seen as violating human dignity. The role of Human Rights is limited therefore to observing and warning against the negative implication particular actions or policies may bring. As the example of genetic tests shows, this role can be seen as fulfilled.

The second role of law, i.e., the efficient regulation of patent rights, raises however some doubts. The economics shows an impasse in the genetic R&D process. It may have deteriorating effects on the human health care reflected by stifling of the development of innovative pharmaceuticals. This proves the existing patent regime is not adequate. Therefore, it should be reshaped in order to redress the balance between protection and promotion.

Appendix

Overview of the Drug Discovery Process I

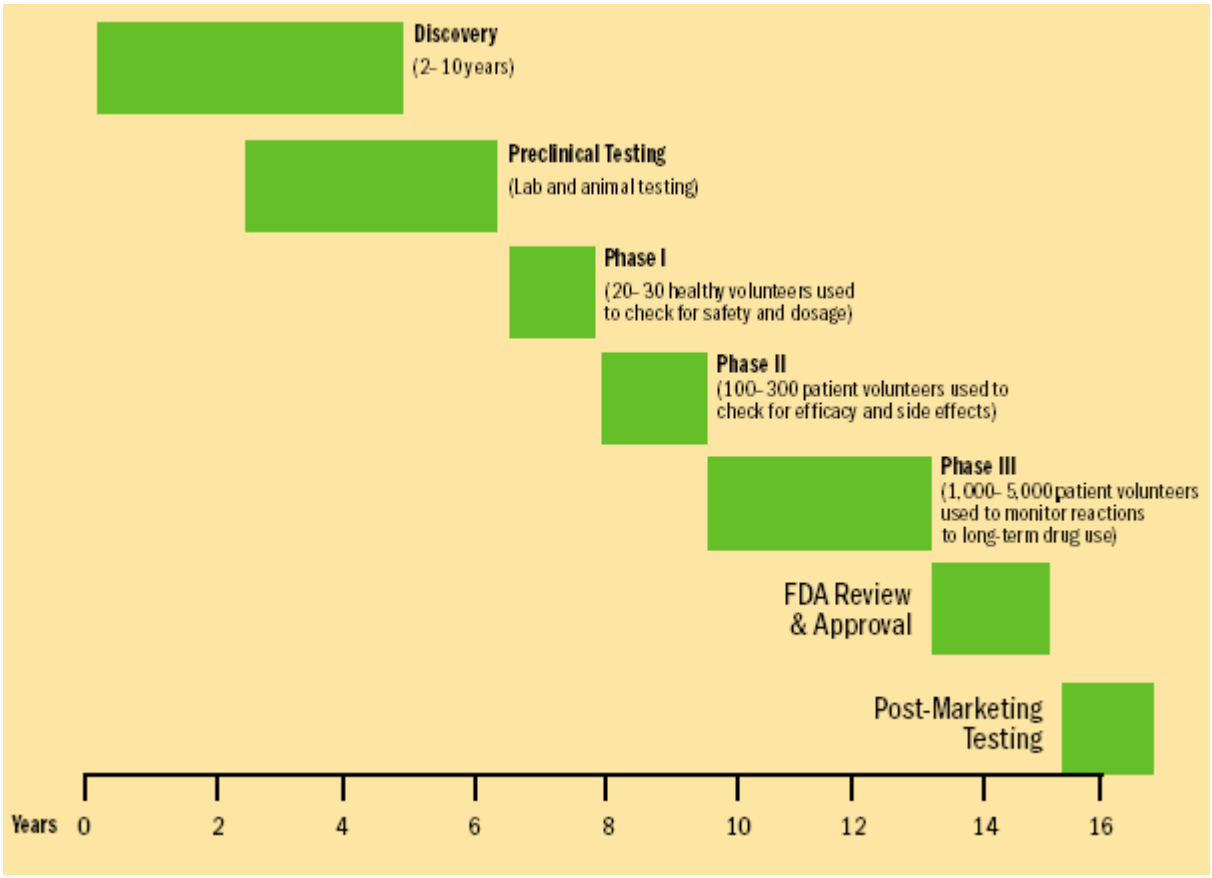

Figure 1:
Pre-Marketing stages of drug development in years on the example of the US.

Source: Ernst & Young Annual Report on Biotechnology Industry 2000, "Convergence – The Biotechnology Industry Report", p. 46.

Overview of the Drug Discovery Process II

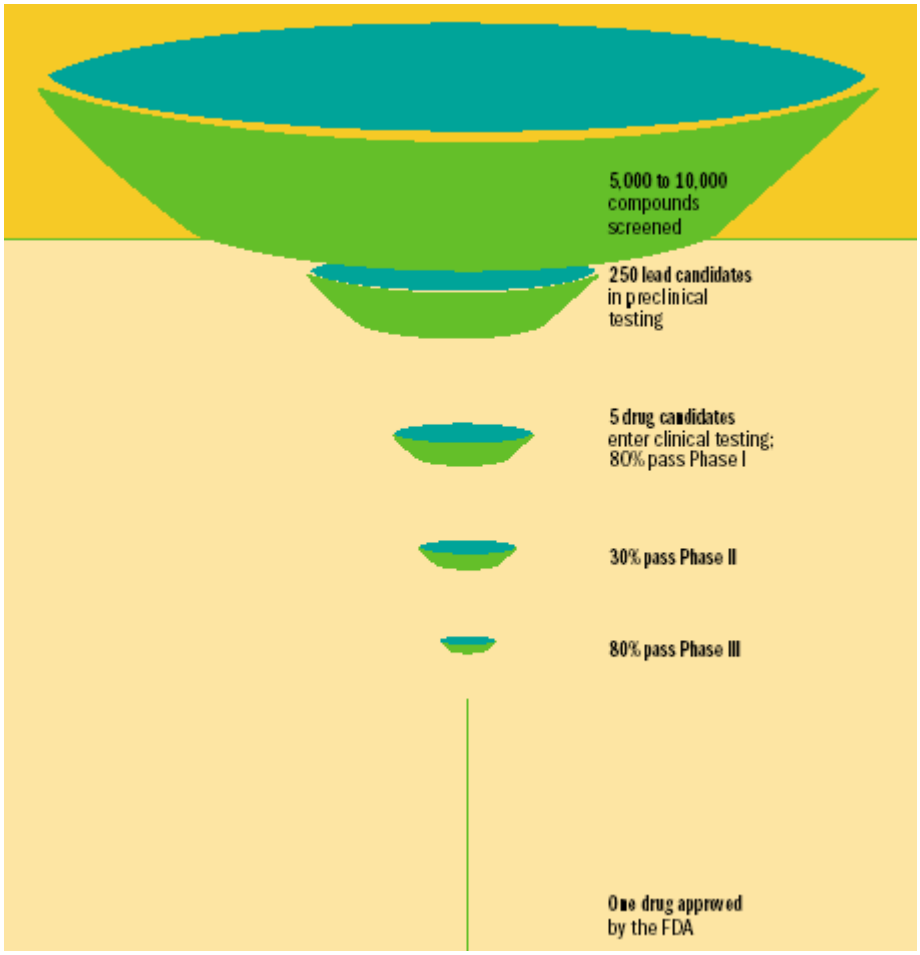

Figure 2:

Selection process of the substances, which are discovered, researched on and developed into drugs put eventually on the market.

Source: Ernst & Young Annual Report on Biotechnology Industry 2000, “Convergence – The Biotechnology Industry Report”, p. 47.

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