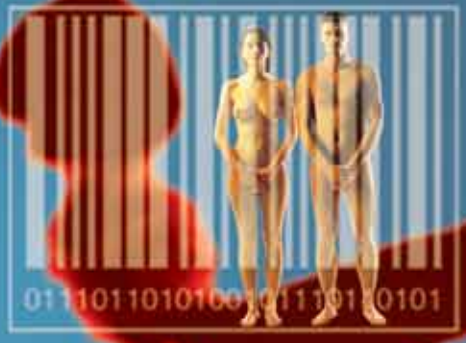

PATENTING HUMAN GENES AND STEM CELLS

A REPORT
THE DANISH COUNCIL
OF ETHICS 2004

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FOREWORD

The Danish Council of Ethics is sending out its report on the ethics of patenting human genes and stem cells. The report is a follow-up to the Council's 1993 report *Patenting Human Genes*, and the present report thus deals with the developments in the field that have taken place in the past 10 years.

During that period, mapping of the human genome has been declared complete, the EU Patent Directive has been adopted (but still not implemented in half the member states) and a debate has flared up as to whether gene patents strike the right balance between public and private interests. Not least, however, stem cell research has made great advances during the period and the need to adopt a position on the special problems associated with patenting human embryonic stem cells and adult stem cells has taken on relevance. Since, in the opinion of the Council, there are still unclarified ethical questions linked to the patenting of both genes and stem cells taken from humans, there has been a desire to review the subject.

In the summer of 2003, The Danish Council of Ethics therefore set up a working party to look into the area, consisting of: Klavs Birkholm, Asger Dirksen, Mette Hartlev, Ole Hartling, Thomas G. Jensen, John Steen Johansen and Ragnhild Riis. Mette Hartlev chaired the group till spring 2004, when the pressure of work imposed by her 'civilian' post forced her to withdraw from the group and hand the chair to Thomas G. Jensen. For the sake of good order the Council would like to point out that, as an inventor, Thomas G. Jensen has applied for a patent on modified adult stem cells and is co-founder of a company whose object is to benefit from this patent.

The Council wishes to thank a number of people for having placed their knowledge and know-how at the disposal of the Council's and the working party's labours

along the way. Those people are: Tine Sommer, associate professor at the Department of Law at the Aarhus School of Business, Anders Børglum, associate professor from the Department of Human Genetics at the University of Aarhus, Niels Holtug, associate professor from the Department of Philosophy at the University of Copenhagen, Niels Holm Svendsen, senior adviser, and Anita Thyrsted, special adviser from the Danish Patent and Trademark Office, Tor Lezemore, assistant director from the Nuffield Council on Bioethics, Peter Lotz, associate professor from the Department of Industrial Economics and Strategy at the Copenhagen Business School, and Professor Torben Kruse from the Institute of Clinical Research at the University of Southern Denmark. The report was penned in collaboration between the following: from the Council's secretariat: Henrik K. Jørgensen, MA, PhD, Berit Andersen Faber, LLM, Nanna Skriver, MSc, and Anne Lykkeskov, MA, who also project-managed the work. The Danish Ministry for the Interior and Health's Analysis and Development Pool has granted funding for the project.

The working party handed the report to the Council in March 2004, and after processing here it was finalized at the Council's meeting on 26 May 2004.

Ole Hartling
Chairman

Berit Andersen Faber
Head of Secretariat

1. INTRODUCTION AND BACKGROUND

Patenting human genes and stem cells

Patenting human genes and stem cells is generally perceived as ethically controversial. The ethical scruples attach partly to the question of whether it is at all acceptable to patent human genes and stem cells, and partly to the consequences such patenting can have for diagnosis, treatment of illness and disease, and research.

With this report The Danish Council of Ethics wishes to contribute to the general discussion about the ethical defensibility of taking out patents on human genes and stem cells. At the same time the Council wishes to contribute recommendations to the rules in force and to the current practice of granting human gene and stem cell patents with regard to how best to safeguard ethical considerations in the process.

But the Council also sees it as one of its tasks to provide a coherent review of the actual implications of gene and stem cell patents, and where the associated problems lie, so as to make it understandable for people other than experts. It is the Council's view that the current rules governing the patenting of human genetic material are highly inscrutable and complex. It is unusually difficult for common citizens, politicians, journalists and others to navigate their way through the discussions between patent administrators and patent lawyers, representatives of industry, public and private sector researchers, and other experts, and to receive complete and clear information as to why genes and stem cells have to be patented, how it is going to be done and what the consequences are going to be. This is also due to the fact that various experts often disagree about how rules and consequences should be construed. The Council hopes to contribute to a clearer public debate on gene and stem cell patents: What do they actually denote, and why do most people react to the thought with distaste?

Resentment towards human gene and stem cell patents

The controversial nature of gene patenting is partly reflected in the fact that it took 10 years' heated discussions in the EU before it was finally possible to adopt the Commission's Patent Directive (Dir 98/44 EC) in 1998. Denmark implemented the directive just two years later, the formal deadline by which member states finally had to make the directive national law. But the majority of other member states did not do so, and today the fiercely discussed directive has been implemented by only eight of the countries that made up the EU until 1 May 2004.[1] The Netherlands instituted proceedings at the European Court of Justice to have the directive declared invalid but lost the case in 2001. However, that has not prompted the last seven countries[2] to implement it, and in July 2003 the European Commission decided to bring an action against those countries before the Court of Justice for breach of treaty as a result of their lack of cooperation.[3]

Despite the problems involved in getting the Patent Directive implemented, the Council for the European Union on 3 March 2003 unanimously adopted a common political line on the introduction of an actual European Community patent, allowing European companies to obtain a patent valid throughout the European Union.[4] Final adoption is a slow affair, however, just as attempts under the auspices of the World Intellectual Property Organization (WIPO) to adopt a worldwide Patent Law Treaty, which were started in Geneva more than 15 years ago, have all foundered without yielding results for the time being.[5]

But why, six years after the directive was adopted, is the discussion about gene and stem cell patents still just as intense and in many ways polarized?

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1 I.e. Denmark, Finland, Great Britain, Greece, Ireland, Portugal, Spain and Sweden. In May 2004 Germany tabled a motion to have the directive implemented.

2 Austria, Belgium, France, Germany, Italy, Luxembourg and the Netherlands.

3 Press release IP/03/991 from the Commission on 10 July 2003: Industrial property: eight Member States referred to Court for failure to implement Directive on legal protection of biotechnological inventions.

4 The present situation is that the award of patents in the EU can be achieved by means of several systems: On the basis of the European Patent Convention, European patents can be granted. Through the Patent Cooperation Treaty and the national patent laws, the national patent authorities can not only grant national patents but may also be obligated to accept international patent applications that have been processed by an international novelty investigation authority. Common to the current systems, however, is that they must be administered nationally in those countries where the patent is in effect.

5 Gallochat, Alain. 2003. *Global Harmonization of Substantive Patent Law*. Paper presented at the IBC's 12th Annual International Conference: Protecting Biotechnological Inventions. 17 & 18 November 2003.

This ties in with the fact that patents for trade and industry—and for the pharmaceutical companies in particular—have assumed increasing importance[6]. Amongst other things, such companies view it as their way of recouping the money they have invested in developing a new treatment, since a patent entitles them to exclusive rights to exploit the invention for 20 years, and developing new medicine is a costly affair. It is also a question of securing the greatest possible return for company shareholders. Publicly employed researchers, too, are being urged to patent their inventions; patents are of mounting importance here.

Among large parts of the populations and with many politicians, however, gene and stem cell patents are unpopular. Many feel an instinctive aversion to these types of patents. Many take the view that genetic information from human beings is entitled to special protection or that no one can be granted sole rights to exploit living human material.

In addition, the patents issued can have a number of built-in problems. The Nuffield Council[7], for example, in a report from 2002,[8] demonstrated that many of the patents already granted on DNA sequences rest on a dubious foundation. Many of the gene patents submitted are too broad, granting the inventor rights over *all* future applications of a particular DNA sequence. Instead of stimulating research, such patents often straitjacket both research and diagnosis.

Completion of the Human Genome Project (or HUGO) was only the start of a process in which researchers are discovering how the genes actually function in interaction with the rest of the organism. But broad patents have already been granted on genes based on the description of a specific function associated with a particular gene. As it is gradually discovered that the gene also codes for other functions, it often transpires that the patent also covers these other functions associated with the gene, although these were not known when the patent was issued.[9]

So patents can be granted on genes before any in-depth knowledge of them exists, and that can cause problems. These problems have to do with this type of

6 OECD. 2002. Genetic Inventions, Intellectual Property Rights and Licensing Practices. P. 8.

7 Nuffield Council on Bioethics is equally financed between the Nuffield Foundation, the Wellcome Trust and the British Medical Research Council.

8 Nuffield Council on Bioethics. 2002. The Ethics of Patenting DNA - a discussion paper.

patenting being a relatively new phenomenon, and one which it has primarily been chosen to manage by the patenting rules already in existence. [10]

How we came to have patents on biological material

Until a couple of decades ago virtually nobody thought of taking out patents on human genes and stem cells. Patent laws distinguish between inventions and discoveries. This distinction reflects a view that an *invention* was made by a researcher using nuts and bolts and other inert materials. If it had any novelty value and involved an "inventive step", it entitled the inventor to a patent. Everything that occurs in nature, on the other hand, could only be discovered, and a *discovery* could not be patented. This classification still holds good, but it has generated debate as to how inventions and discoveries should be separated within biotechnology.

This has happened in step with developments in science. Admittedly, a patent was granted on a biological organism (a yeast culture)[11] back at the end of the 1800s, but that kind of patent was the rare exception to the rule—until recently. In the 1980s biotechnological developments started to take off, and there was a boom in new types of patent. These were patents on human genes and living organisms, originally found in nature and not created by an inventor. In mapping man's genes (the Human Genome Project), researchers have obtained more knowledge about the genes, and that has added impetus to the development of new treatments for disease and methods of diagnosis. It is a field that has seen whirlwind development, particularly since the middle of the 1990s. In 2001 more than 5,000 DNA patents were granted in the USA, more than for the years 1991-95 combined,[12] and Europe has seen a parallel development, albeit the figures are slightly lower than the American ones.

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9 French Council of Ethics, CCNE, mention in their statement no. 64 on the 2000 Patent Directive the example of the CCR5 gene: "It was obtained by systematic random sequencing of DNA code messengers, and it encodes a membrane receptor of a particular type. The sequence was integrated into a patent which claims to cover any use of this receptor. Years later, academics demonstrated that protein CCR5 was a co-receptor for the HIV virus and essential to its intracellular penetration. In spite of the fundamental nature of this latter work, any therapeutic development based on the use of CCR5 as target for a drug could infringe the initial patent."

10 There are, however, some new provisions in Art. 6, para. 2 and Art. 5, para. 3.

11 E.g. The Danish Council of Ethics. 1993. *Patent på menneske-gener - en redegørelse* (Patenting human genes - a report) P. 8.

12 OECD. 2002. P. 8.

In more recent years research into stem cells has gained impetus and has been surrounded by great expectations. Researchers' knowledge of stem cells has grown rapidly, altering previous notions of what the body's cells are capable of. High expectations have been created about the possibilities of using stem cells to develop therapies, though concrete results are still few and far between. This has also made stem cells a target for patenting, and patent offices in Europe, and particularly those in the USA, have begun issuing patents on human stem cells.

Patents on adult stem cells have routinely been granted in the USA and Europe in recent years without causing a stir.[13] A study conducted in autumn 2001 showed that at that point in time 727 patents had been granted on stem cells and 134 on embryonic stem cells in the USA and Europe.[14] The patents are spread across the whole spectrum of human stem cell research.[15]

Patents, then, have gradually begun to be granted on human genes and stem cells alike, according to the rules already in existence. For the first time in European legislation the adoption of the EU directive saw the direct advent of a provision that a human body part is perfectly able to constitute an invention, a patentable one.

In the directive it was attempted to counter the scepticism expressed at the thought of patenting genes. One of the ways this was done was to establish (Article 5, para. 1) that the human body, or parts thereof, for instance genes in their natural surroundings (the human body) cannot be patented. However, para. 2 of the same article shows that parts of the human body that are isolated from their natural surroundings or have been produced synthetically (copies of the naturally occurring gene, say) *can* be patented.

Many people regard this as a creatively worded ploy to avoid the criticism levelled at patents on human material, as does the Danish Council of Ethics:

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13 European Group on Ethics in Science and New Technologies. 2002. *Study on the patenting of inventions related to human stem cell research*. Luxembourg: Office for Official Publications of the European Communities. P. 19. (See: Study on the patenting of inventions related to human stem cells <http://Europe.eu.int/comm/european_group_ethics/docs/stud-vanoverw.pdf>)

14 Ibid, p. 23.

15 Thus, a patent has been granted on pluripotent embryonic stem cells, on pluripotent fetal stem cells, multipotent adult stem cells and multipotent fetal stem cells. Both product and process patents have been granted, which is to say also product patents granting unlimited protection. Ibid, p. 34.

The Council of Ethics' view on gene patenting

The Danish Council of Ethics was asked to state its comment to the Patent Directive before it was enacted in Danish law in May 2000 by Danish parliament. The Council did this in a consultative reply to the Minister for Business and Industry[16]. The consultative reply was highly critical of those parts of the bill dealing with the ethical consequences of the law relating to the treatment of human beings. The Council's statements related chiefly to the patenting of genes, since stem cells were a rather new field of research at that point.

The Council's principal objection to the wording of the directive was precisely that in reality it rubber-stamps the practice that has gradually evolved in the USA, Japan and Europe whereby, under certain conditions—which it turns out to be very hard to get a grasp on in practice—parts of the human body can nevertheless be patented.

Apart from Article 5, mentioned, Articles 6 and 7 of the Patent Directive also state that ethical considerations must be included when processing applications for patents in connection with human genes. But it is altogether unclear how such stipulations are to be complied with and administrated.

Article 6 establishes that inventions must not be patentable if their application would violate ordre public or morality in a society. But what do "ordre public" and "morality" mean? This must presumably be interpreted as the ethical standards prevalent in a society, but is it possible to speak of common, European-wide standards? (As we all know, it is difficult enough to speak of common standards at national level.) Or are the provisions on morality to be interpreted nationally? From a European perspective it can be hard to see how the particular moral conceptions of the individual countries can feasibly be accommodated in a collective patent system.

The directive further includes stipulations that ethical assessments and deliberations must be taken on board when awarding patents (Article 6). However, no clear stance has been taken on the way this is to be done. Is a special ethical

16 Danish Council of Ethics. 2000. Consultative reply concerning a draft bill on an amendment to the Patents Act (L 66). Submitted on 11 May 2000. Appendix 10 of the Council's Danish annual report from 2000.

committee to be set up for the purposes of the patent system, possibly even a European committee, that can consider applications for patents on genes and human material?

Article 7 of the directive provides the European Group on Ethics in Science and New Technologies (EGE) under the Commission with a mandate to evaluate all ethical aspects connected with biotechnology, but the group can only express its views on basic ethical principles, not on specific patent applications.

There are examples of national bodies that do evaluate specific applications. In implementing the Patent Directive in Norwegian legislation, a clause has been introduced to the effect that the Norwegian Patent Office must confer with an ethics committee if in any doubt whether an invention is compatible with the provision on ordre public or morality.[17] The committee must consist of five members with competence in philosophy (ethics), medicine, biotechnology and animal welfare, and be positioned relative to the scientific ethical committees that already have experience of producing ethical assessments of concrete research applications. The Danish Patent and Trademark Office has formed an internal working party with a similar mandate[18], but this group is not independent of the patent system.

Against this background, in both 1997[19] and 2000, The Danish Council of Ethics spoke out against the draft directive and its embodiment in Danish law. The Council referred to the fact that the draft directive contains major unresolved problems and unclarified questions in terms of ethical assessment of gene patents.

As regards the fundamental discussion as to whether the ethical arguments against allowing gene patents have sufficient weight to ban them entirely, however, the members of the Council have not been altogether concerted in their judgements

17 Section 47 of Norwegian Act No. 127 of 19.12.2003: Act on Amendments to the Norwegian Patents Act and the Plant Breeders' Act (implementation of the EU Patent Directive in Norwegian law etc.).

18 One of the group's briefs is to evaluate patent applications containing patent claims pertaining to animals and/or human beings or parts of the same as well as gene-diagnostic methods. In addition, the group is mandated to ensure that patents with too broad a scope are not issued within the field (see Danish Patent and Trademark Office. 2003. R*eport on ethical aspects of patent practice as a result of implementing the directive on the protection af biotechnological inventions.* Pp. 14-15).

19 The Danish Council of Ethics. 1997. *Consultative letter regarding amended draft directive on biopatents* (KOM (97) 446). Submitted on 3 November 1997. Appendix 11 of the Council's Danish annual report from 1997.

over time. In the Council's first report on the subject from 1993 members did not consider the ethical arguments weighty enough to dismiss gene patenting entirely in all situations.

In the light of the latest discussions on the problems of gene patenting, the resistance to the EU Patent Directive and concurrent plans to introduce a collective EU patent system—and the additional ethical problems to which stem cell patenting can give rise—there may therefore be good reason to re-embark on a thorough ethical discussion of the problems and advantages of permitting patents on human DNA.

Readers' guide

The first Chapter provides a relatively detailed "situation report", i.e. the background to this report. Chapter 2 describes the patent legislation, with the main emphasis on rules of importance to gene and stem cell patents. The area is largely subject to international regulation, and within the EU all member states are under an obligation to implement the 1998 Patent Directive. At the same time, the fact is that there is no real legal practice in the field of the directive as yet. That is to say that only when the courts have taken a position on a number of appeals against various types of patents will any clarity emerge as to how the provisions of the directive are to be construed. For this reason, rulings are discussed in two respective cases on a gene patent (the Myriad Genetics patents on the BRCA1 and -2 genes) and a stem cell patent (the so-called "Edinburgh patent").

Chapter 3 gives a description of what genes actually are and what is known about their functions. Despite the mapping of the human genome having been completed in 2001, there is still a long way to go before researchers have a complete understanding of the functioning of the genes. Nevertheless, patents have begun to be granted on genes, which has given rise to problems.

Chapter 4 is headed *"What is being patented?"* and discusses the way this apparently simple question is actually not as straightforward to answer when it comes to gene patents. Are genes, for example, merely a kind of biochemical material that forms part of human beings, or are they primarily a kind of "collection" of information, identical for the most part to the information in other living organisms, yet containing a small part that is unique to the individual person? The view taken on this can be decisive to the approach adopted to the ethical discussion.

Chapter 5 discusses how far the main argument for permitting gene and stem cell patenting, i.e. that it promotes research and development of new forms of treatment, holds water. In the genome field, there are several examples of patents being counter-productive, in as much as they do quite the reverse, contributing to greater concealment of knowledge, preventing others from developing new therapies on the basis of patented genes.

Chapter 6 is entitled *"Patents, property rights and equity of distribution"* and deals with whether there is any sense in regarding gene patents as a form of ownership of the genes, discussing whether other concepts such as scope for action or personal integrity and equity of distribution might not perhaps be central to the discussion of who should have right of disposal over genes and stem cells.

Chapter 7 presents some of the most central arguments against patenting human genes. What the arguments have in common is that they view patenting as a violation or an inadmissible reduction of something that possesses sovereign integrity of its own. It may be nature; it may be humankind's dignity as a species being. It may be humankind's individual identity. And it may be God's creation.

Chapter 8 gives a description of stem cells: the types of stem cell that exist, and the hope attached to them of being able to develop treatments for disease in the future. The Chapter also examines the differences between genes and stem cells and the practice that has arisen for patenting stem cells.

Chapter 9 sets out the particular ethical problems associated with patenting stem cells. Many of the issues associated with patenting genes are the same, but in addition other questions present themselves in connection with stem cells, to wit that patents on embryonic stem cells are made possible only by research on embryos, which cannot be divested of their ethical status; that stem cells can be regarded as living human tissue that should not be commercialized; that stem cells contain the unique and complete genome of one individual; and that great therapeutic potential may be tied up in stem cell research.

Finally, Chapters 10 and 11 include members' recommendations on the patenting of genes and stem cells, respectively.

In Chapter 10 a unified Council of Ethics states that there are many problems linked with patenting human genetic material. One view is that patents permit the monopolization and financial domination of the living as such, that this reduces humankind and fails to grant nature the respect which is its rightful due. Nonetheless, the members find that even if human genetic material has different status to traditional materials, this per se does not preclude genes being able to be patented. But given the special status of the genes as carriers of information about the individual as well as all living beings, patenting must be done taking more comprehensive account of both the individual and the common good than is the case with patenting that involves traditional materials. Working on the basis of these provisos, the members posit eight recommendations-in-principle for formulating the patent system in this domain.

Chapter 11 mentions that all members find all forms of stem cell patenting problematic, principally because stem cell patenting includes commercialization and commodification of the human organism, which is inconsistent with respect for man's dignity. Such commercialization thus turns stem cells into an object that can be used as a pure means of financial agreements. However, this has to be weighed against the stem cells' potential to contribute new know-how and new lines of action that may prove of benefit in preventing and treating disease. On this basis the members find no grounds for rejecting all patenting of adult stem cells out of hand, but a number of the members *do* reject the patenting of embryonic stem cells.

2. WHAT DOES THE LAW SAY ABOUT GENE AND STEM CELL PATENTING?

This section offers a concise review of the key concepts in patent law. Those rules with a bearing on gene and stem cell patents have been highlighted.[20]

What is a patent right?

Patent protection gives the inventor sole right to exploit the invention for business and commercial purposes. This right is subject to a fixed term. A patent accords the holder sole right for a maximum of 20 years to prohibit others from manufacturing, using or selling the patented invention within the geographical area where the patent is in effect. The patentee is not entitled to exploit the patent prima facie.

Patent rights therefore assure the inventor the opportunity to exploit his or her inventor's efforts commercially. The purpose of giving the inventor

INTERNATIONAL PATENT LAW

Patent law was already regulated internationally in the **Paris Convention** (1883), the **Patent Cooperation Treaty** (PCT, 1970), the **European Patent Convention** (EPC, 1973) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (**TRIPS**, 1994). In addition, patents on biotechnological inventions are regulated in an EU directive from 1998: "**Directive 98/44/EC** on the legal protection of biotechnological inventions".

The European Patent Organization (EPO) deals with applications on the basis of the rules in the European Patent Convention (EPC). If the European Patent Organization deems that an invention fulfils the conditions in EPC, EPO issues a patent. EPO can issue patents effective in all countries that are members of EPC. All EU countries are members of EPO.

When submitting a (European) application, the inventor chooses the country or countries in which he/she wishes to have the patent. The European system is open to inventors from all over the world.

20 The review is based on Tine Sommer. 2004. *Patentret og det humane genom* ["Patent Law and the Human Genome"]. Expert opinion printed as an appendix to the Danish version of the report; Mogens Koktvedgaard. 2002. *Lærebog i Immaterialret* ["An Intellectual Property Law Primer"], 6th revised edition, DJØF-Publishing. Copenhagen; and contributions to the Danish Board of Technology's conference on patents, June 2002, by Jens Schovsbo: "What patenting legislation is in place in the field?".

patent rights is that he or she has a chance to cover his or her investments together with the risk etc. the inventor has had in arriving at the invention. At the same time, the intention of the patent system is to ensure that the invention imparts something 'novel' to society in the form of technology dissemination and development.

The patent does not, then, give the patentholder any absolute right to commercial exploitation. If there are other laws that would be infringed by the patent, were it to be realized, these laws will be capable of preventing a patent from being exploited. For example, environmental legislation, health and safety legislation, and regulations concerning prevention of cruelty to animals and nature conservation could prohibit the exploitation of a patent.

Legislation in the field

The issuing of Danish patents is regulated in the Danish Patents Act[21], but these rules are largely determined by international controls on patent rules, particularly the EU directive (see fact box on international legislation). These rules put in place an overall framework for patenting:

Conditions for obtaining a patent (formal patent rights)

In order to obtain a patent on an invention, certain conditions must be met: the invention must involve an industrial application; it must have novelty value and involve an inventive step.

By way of overview, then, it is required that:
The invention must be produced by means of a technical process. This means that a pure discovery cannot be patented. If a discovery merely entails finding something that already exists in nature but has previously been unknown, it does not count as an invention.

The invention must be reproducible. That is to say that the invention must be able to be produced "in real life"—the technical problem to which the invention relates must have been solved. This means that it must be possible to re-create the invention if in possession of the technical descriptions and expert knowledge needed to replicate the invention.

21 Danish Consolidation Act No. 781 of 30 August 2001.

The invention shall be new (global novelty). It must involve an objective, global novelty.

There shall be an inventive step. This means that the invention must differ essentially from what is known (the prior art). The invention must be of a quality superior to that perceived to be trivial in the field. The counterpart to the invention is the discovery. The notion of inventor in patent law has an independent legal meaning.

The rules in the Danish Patents Act and EPC are identical with regard to the central questions of what constitutes an "invention" and "novelty", "inventive step" and "industrial application". The Danish Act is thus framed in close conformity with EPC.

What cannot be patented?

Not everything is patentable. The Danish Patents Act lists a number of exceptions, including:

- discoveries, scientific theories and mathematical methods.
- procedures for surgical or medical treatment or diagnosis used on human beings or animals—but the manufacture of medicinal products, drugs and diagnostic agents can be patented.
- inventions whose exploitation is contrary to ordre public and morality. The invention of an instrument of torture cannot be patented, for example.
- plant and animal varieties or essential biological processes for producing plants and animals. (Patents can, however, be issued on microbiological processes and the products of such processes).

In connection with patents on human genes, it is worth stressing that the gene cannot be patented in the shape and form that occurs naturally in the human organism. What *can* be patented is a "copy" of the gene re-created outside the human organism.

Various types of patent

The patents awarded are arranged into different categories. The rights associated with each patent depend on the category of patent to which it is linked.

Product patent: Grants protection of the actual product or appliance. The product patent is the most extensive form of patent because it protects the invention from any commercial application. In the sphere of chemistry or biotechnology a patent

can be obtained on the actual chemical formula, or on a gene, sequence or protein. There is discussion as to whether it is altogether apt to grant product patents on genes, since the protection afforded is so extensive. In relation to gene patents a product patent can prevent all conceivable potential applications of the gene, including the diagnosis of genetically conditioned disorders. It may thus be necessary to obtain the patentholder's consent for such other applications of the sequence.

Use patent: In the case of a "use patent" only the application of the chemical formula or gene is patented.

Process patent: Here the process is patented, i.e. the manufacture of a substance, for instance a hormone or an enzyme, but not the gene sequence underlying the substance. The manufacturing process must be new in order to be patentable, but the actual substance may well be familiar.

Narrow and broad patents: All patents include one or more claims, which are important to the scope of the patent. Whether such claims are broad or narrow is crucial, since it is the claims that determine the extent of sole rights. As the names suggest, broad claims afford sole rights to a greater range of exploitations of the patented than narrow claims.[22] A product patent can thus be termed a broad patent, although in principle it only provides coverage in relation to a specific industrial application of a gene, say, whereas application and process patents can be more or less broad.

Compulsory licence

The patentholder's sole right to exploit the patent can be restricted by the compulsory licensing rules of the Patents Act. A compulsory licensing system permits someone other than the patentholder to exploit the patented invention. Obtaining a compulsory licence requires the involvement of a court of law. A compulsory licence can be granted if, after four years from submission of the patent application, the invention is not being sufficiently exploited or if important general interests may warrant permission being granted for commercial exploitation by parties other than the person holding the patent. The patentee is

22 Nuffield 2002, p. 24

perfectly at liberty to exploit the invention himself or to assign the right of exploitation to others through a licensing agreement—a compulsory licensee has no way of stopping that. Apart from the rules in the Danish Patents Act on compulsory licensing, sole rights can be restricted by competition legislation.

EU regulations on patenting biotechnological inventions

Biotechnological inventions are regulated under an EU directive, EC 44/98, from 1998. This directive was implemented in Danish law by an amendment in 2000 to the Patents Act (Danish Act No. 412). The European Patent Convention also contains a reference to the EU directive, whereby the EPO must abide by the principles in the directive. The regulations in the EU directive pertaining to patenting human genes are dealt with in more detail below.

The draft directive, as mentioned in the introduction, generated vehement and protracted European debate, stretching over more than 10 years. The directive was passed in 1998 and implemented in Danish law by means of Act 412/31.5. 2000.

Resistance to the directive has also been considerable subsequently.[23] Amongst other things, the Netherlands (with the support of Italy and Norway) instituted proceedings at the European Court of Justice, where it was asserted that the directive should be cancelled, partly with reference to the fact that the directive ignored fundamental rights, involved tampering with human dignity and infringed the convention on biodiversity. The case ended with the directive not being ruled null and void. The Court did emphasize, however, that Article 6 of the directive (see below) gives member states' authorities and legal authorities ample latitude to apply the criterion of whether an invention violates morality and ordre public.[24]

The directive regulates an area in which there are no actual authorities as yet. That is to say that only when the courts have adopted a position on a number of appeals against various types of patents will clarity be achieved surrounding the specific construction of the provisions. In this way, shape is given to judicial practice in the field or to a Community law interpretation of international concepts taken from international agreements to which the member states have acceded.

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23 See, amongst others, Mogens Koktvedgaard 2002.

24 The European Court of Justice did point out, however, that the latitude referred to does not imply any judgement, as the directive sets out the framework for the concepts.

An example of this is Myriad Genetics' hotly debated patents. On Tuesday 18 May 2004 a panel set up by the European Patent Office (EPO) decided to revoke a highly controversial patent (EP 699754) on the breast cancer gene BRCA1.[25]

OPPOSITIONS TO THE PATENT

Once a patent has been granted, it is possible to file objections to it with the EPOS or the national patent authorities. Objections to a European patent can be lodged for up to nine months after the publication of the patent. This may lead to the patent either being overridden (declared invalid), in part or in full, or upheld.

Women with mutations in either of the two genes BRCA1 and BRCA2 are particularly prone to contracting breast and ovarian cancer. The biotech company Myriad Genetics, which offers a gene test for mutations in these genes, has obtained very comprehensive patents on the BRCA genes in America as well as Europe. In the case of BRCA1, therefore, the company has acquired both a product patent on the DNA sequence and the proteins that can be decoded from the gene, and a use patent giving the company sole right to use the DNA sequence to diagnose the mutations.[26]

For the duration of the patent, Myriad Genetics' product patent prevents others from both screening for the mutations and developing alternative methods of testing for the mutations, and it is not possible to screen for mutations without having access to the gene.[27] At the same time, the company has set the stage for its demand that all mutation screening, which is to say by European hospitals as well, must be undertaken at their laboratories in the USA, which would not only be expensive but also prevent researchers in other countries from gathering knowledge about local variations in the genes.

Initially, the EPO awarded Myriad three European patents on BRCA1 in 2001. It is the first of these patents that has now been invalidated. The BRCA patents have been highly criticized, and the Danish Society for Medical Genetics has co-filed objections to the BRCA1 patents. The gist of these objections is that the diagnostic

25 Press release from the EPO on 18 May 2004: *'Myriad/breast cancer' patent revoked after public hearing* (http://www.european-patent-office.org/news/pressrel/2004_05_13_e.htm) and the New Scientist on 19 May 2004: *Europe revokes controversial gene patent* (http://www.newscientist.com/news/news.jsp?id=ns99995016).

26 Nuffield 2002, pp. 39 and 48.

27 Information from Professor Torben Kruse, Odense University Hospital.

method is not novel, because pathogenic mutations in the BRCA genes were indirectly detectable by marker screening even before a patent was applied for.[28]

The points to which the EPO has ascribed importance in its judgment will not be published for a couple of months yet. Currently, then, it is not known whether the patent has failed on issues of principle, and will therefore set a precedent, or on pure technicalities. Once the reasoning is made available, Myriad can opt to appeal the ruling. It is not known at present when the objections to the last two patents on BRCA1 will be considered.[29]

EU directive's provisions on gene patenting

In relation to the patenting of human genes and stem cells, the following articles of the directive in particular are of relevance:

Under *Article 3* of the directive, the general patentability criteria must be met in order to qualify for the award of patents in this field.

Article 5 deals with patenting of the human body, and this article has been the subject of great debate. The article was implemented in Section 1a of the Danish Patents Act:

Article 5 of the directive:	**Section 1a of the Danish Patents Act:**
1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.	The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including a sequence or partial sequence of a gene, cannot constitute patentable inventions.

28 Torben Kruse. 2002. Monopol på gendiagnostik? [Monopoly on genetic diagnosis?] In: *Ugeskrift for læger* (journal of the Danish Medical Association), vol. 12.

29 In the case of the BRCA2 gene, Myriad Genetics also has a European patent that covers it. This was superseded in February of this year, however, when the charity Cancer Research UK obtained a patent on the gene on the grounds that it had filed its application earlier. The organization subsequently made the patent available to all European research institutions free of charge. Press release from Cancer Research UK on 11 February 2004: *Charities to make breast cancer (BRCA2) gene freely available across Europe* (http://www.cancerresearchuk.org/news/pressreleases/breastcancergene_11feb04) and Oncolink on 11 February '04: *Cancer charity waives patent rights to breast cancer gene* (http://www.oncolink.org/resources/article.cfm?c=3&s=8&ss=23&Year=2004&Month=2&id=10489).

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.	*Subs. 2.* Notwithstanding subsection 1 hereof, an element isolated from the human body or otherwise produced by means of a technical process, including a 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."
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.	In the Danish regulations, Article 5, subs. 3 has been set out in the statutory instrument on patents.

Article 5, subs. 3 contains a more rigorous requirement calling for the detailed specification of the industrial application. The reasoning behind the intensified requirement is a wish to discourage or prevent patents on gene sequences researchers have been able to isolate but for which no industrial application has yet been found.

Reading the regulations, the first part says that "The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions." But the second part says that a sequence or partial sequence of a gene may constitute a patentable invention. In order for patenting to be possible, it must be the case that the human gene or elements thereof are not the gene natural to the human being, but the gene or element of the gene must occur "in isolated form".

Most people think there is a conflict between these two provisions. You cannot simultaneously forbid patents on the human body or elements thereof and then permit a sequence or partial sequence of a human gene, albeit isolated from the human body, to be patented. This is also adduced as one of the principal arguments against implementing (introducing) the provisions of the directive into the national legislation of countries like Sweden and France.

In the explanatory memorandum to the Act, importance is attached to the fact that patents on a gene or an element of a gene can only be obtained when the gene is isolated from, i.e. is external to, the human body. Apart from the gene having to be outside the human body, patenting is conditional on the possibility of stipulating an industrial application and on the application in which the gene is included having the requisite novelty value. It is stressed that although such a patent has been awarded, it cannot provide any rights over the gene, which is inside the human being.

A hypothetical example[30] will illustrate this thinking:
The human genome controls growth and restoration, and it might possibly be conceivable, therefore, that a DNA sequence could be taken and isolated from the gene linked to hair loss. Company A wishes to develop a treatment for hair loss. The company now finds a method for isolating the gene related to baldness. The genetic material is still accessible for other researchers to do research on, but the technique and procedure for isolating the gene are complex and have novelty value, and cannot be said to exist in nature. Therefore, the product—the isolated gene—can be patented. It has novelty value in the sense of the Danish Patents Act, involves effort on the part of an inventor and has industrial applicability. Using the patent, company A has protected its investment in the invention.

In the context of such examples, of course, it is essential to remember that the boundaries of what constitutes an invention are constantly changing with technological developments. For example, the procedures for isolating genes are constantly undergoing development, and that development is heading towards there being less and less ”inventive value” in the isolation processes as they are refined. Similarly, in recent years, some discussion has arisen as to whether entire genes should be patentable.

Article 6 of the directive deals with exceptions to patenting. These exceptions will be found in the Danish patent rules in Section 1b of the Patents Act and are worded almost identically:

30 On loan from Torsten Bjørn Larsen in *Patent Law Seminar—Summary no. 4*. Stockholm University.

Article 6 of the directive:	Danish Patents Act:
1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.	*Subs.1.* Patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to ordre public or morality.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:	*Subs. 2.* An exploitation shall not be deemed to be contrary to ordre public or morality merely because the exploitation is prohibited by law or administrative regulation. *Subs. 3.* Pursuant to subs. 1, patents may, however, not be granted for, among other things:
(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.	i) processes for cloning human beings; ii) processes for modifying the germ line genetic identity of human beings; iii) uses of human embryos for industrial or commercial purposes, and iv) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

The provision that an invention must not be contrary to morality or ordre public is not unusual in the context of patent law, but it does take on special meaning in connection with biotechnology.[31]

Plans for a new European Community Patent and a world patent

Despite the problems involved in implementing the Patent Directive, the Council for the European Union reached agreement on 3 March 2003 on a common political line concerning the introduction of an European Community Patent. The purpose is to establish a system under which European companies can obtain a patent that applies throughout the European Union.[32] The purpose of the new patent system, which according to the announcement is set to come into force after three years, is to make it simpler and cheaper for European companies to

31 Tine Sommer. 2004. Expert opinion, only in Danish.

32 See note 4.

obtain a patent throughout the EU. By 2010 at the latest, the system will be enlarged further with a joint court, which will have sole competence to settle patent disputes. By all accounts the latter will mean that the countries have to relinquish sovereignty to the court.[33]

In Denmark, endorsement will presumably require either a five-sevenths' majority in Danish parliament or a referendum and, similarly, most other EU countries have various misgivings about the system. The Commission did not manage to have the proposal to establish an EC Patent adopted by May 2004, when the new participating countries were absorbed into the EU, and it is highly likely that these will now be able to demand a fresh start to negotiations, with them taking part. At its last assembly in March 2004, the Council for the European Union announced that it is now going to consider how headway can be made. When the Community Patent will become reality is uncertain, therefore, just as all efforts under the auspices of the World Intellectual Property Organization (WIPO) to adopt a worldwide Patent Law Treaty, which were started in Geneva more than 15 years ago, have so far been unsuccessful.[34]

Stem cell patents

Patents on embryonic stem cells are another example of the way in which the clauses of the directive are to be interpreted in order to secure the right implementation into national legislation. In 1999 heated public debate arose over the patenting of stem cells on account of the so-called Edinburgh patent. The patent relates partly to a genetic method for isolating stem cells, including embryonic stem cells, from differentiated cells in a cell culture. The experiments on which the patent is based were carried out on animals, and since the term "animal" can also denote human beings (in English at least), the claims could also be interpreted so as also to cover human, embryonic stem cells and human cloning.

The issuing of the patent therefore led to objections to the patent being filed by 14 parties, including the governments of Germany, the Netherlands and Italy. In July 2002 that resulted in the EPO ruling, after an inquiry, that the patent was contrary

33 Bostyn, Svend. 2003. *The Community Patent: Value for Money?* Paper presented at "IBC's 12th Annual International Conference: Protecting Biotechnological Inventions. 17 &18 November.

34 Gallochat, Alain. 2003. *Global Harmonization of Substantive Patent Law.* Paper presented at "IBC's 12th Annual International Conference: Protecting Biotechnological Inventions. 17 & 18 November.

to, inter alia, Section 23d8(c) of the implementation rules for the European Patent Convention, which says that human embryos cannot be patented for industrial or commercial purposes. The EPO's Opposition Division therefore ruled that the patent should be upheld in modified form.[35] Now it no longer includes embryonic stem cells from human beings—or animals—but continues to pertain to modified human or animal stem cells.[36]

The EPO has interpreted the ruling in such a way that patents cannot currently be granted on human embryonic stem cells in Europe, as the directive does not relate explicitly to whether embryonic stem cells can be patented. In Denmark, too, prevailing practice is for human embryonic stem cells to be excluded from patenting because, from an ethical point of view, stem cells are commensurate with embryos. Stem cells isolated from adults, by contrast, are not excepted from patenting.[37]

Embryos and "morality"

In the case of embryonic stem cells, then, there are particular ethical concerns, to do with the fact that the cells originate from fertilized eggs (embryos). As a result, these patents may possibly come within Section 1b, subs. 3, subpara. 3 of the Danish Patents Act. If future consideration were to be given to using embryonic stem cells produced by nuclear transfer, which is a cloning technique, it would presumably contravene Section 1b, subs. 3, subpara. 1 of the Patents Act, which says that procedures for cloning human beings must be excepted from patenting.[38]

The need to say that it "presumably" contravenes the Danish Patents Act is due to the fact that the act says nothing outright about whether stem cells from human beings can be patented. Here again, therefore, practice must first be laid down through interpretations and court rulings.

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35 The Edinburgh patent was thus amended by the Oppositions Division of the EPO. Legally speaking, the question is whether the EPO's Oppositions Division should be regarded as a court of law proper or an administrative authority?

36 See: EPO press release, 24 July 2002. *"Edinburgh" patent limited after European Patent Office opposition hearing* and Danish Patent and Trademark Office. 2003 p. 23.

37 Danish Patent and Trademark Office. 2003. Pp. 10-11.

38 The general provision in Section 1b, subs. 1 might conceivably also be applicable. Subs. 3 is purely for illustrative purposes and is non-exhaustive.

Amongst other things, this practice may be challenged by national rulings. In April 2003 the UK Patent Office issued a report on what practice to apply to the granting of patents for inventions involving embryonic stem cells. The Patent Office considers that human embryos and totipotent stem cells, which have the ability to develop into a child, must be excepted from patenting. However, the Office distinguishes between these totipotent stem cells and the pluripotent stem cells (see Chapter 8 for an explanation of pluri- and totipotent stem cells). Admittedly, the latter originate from embryos and can turn into any of the body's cells, but having been harvested from the embryo, they no longer have the ability to develop into a child. It is these cells that will normally be used in research. Since Great Britain permits research into pluripotent embryonic stem cells under certain circumstances, the Patent Office does not consider it contrary to ordre public and morals to permit patents on inventions using embryonic stem cells.

Other legislation on patents

Act on Inventions at Public Research Institutions

The Danish Act on Inventions at Public Research Institutions (Act No. 347 of 2 June 1999) serves to ensure that research results generated with the aid of public funding are put to some use beneficial to Danish society by means of commercial exploitation. The Act applies to inventions that have been made by employees as part of their work at universities, a government research institute or a public hospital.

Sections 10 and 11 of the Act provide that if an employee has made an invention, that person must notify the institution in writing. The employee may not publicize or manage an invention until the institution has confirmed receipt of notification in writing. Within two months of the time of notification the institution must have an evaluation made of the invention's potential for commercial exploitation. The employer can also order the employee not to publicize or manage an invention for up to two months from receipt of such notification.

There is some discussion about the extent to which the provisions of the Act hamper the free exchange of information and knowledge between researchers, and whether this also puts a brake on research and development.

3. THE GENOME—KNOWLEDGE AND PERSPECTIVES

On 14 April 2003 the members of the Human Genome Project announced that they had completed the ”rough draft” of a map of the human genome. The work was finally declared complete by President Bush together with heads of state from China, France, Germany, Japan and Great Britain on 14 April 2003. This venture is a remarkable piece of collaboration between researchers from these countries, and above all it is worth noting that the results of the work by the many researchers affiliated is openly accessible to everyone—they have simply been set out on the project's official webpage and made freely available to anyone interested.

The completion of the Genome Project was surrounded by great publicity and a lot of grandiose words were spoken. Thus, the declaration from the six heads of state was "We are proud to announce that scientists from our six countries have completed the essential sequence of three billion base pairs of DNA of the human genome, the molecular instruction book of human life." The view that knowledge about the genome provided a gateway to a fundamental understanding of mankind reverberated in many settings.

The more extensive knowledge of the human genome has prepared the ground for the emergence of an entirely new medical discipline, molecular medicine. At a conference held by the Danish Council of Ethics in 1999, Professor Lars Bolund stated that the Genome Project had given researchers an opportunity to start reading mankind's genetic information. That signifies a fantastic breakthrough for the possibilities of understanding man's biology and hence of understanding the different disease processes.[39]

39 Bolund, Lars. 1999. *Kortlægningen af menneskets arvemasse med håb om sygdomsforebyggelse og behandling - eller forestillinger om det genetisk designede menneske* [”The mapping of the human genome with hope of preventing and treating disease—or notions of the genetically designed person”]. In: Det menneskeskabte menneske [”Man-made Man]. Copenhagen, Danish Council of Ethics.

At the same time, however, Bolund pointed out that it is important not to cherish exaggerated notions of the extent of knowledge to which the Genome Project provides access. To illustrate the level researchers are now at, Bolund used a six-year-old who has just learned to spell his way through the letters of the alphabet.

> *In the same way, I perceive that we as geneticists have begun to spell our way, sentence by sentence, through man's genetic instruction manual and are concurrently setting out to gather experience. It will take us at least the next century before we start to reach the cutting edge of mankind's biology and obtain really sound biomedical wisdom.*[40]

The conclusion of the Genome Project does not mean, then, that the researchers now know everything about the genes and their function in the body. Researcher Marc Vidal from the Dana-Farber Cancer Institute/Harvard Medical School in Boston put it this way: although the completion of the Human Genome Project was an important milestone in our understanding of the way cells work, there is still far to go before we have a complete understanding.

> *But the fact is, our current picture of the 'parts list' of the human genome is rather fuzzy. Computer programs have been used to predict the position and structure of genes. However, we don't know exactly where most genes begin and end, and there are literally thousands of gaps in our picture of how the building blocks of genes are arranged. Even the frequent claim that there are about 30,000 genes within the human genome is only an estimate.*
>
> *Of the 30,000 genes believed to be in the human genome, only about 5,000 have been well defined. The structures of the other 25,000 have yet to actually be confirmed. Plus, there are long stretches of the chromosomes that remain terra incognita – that may contain genes yet to be discovered.* [41]

As mentioned in the introduction, the patent offices have actually issued patents on biotechnological inventions previously. As far back as the end of the 1800s, a

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40 Ibid

41 Press release from the Dana-Farber Cancer Institute on 6 April 2003: New technique gives scientists clearest picture yet of all the genes of an animal. May lead to sharper picture of human genome as well (http://www.dana-farber.org/abo/news/pressarchive/040703.asp)

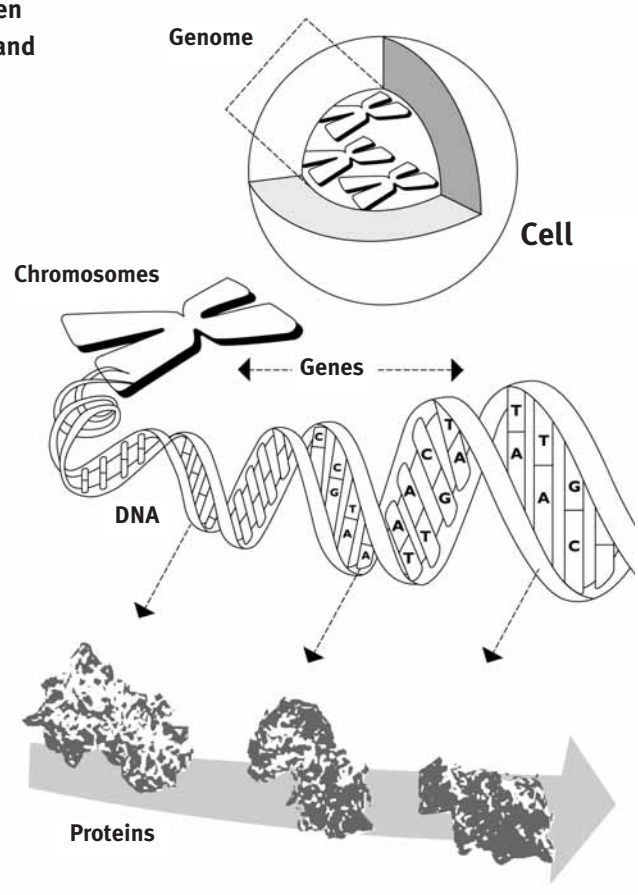
patent was granted on a biological organism (yeast culture) [42], but that kind of patent was the rare exception—until the last quarter of the 1900s. From the 1980s an entirely new development began, and patents on human genes and other organisms in biotechnology have gained great ground. Particularly since the mid-1990s the field has seen sharp growth.[43]

Patents, in other words, have been granted on genes according to the rules in the existing patent system, before scientist had an in-depth knowledge of the function of the genes. Patents have been issued on genes while researchers have simultaneously been developing their knowledge about the function of the genes, and that can cause problems. It can do so because genes differ from the traditional materials for which the patent rules were designed, and in a number of ways. In a patent setting, the most important are:

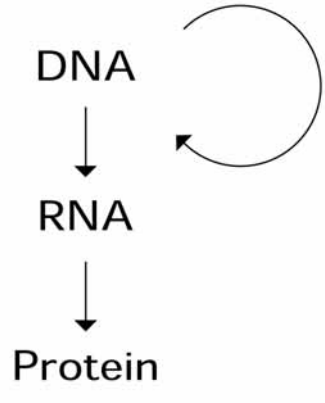
- Naturally occurring genes cannot be invented but are discovered.
- Genes can have several functions, and a patent on a gene can also prove to cover completely different functions of the gene that are not discovered until later on.
- The genes are part of ourselves and exist within us. They are at the same time unique to each individual and common to all human beings—indeed, the bulk of the genes exist in related versions in all mammals.
- The genes have a certain bearing on who and how we are, on the diseases and characteristic we come to have.

42 E.g. The Dansih Council of Ethics. 1993. P. 8
43 OECD. 2002. P. 8

The correlation between chromosomes, genes and DNA sequences



1) Classical biology:
The central dogma



2) Modern biology: Network theories

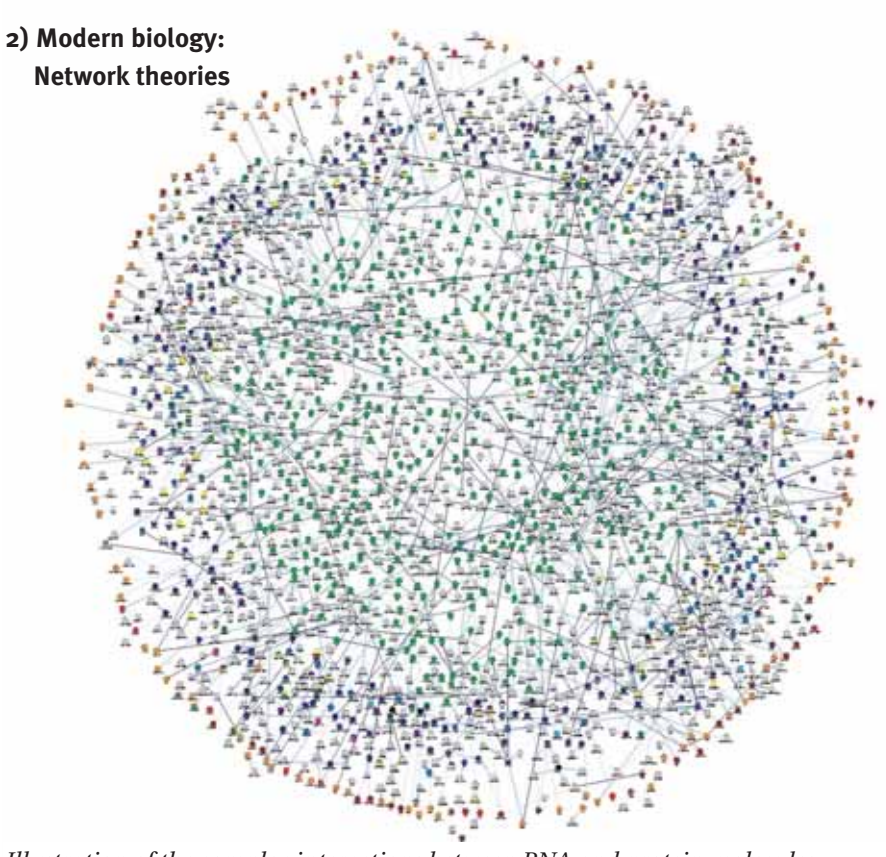


Illustration of the complex interactions between RNA and protein molecules

About the nature of genes and what they do

The short definition of a gene is that it is a functional unit of the genome. By this is meant a DNA sequence that codes for RNA or a protein (a hormone, muscle fibre and much more). In terms of gene patenting, a distinction needs to be made between the tangible gene concept and the information content of the genes. The gene is a biological substance; this substance, however, is less interesting in its own right. The interesting feature in a patent context is the function of the substance—i.e. to code for RNA/protein.

According to what is called the central dogma of biology, the cell's information flow is from DNA to RNA and on to protein, never the other way around. Broadly speaking, proteins are the molecules that control which chemical processes are to take place and how the cells are to appear and function. Thus, in reality, they

determine the entire behaviour of the organism. Taking the central dogma as a point of departure, the notion of the genes as the molecules that determine our fate seems straight forward.

But the central dogma is subject to intense modification in current years.

It turns out, for instance, that many genes code for RNA, which is never translated into proteins. The RNA molecules in themselves make up a large and complicated network of great importance to the functions of the body. The RNA molecules are crucially important, for example, to the way in which the genes are activated. The determinism from gene to function thus becomes less clear than stated by the central dogma.

INTRONS:

Most protein-coding genes contain regions, introns, that are translated into RNA, and subsequently cut out before the translation into protein. Interconnection of the remaining RNA molecules can take place in many ways, for example depending on the cell's current situation—we refer to RNA editing.

Since all the cells in an individual contain more or less the same genes, there are important controls as to which genes are to be activated/adjusted downwards at various times. This regulation is extremely complex, and is often influenced, inter alia, by which signals the cell receives from other cells and from the surroundings in general.

GENE REGULATION, which is one of the central areas of biology, is partly based on enzymatic modifications of the DNA strands, and varying packaging of the DNA strands, partly as a result of interactions between the DNA and DNA-binding proteins and hence coiling or "packing" of the DNA, making it inaccessible to other proteins that participate in connection with the reading of the genes.

Collective yet altogether individual

Similarly, the great similarities between the genes in different mammals and human beings can be used as an argument against genetic determinism. A study from 2002[44] shows that although the human genome is 14% larger than that of the mouse and only 40% of the mouse's DNA sequences are shared with man's, 99% of the mouse's genes on the mouse's 20 chromosome pairs match genes on man's 23 chromosome pairs. The great difference that exists between these creatures,

44 Mouse Genome Sequencing Consortium. 2002. Initial sequencing and comparative analysis of the mouse genome. *Nature*. 5 December 2002, pp. 520-573.

then, is scarcely purely at gene level but is probably a consequence of the widely divergent regulation of—at least some—genes. To the extent that gene regulation is controlled by the cells' surroundings, then, an important information flow takes place in the reverse direction in relation to the central dogma.

Mankind is a relatively young biological species, that has not had that much time to accumulate genetic variation like most of the other species on earth, which have had a longer history than man's. Nevertheless, there is considerable genetic variation in human beings. The human genome contains approximately 3 billion base pairs (the building blocks that can be the bases adenine (A), thymine (T), guanine (G) or cytosine (C)) and the genetic variation is so great that no two human beings will ever be genetically identical. Between two random human beings the genetic variation is approx. 0.1%.[45]

Despite this variation all human beings have most of their genetic information in common. The genetic variation in geographical areas on earth is spread continuously—there are no sharp genetic borders between different population groups. Actually, it has proved that only a small proportion of the total genetic variation between individuals can be attributed to differences between various population groups.

As far as is known, the majority of the genetic variation is insignificant in biological terms, and for the most part does not result in any change in functions at RNA or protein level. Some of the genetic variation, however, does have functional consequences. For example, there are changes in the genome (mutations) that directly bring about or predispose people to diseases, just as there are changes that result in physiological, morphological or behavioural variation.

Genes can be used in the diagnosis and treatment of disease

The knowledge provided by genetic mapping is already being put to use in biomedicine for both diagnostic and therapeutic purposes.

In the case of diagnosis, it takes advantage of the catalogue of human genes that has come to our knowledge through mapping the human genome to scan the

45 That means that on average 1 base pair out of every 1,000 will differ between two individuals. Two people taken at random will have about 6 millon base pairs that are different.

entire genome in a single person. The process is able to find mutations or gene variants that are passed on together with diseases—or characteristic.

By now the genetic background to more and more of the 10,000 plus—generally rare—hereditary diseases attributable to flaws in an individual gene has gradually become known. A number of multifactorial—and often more common—diseases have also been identified that are attributable to flaws in several genes combined with lifestyle and environmental impact. When these mutations are found, therefore, it will often be possible to use them to diagnose the disease as well.[46]

Work is also in progress to develop therapies on the basis of knowledge about the genes. If a medicine can be devised that targets only the enzyme, process or DNA sequence that causes the problem, much more effective treatment can be given. Several types of medicines are expected to be developed on the basis of this genetic knowledge, as it will be possible to extend the number of angles from which the disease is attacked once the function of the genes is known in more detail.

Work also continues to develop gene therapy, i.e. treating disease by transferring genetic material (DNA or RNA) to patients. The goal can be to insert a gene into the patient's cells, where it will produce a protein which the patient lacks, or to produce a protein that can have a beneficial effect on the progress of the disease generally. Gene therapy has been attempted in treating many different monogenic diseases (that is to say, diseases due to errors in a single gene). It is also possible that gene therapy can be used to treat or prevent common diseases like cancer, cardiovascular disorders and infectious diseases. In the past 10 years more than 3,000 patients have taken part in over 300 gene therapy trials. The clinical return has been limited, however. It shows that the techniques in use still needs to be improved before gene therapy can become a realistic alternative to the already existing methods of treatment.

They control but are also controlled themselves

As previously mentioned, the latest knowledge about the function of the genes indicates that the correlation between genes and our fate, who or how we are, is

46 Børglum, Anders D. and Lars Bolund. 2001. Det humane genomprojekt - status og perspektiver ["The human genome project—status and perspectives"]. *Ugeskrift for læger[Weekly Journal fo rmedical professionals]*. 3 September 2001.

not unambiguous. New molecular techniques and twin studies teach us much about the link. By comparing monozygotic (identical) and dizygotic pairs of twins, a measurement can be obtained of the importance of heredity for a number of normal characteristics and the susceptibility to contract diseases.

For many normal traits and the predisposition to contract common diseases, the genes do play a part (which in many instances can be expressed as a percentage). For the classic monogenic hereditary diseases, where specific errors in just one gene result in disease in the vast majority of cases, some degree of genetic determinism is justified. Even in these situations, however, it is known that there can be modifying factors, for example "modifier genes" or environmental factors, which affect the individual's likelihood of developing the disease in question. For the more common diseases due to errors in multiple genes, the picture is even more motley. Most diseases and the most frequent ones are due to combinations of errors or variations in several genes and influences from the surroundings in the form of environmental factors, growing up, stochastic events. For a high-incidence disease like breast cancer, several forms are currently known. With familial breast cancer, a hereditary error in a gene will result in the individual having a sharply increased risk of developing breast cancer. Non-familial breast cancer is probably due primarily to exogenous factors, combined with errors in the normal processes in the cells, including the genes.

Not even monozygotic twins are completely identical. During their development, a number of events have taken place—including many stochastic ones—that will have affected the way the genes are expressed. Moreover, there will always be mutations, meaning that after some time the genes are not identical, as they were to start with.

Genetic engineering enables specific genes in mice to be destroyed and the consequences of doing so to be subsequently investigated ("knockout mouse"). Using such techniques, single genes of significance to the development of a particular behaviour or particular diseases can be identified. However, such experiments only show that a given gene is involved in that particular development, not that it is a determinant. Often other genes or factors are required too.

When it comes to diseases that involve mental retardation, genetic factors play a large part. For many mental diseases, the genetic constitution is said to lay the foundation of a person's frailty.

Genetic manipulation can be used to modify animals' behaviour, appearance, manner etc. However, the effects are often difficult to predict. It turns out that in animal models at least, it is often possible to repair defective processes (by supplementing), but modification (genetic enhancement) of normal characteristic is more problematic.

Synthetic genes

Genes can be manufactured synthetically in laboratories as identical copies of naturally occurring genes, or as altered/modified genes. The laboratories thus provide access to apparatus that can manufacture genes on the basis of directions fed into the machine. Genes—unlike cells (see later)–are not living material.

Genes can be modified, which is to say that small or large changes can be made in relation to the naturally occurring gene. In reality, such changes may have no bearing on the function of the gene, but they can also be significant and alter the function completely.

Is there anything in the nature of genes that may mean gene patents become broader than intended?

Owing to the RNA editing mentioned earlier, it is not always easy or possible to predict for any one particular gene which protein the gene codes for. The function of the gene is not unequivocal either. Examples are known of RNA editing resulting in a profusion of different RNA molecules, all stemming from a single gene. As described previously, most genes are interrupted by introns, which are cut out at RNA level. However, it is known that introns can have independent functions; there are examples of entire genes being found inside introns, and of a gene being readable in both directions, and therefore coding for proteins with vastly differing functions.

A naturally occurring DNA sequence can contain items of genetic information other than those listed in a particular patent relating to the sequence concerned. If a patent is awarded on the actual gene sequence, and not merely on its application in a specific context, in reality a patentholder can also have a patent on entirely unforeseen applications of the sequence.

Do genes from different organisms or individuals resemble each other?

One of the most important results of the Human Genome Project and the sequencing of other biological species' genomes is that DNA sequences become

comparable. Within evolutionary biology the degree of DNA homology is often viewed as an end for evolutionary kinship, so that the similarity between two organisms' genomes is taken as a sign of close relationsship. For example, human beings and mice share some 99% of their genes. Those differences that exist are crucially important to the differences that exist between animal species. Genes from different species of animals may well be identical, therefore—that is to say that if you patent a gene from a particular animal, it may well be identical with a human gene.

How much control do the genes have in relation to our consciousness and in relation to who or how we are?

In a special feature issue of The New Scientist from 17 May 2003, Matt Ridley[47] writes that:

> *"WHEN genes came along, late in the second millennium of the Christian era, they found a place already prepared for them at the table of philosophy. They were the fates of ancient myth, the entrails of oracular prediction. They were destiny and predetermination, the enemies of choice. They were constraints on human freedom. They were the gods. The very phrase "genetic determinism" has come to be synonymous with inevitability."*

The choice of words here describes the great faith in the significance of the genes for our formation that followed in the wake of mapping the genes. New discoveries about linkages between diseases or characteristics and specific genes resulted in the genes being ascribed great importance for who we each individually are.

It's the old discussion about heredity and environment, which has washed back and forth. In the period before the mapping of the genome, the sixties and seventies, the genes were not ascribed much importance in respect of who we turn into; here, in particular, it was environmental factors that were attributed importance for our development.

This discussion presumably also has a bearing on the way we look at patenting genes. If we are to evaluate whether gene patents can be permitted, then we also

47 Ridley, Matt. 2003. *Genes are so liberating*. New Scientist Magazine. 17 May. See http://www.newscientist.com/hottopics/humannature/article.jsp?id=23955200&sub=The%20brain

need to examine whether patents on genes are, to some extent, also patents on ourselves and our identity.

We are—and we aren't—our genes

So there is much to suggest that the genes are at once instrumental in determining who we are: our physique and mental characteristics, while also working in interaction with the influences from our surroundings: the environment, childhood and adolescence, random happenings etc. The surroundings interact backwards on the genes.

We are not our genes; they determine something about us, but we and the surroundings also react to them. As Matt Ridley puts it: *"Human nature is indeed a product of genes in every particular, but so is human nurture, because genes spend just as much of their time responding to our actions as they do causing them."* [48]

Hence, it would not be correct merely to assert that patents on genes are actually patents on ourselves. But they are patents on *some* information about us; particularly if the patent covers a whole gene, not just a particular application of the gene.

No matter how much the genes influence us, the perception of the genes reflected in the linguistic usage around them, is most thought-provoking. Usage speaks, for example, of "information" that can be "read", and of sequences that "code" for particular processes. Similarly, the genome as a whole is compared with an instruction manual. Such comparisons with conscious information management and computer technology can also fit in with a religious interpretation of life and its origins. On the other hand it may be thought that the similarity between the genetic system and conscious information management is only seemingly so, and that it is not rooted in anything metaphysical. Irrespective of one's interpretation of life, however, most people will certainly agree that life's biochemical system (including the genes) is characterized by a uniquely refined complexity and functionality that no one has probably fully come to terms with yet, and that life thus plays host to a wisdom that gives it a very special value.

48 Ridley. 2003.

4. WHAT *IS* BEING PATENTED?

In this and the following three chapters, the most essential ethical arguments for and against patenting human genes are reviewed. These are primarily arguments that have been put forward by different groups, be they researchers, patentholders, religious leaders, doctors' associations or patients' groups. As will be clear, a multiplicity of arguments is represented, resting on widely divergent assumptions about the nature of genetic materials and the merits and demerits of patenting. This diversity demonstrates that there are many different interests involved in the question of patenting, for example interests of a financial or therapeutic nature. But it also demonstrates that the debate on patents is so multifaceted as to make it difficult to reach a consensus on what is actually being discussed.

By way of introduction to the ethical discussion of patents, therefore, this chapter will highlight some considerations regarding genes and patenting essential to our understanding of the ethical arguments involved. From this and the following sections, it will become apparent that the position a person takes on the issues mentioned can be crucial to the way he or she relates to the ethical discussion.

The question is whether it is significant that the patent does not include the actual genes, rather than a synthetic copy. The answer to this depends partly on the nature of the genes: Should they be regarded as biochemical material or as general information—and is patenting information from the genes unproblematic? The two descriptions of genetic material as biochemical material and general information, respectively, are not mutually exclusive, in the sense that it is not possible to simultaneously acknowledge that there is something right about both of them. But it is essential to realize that great importance attaches to which of the two descriptions is used as a basis for the ethical debate, since the two points of departure lead on to widely divergent evaluations of when patents on human

genes may be considered acceptable. In some cases, therefore, differences in the ethical evaluation of patents will be attributable to the different descriptions of the genes taken as a basis.

A central criterion for whether something can be patented under the terms of the Danish Patents Act is whether it involves an invention, not just a discovery of something that already *is*. However, it is not always obvious whether the patented item should be described as a discovery or an invention. One source of disagreement over patenting genes can therefore be that, at a more basic level, there is disagreement as to when something can be said to be an invention.

Finally, it is essential that two patents be able to encompass widely differing aspects of the genetic material.

Actual genes or synthetic copies

In legal terms, as mentioned, the thing on which a patent is taken out is not the naturally occurring gene. On the contrary, it is a synthetic copy, which may nevertheless perfectly well be " identical to that of a natural element."[49] Thus the wish has been to assure that no human being's right of ownership or disposal over their own genes is violated, or to prevent them from exploiting the genes for, say, producing insulin for their own use. For the legal profession this is an important point, but the question is whether it is also important seen from an ethical viewpoint.

Many researchers are of the opinion that patents on genes cannot be regarded as patents on the actual genes found in some or all human beings' cells. The patents deal instead with the information that can be extracted from working with the genes. For this reason the question of who owns the individual human being's concrete genes can, according to a number of debaters, be dismissed as an out-of-place question, for example:

> *With the issuance of all of these patents to human genetic material, the popular press has become fond of asking the question of who "owns" a person's genes. We submit that this is the wrong question. A more*

49 See chapter 2 on the legislation, which reproduces Article 5 of the directive.

> *appropriate question is, Who owns the intellectual property associated with a person's genes? … Newly discovered genetic material can be patented as long as it is isolated from its natural environment and purified so as to separate it from extraneous material.*
>
> *Thus, does the existence of a patent owned by Amgen on purified genes for EPO, or by Genentech on isolated genes for TPA, mean that Amgen or Genentech owns my genes for these proteins? Of course not. The genes in my body are neither "purified" nor "isolated". Consequently, these companies' patents do not cover my genes, and that settles the issue.* [50]

If patenting human genetic material is thought of primarily as patenting information that does not concern the individual's actual genes, some will not find it so difficult to accept patenting of genetic material. The patents are not in conflict with the individual's right of ownership or disposal over his or her own genes. Others, however, will take a sceptical view of patents, precisely on the grounds that they include what in the quotation is termed the intellectual property. Based on this view, then, it is fundamentally immaterial whether the copies are synthetic or not.

In the following section on the nature of genetic material, the views mentioned will be described in more detail, including whether accepting gene patents can be regarded as ethically straightforward because only synthetic copies are involved. First, an outline will be given of the two views of how best to describe genetic material, i.e. as either concrete biochemical material or as general information. Subsequently, a stance will be taken on the ethical implications of taking each respective view as a point of departure. As will be shown, it is perfectly possible to argue, based on the description of genes as general information, that accepting patents on human genetic material is not unproblematic, even though the patent includes only synthetic copies.

The nature of genetic material

As mentioned, pinpointing and describing the nature or character of genetic material is no straightforward matter—what in a philosophical context might be

50 Goldstein, Jorge A. & Elina Golod. 2002. Human Gene Patents, *Academic Medicine*, Vol. 77, No. 12/December, Part 2, p. 1320.

called ”the ontology of the genes”[51]. The human being’s actual genetic material can thus be described in at least two different ways.

One description of the genetic material is that it is primarily to be seen as some concrete biochemical material found in and forming part of a particular person. There is therefore no vital difference between genes and other human tissue, although of course it must be acknowledged that the genes have other and in certain respects more fundamental functions than other parts of the human being.

Another point of view is that the genetic material should not be described primarily as some concrete substance or altogether concrete molecules. For the essential thing about concrete genetic material is that it represents something more general. The individual person’s genes are largely identical with all other humans’ genes, so when insight is gained into the structure or functions of genetic material from one person, knowledge about the structure and functions of the genetic material in a number of other people is simultaneously obtained. To what extent this knowledge is realized through the production of synthetic genes or in other ways is less interesting, from this angle. The crucial thing is that the information is general and more often than not represents the traits of a large group of human beings.

To judge from the first mode of description, there is nothing special about genes that makes them more problematic to patent than other materials. What is important is whether such patenting may have a bearing on our right to act and transact, as it were, the genes specifically found within us, which in principle it has not if the patent pertains purely to the synthetic copies. The description thus makes it natural to assume that the actual individual can act and transact the genetic material and, for example, ”dispose” of it for particular forms of research. Overall, the view revolves around making the most essential ethical questions associated with patenting genetic material into an issue of the individual’s possibilities for granting consent for different applications of the material.

To judge from the other mode of description, in which the essential thing about the genetic material is above all its general nature, the individual, on the other hand,

51 Ontology means ”the study of the nature of being”, i.e. how an object or a phenomenon is to be perceived and described.

can be said to have a more limited right of disposal in relation to their own genetic material. The individual person can never be said to merely represent themselves in matters of their genetic material. Rather, they must be said to represent the whole of humanity and, in a sense, the whole of nature, which obligates the individual to act in a manner consistent with the interests of the general public. Whether patenting human genes is ethically unproblematic, therefore, is basically an open question, as the reply depends on whether it is sufficiently in the interest of the public to permit patents, i.e. whether the potential for patenting benefits everyone to a reasonable extent. As will emerge in a later section, it may thus be asserted perhaps that genetic material is the communal property of all mankind, and that special requirements can therefore be imposed on the rules governing patents.

Neither point of view can be said to be definitively correct in connection with the ethical discussion on the justification for patents. Rather, they can be said to complement each other, in the sense that neither can be dispensed with entirely. For example, none of those advocating that genetic material should be regarded primarily as general information would presumably endorse a single individual being forced outright to hand over some of their tissue on the grounds that it holds general information to which the whole of humanity is duly entitled. In this situation everyone resorts to the view that the tissue must be regarded primarily as concrete biochemical material, which the actual individual has the right to act or transact. Conversely, everyone will presumably acknowledge that the genes are not just concrete biochemical material, as the general information content is ultimately what makes research into the individual gene relevant.

But although the two points of view are complementary in this way, it is not always obvious in a given context which of them it is appropriate to use as a basis for an ethical evaluation of a concrete patent, or of the patent system as such. One of the reasons why different assessments are arrived at may thus be that different points of view are taken as the basis for the nature and character of the genetic material.

Invention or discovery

When the patent authorities award patents on genes and gene sequences, it is done on the basis of the criteria of novelty and inventive step. That is to say that the patentholder must in some way have invested some effort to warrant the description of a genuine invention. However, that effort can be confined to

creating, with the aid of synthesizing techniques, an artificial molecule in such a way that it contains the same genetic information as the natural gene. Technological developments have made it possible to map DNA sequences as a matter of routine, however, which is why the European Patent Office (EPO) has recently "stepped up" its inventive step requirements.[52]

As previously mentioned, however, it is not sufficient to create a synthetic copy to obtain a patent on a gene. The applicant must also be able to substantiate that the gene sequence can be used industrially in a way that has novelty value.

The patent system therefore rests on the assumption that the patented item constitutes an invention. But some will refute the view that genes can constitute an invention. This can be illustrated by the following statement:

> *Human gene sequences are not inventions. Sequences are discovered, but they're products of nature. When you discover a new mineral you can't patent it. Just like the bottom of the ocean, just like the atmosphere, just like the moon are the common heritage of the whole species, the genome is absolutely the common inheritance of the entire species. The notion that the human genome should be private property is an egregious form of theft of this common biological heritage.*[53]

The claim in the quotation is that patents on human genetic material should be regarded as patents on discoveries, regardless of whether the genes are isolated outside of the body or whether the patent pertains solely to particular functions of a gene etc. In most cases, it will mainly be a case of ascertaining that specific structures or regularities exist. It can therefore be maintained that genes in no way meet the criteria for patentability, because only inventions according to the rules can be patented, not discoveries.[54]

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52 Nuffield. 2002. Pp. 27 and 30.

53 The quotation is taken from Jonathan King, professor of molecular biology at the Massachusetts Institute of Technology in Cambridge (USA) and member of *The Council for Responsible Genetics*. The statements in the following are from Richard Dahl. 2001.Pending Resolution: The Question of Who Owns DNA. *Environmental Health Perspectives*, Volume 109, Number 1, January.

The assertion that patents on genetic material are patents on discoveries, however, is complicated by the fact that human genetic material can be modified. For instance, when manufacturing a synthetic gene, a researcher can modify it, as described in the chapter on synthetic genes, so that it is no longer identical with any naturally occurring gene. And yet it can perfectly well code for the same protein in the same way as a naturally occurring gene does. It is arguable whether such a modified gene is an invention or a discovery. By the same token, it is debatable whether it makes sense to describe a synthetic gene as a discovery, if it has been substantially changed in relation to a naturally occurring gene or maybe even manufactured with absolutely no eye for the way in which some naturally occurring gene functions.

On the basis of the examples mentioned, it may seem most correct to say that there is a seamless continuum in terms of classifying a patent as either a discovery or an invention. If a synthetic gene is completely identical with a naturally occurring gene, it may be difficult to think of it as anything other than a discovery, and the more the patented gene deviates from a naturally occurring gene in terms of both make-up and function, the more natural it would seem to characterize it as an invention. Another question, then, is what ethical consequences can be drawn from whether a gene or an application of a gene is classified as a discovery or an application. This question will be discussed in a later section.

The deliberations above demonstrate that it is not altogether manifest whether a particular patent should be perceived primarily as a discovery or an invention. The discussion further shows that the classification adopted is not altogether a matter

54 This philosophy is in keeping with the patent law prescription that naturally occurring substances and objects cannot be patented. In the age of industrialism, a chemist who discovered new substances and new natural processes could only patent his method for extracting and distilling the substance concerned or for initiating the natural process in question. The actual discovery of occurrences in the wild—what the US Patent and Trademark Office (PTO) terms "discoveries of nature"—could not be patented, either in the USA, Denmark or presumably with any other national patent office. Who would have originally thought of awarding Madame Curie a patent on radium? Or awarding a patent on aluminium to the person who first developed a method of isolating this element? In actual fact, the PTO rejected a patent application for wolfram in 1928, a decision that has since been affirmed by the federal courts with reference to the fact that the applicant may certainly have been the first to have both discovered and extracted this element, but since wolfram had always existed in nature, it was purely a case of discovery, not of invention. General Electric Co. v. De Forest Radio Co. et al., no. 3654, Circuit Court of Appeals, 18 September 1928.

of indifference. If patents include inventions, many people will probably think that there is no problem in permitting patents. If, on the other hand, patents pertain to discoveries of facts about our collective genes, it may be felt that there are problems associated with patenting, not least if research into genes and the development of therapeutic methods fails to benefit everyone.

Genes and identity

One last divergence in the perception of the nature of genetic material should be mentioned briefly here. This will be revisited in the section on ethics under the heading *"Our view of humanity, approach to nature and patenting".*

The question is whether genetic material constitutes a special, central component of man, i.e. a sort of essence of man which has some fundamental meaning for man's dignity and identity; or whether genetic material has the same status as other human tissue, i.e. it is a necessary condition for maintaining the individual and the species without enjoying special status on that account.

Many have attempted to argue that adopting a stance on the problem above must be crucial to one's stance on whether it is ethically acceptable to patent human genetic material. If anyone were to assert that mankind, in some sense, "is his genes", patenting those genes would constitute a violation not only of the individual but of humankind as such. For in the process, it submits humankind to an economy of logic that is incompatible with the dignity and respect with which humans should be treated.

Patents cover different aspects of the genetic material

As previously discussed, it is possible to distinguish three different types of patents: product patents, process patents and use patents. Whether a particular argument for or against patents is justified often depends on the type of patent involved. This is to do with the fact that the three different types of patents to some extent grant a patent on widely divergent things.

The most far-reaching patent is the product patent, which in principle gives the patentholder right of disposal over all applications of the patented material. In this way, the patent is reminiscent in many respects of an actual proprietary right over the genetic material[55]. Conversely, neither process patents nor use patents bear any special similarity to a proprietary right over the patented material, since it is

only concrete procedures, applications and forms of production etc. which the patentholder is entitled to make exclusive use of.

Some ethical arguments pertain to product patents, first and foremost, and are more difficult to apply in connection with process or use patents. For instance, one argument against patents may be that genetic material is a collective resource, which no individual or single organization should be capable of disposing over alone. Whether the argument is tenable is debatable, but at any rate it is more hard-hitting in relation to product patents than in relation to use or process patents, because product patents resemble a proprietary right to a greater extent than the other forms of patent.

55 Compare the deliberations on the concept of property rights in the subsection *property rights and patenting*.

5. DOES PATENTING PROMOTE RESEARCH AND DEVELOPMENT OF TREATMENT PROCEDURES?

The ideal main argument for making it possible to patent human genetic material is the need to do so in order to promote research in the field and thus stimulate the development of, amongst other things, new forms of treatment within the health sector. Two reasons are normally given to explain why the possibility of patenting human genetic material will have these consequences.

Firstly, the possibility of obtaining patents is an incentive for commercial companies to invest in research and development. Having been patented, any results to emerge from the research or development work can secure companies a financial return equivalent to the investments and efforts put into the development phase. Such financial return would not necessarily be achievable if the possibility of patenting did not exist, because other companies would simply be able to copy the product developed.

The fact that commercial companies may need an incentive to embark on the necessary research is largely to do with the fact that developing new products in the field involved here can be extremely intensive indeed in terms of expenditure. The Nuffield Council on Bioethics, for example, refers to studies indicating that it costs about £110m to develop a new medicine, including conducting clinical trials and complying with existing safety requirements.[56] No company is willing to undertake such an investment unless there is some prospect of a satisfactory financial return, at least equal to the investment and risk associated with developing the product.

56 Nuffield. 2002. P. 14

Secondly, the patent system ensures that the knowledge and research results on which development of the patented product is based do get published. It is simply a requirement for the approval of a patent that the underlying research results be publicized in the patent application. This gives other researchers access to the new knowledge and enables them to continue researching on that basis, instead of having to start from scratch themselves.

In most European countries—including Denmark—the research exemption applies, which says that research into patented material is legal until the research reaches the stage where it is potentially exploitable commercially. The rules do vary from one country to another, however, for example with regard to whether the exemption also applies to the phase where research results are verified by trials on patients (clinical trials). The USA and Canada have no formal research exemption at all.[57]

Without a patent many researchers and companies will generally be tempted to keep their research results secret so that they themselves can be the first to exploit their knowledge commercially. In this sense, the patent system clearly contributes to greater openness and hence fuels more research by publishing the knowledge on which patent issues are based.

Nevertheless, there is no ignoring the fact that the patent system can also have an inhibiting effect on researchers' opportunities for accessing colleagues' knowledge—particularly in more recent years, when researchers employed in the public sector have also been ordered to patent the results of their research.[58]

Two American attorneys, Arti Rai and Rebecca Eisenberg, have argued that openness within biomedical research has lessened considerably since the mid-1970s. This is due to the distance between basic research and its commercial exploitation having shrunk, in as much as the manufacture of medicine from biomedicine has become more dependent on a basic knowledge of genes, proteins etc. Given that it is often obvious how knowledge about e.g. DNA sequences, protein structures etc. can be used commercially, patents are now being awarded

57 Nuffield. 2002. Pp. 60-61.

58 In Denmark, as mentioned in chapter 2., through the Danish Act on Inventions at Public Research Institutions

for discoveries that would once have been far from capable of resulting in an industrial application that might warrant a patent.[59]

At the same time, the governments of the USA and the majority of western countries, as mentioned, have ordered their university-employed researchers to take out patents on their research results. The purpose is supposed to be to utilize the research and generate collaboration between the universities and the business community by having researchers sell their patents on to industry, which can then turn them to commercial account. But since the primary value of the results patented often lies in using them as a basis for further research, this development is resulting in the patent system penetrating ever further into the domain previously reserved for open research. For even if the universities do not attempt to take out patents initially, they can sometimes conceal their results pending the possibility of obtaining profitable patents.

Partly in relation to the universities, new types of company have arisen that live off developing and marketing the research protected by monopolies located somewhere between traditional academic research and the development of medical products proper.

Naturally, this development will be more of an inconvenience to free research in the USA and other countries which, as mentioned, have no research exemption to ensure that others are free to do research into patented knowledge. But in Europe, too, the trend towards early patenting and concealment of knowledge is posing an obstacle to collaboration and openness in research.

The problem can be illustrated by two cases:

Case 1: Patent war on SARS virus

In spring 2003 the US Center for Disease Control and Prevention and the Canadian British Columbia Cancer Agency applied for a patent on the corona virus thought to cause SARS. They did so in order to prevent private companies from monopolizing the future diagnosis and treatment of SARS, and in the realization that patents on early research results can prevent others from exploiting this

59 Rai, Arti K. and Rebecca S. Eisenberg. 2003. Bayh-Dole reform and the progress of biomedicine. *Law & Contemp. Probs.* 66, no. 1/2: 289-314. Also available at: http://www.law.duke.edu/journals/lcp/downloads/LCP66DWinterSpring2003P289.pdf

knowledge in their quest for treatment.[60] The idea, then, was to ensure that no one had a monopoly on knowledge about the disease, thus delaying the development of a treatment for it.

But these public organizations are not the only ones to have applied for a patent on the SARS virus; a number of pharmaceutical companies and scientists in Canada and Hong Kong also filed patent applications in autumn 2003, with claims ranging all the way from parts of genetic material to the virus itself.[61]

It will take anything from several months to a number of years before the patent cases are decided.

In an article in The Lancet[62] Richard Gold from the Centre for Intellectual Property Policy at McGill University in Montreal thus explains how the two institutions were compelled to apply for a patent on the SARS genome, despite the huge outlay on patent lawyers, if they wanted it to be publicly accessible to all researchers. The alternative would have been to publish the genome, because others cannot patent something that has already been brought into the public domain. But this strategy would not prevent others from patenting various applications and products that interact with the SARS virus, thus removing them from the public domain.

This, in Gold's opinion, shows that the patent system does not work as intended to create openness and promote the development of new treatments. And the lead writer of Nature wrote[63] that the race for a patent on the SARS virus once again questions the patent system's ability to handle biotechnological inventions.

Case 2: Australian company demands licence for use of patented 'junk' DNA
In spring 2003 an Australian company, Genetic Technologies (GTG) also began charging universities licence fees if their researchers were using the company's

60 *Nature,* 2003. *Gene patents and the public good*, p. 207 and "US acts to keep SARS sequence public" p. 214. 2003.
61 *Associated Press,* 4 November, 2003: Scientists race to patent SARS virus. Efforts to claim property rights spark ethical debate. See: http://www.msnbc.msn.com/Default.aspx?id=3076748&p1=0
62 *The Lancet,* June 14, 2003. SARS genome patent: symptom or disease? Pp. 2002-03. See also: http://www.las.ac.cn/bulletin/sars/50008.pdf
63 *Nature,* 2003. P. 207 and 214.

patented gene sequences in their research. Over a number of years during the 1990s a former employee of the company was granted a variety of patents on methods for analysing variations in non-coding DNA (also referred to as 'junk' DNA) for the purpose of mapping disease genes.[64] Apart from criticisms that the patents were too broad and failed to meet the requirements of novelty value, inventive step and industrial applicability[65], it has created something of a stir that the company has levied a licence fee from the universities.

Patentees do not normally levy licence fees from basic researchers, at any rate not until the researchers have possibly developed a diagnosis or treatment and start making money out of it. But GTG has broken with that practice by approaching a large number of research groups in Australia, the USA, Japan and Europe to demand payment of a licence fee if the company's patented gene sequence is incorporated in the basic research. According to the company's Executive Chairman, Mervyn Jacobson, the motivation for demanding licences from the universities is that:

> *Research is now big business for universities, hospitals, companies—they're all in business. The historical boundary of academic and public fund organizations doing research at a pure level is simply not correct any more. (..) A lot of academic organizations are under pressure to generate revenue. Why should they be exempt from the rules of the market?* [66]

Many researchers are dissatisfied with the move and claim that levying licence fees from basic researchers only serves to hinder research.[67] But legislation in the USA and Australia does permit the company to do it because these countries have no provisions on research exemptions.

To tie things in, then, it can be said that the patent system's ideal of promoting research and development is not automatically fulfilled. In principle, the patent

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64 Davies, Kevin. 2003. First Base: Guardians of the Genome. In *BioIT World*, 21 August 2003. See: http://www.bio-itworld.com/archive/bases/082103.html

65 Interview with Francis Collins, Director of the National Human Genome Research Institute, in *BioIT World*, 13 August 2003.
See: http://www.bio-itworld.com/archive/081303/horizons_aussie_sidebar_1.html

66 Quotation from *BioIT World*, 13 August 2003. Playing by Aussie Rules.
See: http://www.bio-itworld.com/archive/081303/horizons_aussie.html

67 See: *Nature*, 2003. *Geneticists question fees for use of patented 'junk' DNA,* p. 105

system should be organized in such a way as to satisfy the public's interest in research and development of treatment procedures as best possible. For example, the duration of patents should be just long enough to create the right balance between incentivizing the development of new products and avoiding the concealment of results that might benefit the general public. But in research circles, as shown, there is some disagreement as to whether this balance has been struck with the current patent system.

6. PATENTS, PROPERTY RIGHTS AND EQUITY OF DISTRIBUTION

Property rights and patenting

In the ethical debate, many commentators liken patents to a form of ownership, while adherents of patents usually dismiss this description. A legal expert will refer to the Danish Patents Act and assert that a patent does not confer property rights on, say, a gene or a gene sequence. What it does afford, by contrast, is a fixed-term sole right to exploit the invention commercially—providing such an application is not prohibited by other laws, incidentally.[68]

For a legal expert this is an important nicety, but it is difficult to determine precisely whether a patent right can meaningfully be described as a property right or not. Since many discussions take the concept as their basis, some of the most essential arguments and reasonings will be presented below.

Before the discussion on ownership, some account will be given of what it *means* to own or have property rights over something, because the difficulty of determining whether a patent can be described as a property right ties in with the concept's very vague or imprecise meaning in more than one respect.

The meaning of the concept "property right"

The central meaning of the concept of ownership[69] is presumably that one has the right to act and transact the object owned in different ways. It is no coincidence,

68 Section 1 of the Danish Patents Act says that "Any person who has made an invention which is susceptible of industrial application, or his successor in title, shall, in accordance with this Act, have the right on application to be granted a patent for the invention and thereby obtain an exclusive right to exploit the invention commercially. Inventions can be patented in all fields of technology."

69 The following review is based partly on Lars Bergström. 2000. The concept of ownership. In *"Who owns our genes?"*, Nord, 2000:11.

then, that ownership is always associated with rights, since the rights afford the owner certain options in relation to that owned. In addition, ownership is often interlinked with duties which make it incumbent on the owner to do particular things with that which is owned, for example to take the car in for an MOT every other year or to refrain from driving more than 130 km an hour on the motorway.

If it were possible to highlight rights or duties essential to the notion of ownership, the concept would have a more or less precise meaning. But there is nothing to suggest that the concept has such a central core. Although it is possible to have ownership of something, there is a great difference between the rights associated with this, e.g. ownership of an object and ownership of a dog. Not even the possibility of disposing of ownership by one's own request is consistent with the concept: a car may be pledged as security, castle grounds may be listed, and a buyer of spirits may be under 18 etc.

The mere fact of a person having property rights over something does not enable one to infer anything unequivocal as to what the person may do with the item owned. So even if there is reason to assume that a person can be said to have ownership of their genes, there is no knowing whether they are entitled to hand over parts of that ownership to a future patentholder. This very course of action may be one of those not covered by the right of disposal, for whatever reason.

The other problem about the concept of ownership or property rights is that it is not clear when, in a relevant sense, ownership of something is held or has been achieved. Certainly, in the legal sense, ownership is often very well defined, often laid down by the laws, conventions and rules enforced by the country or area in question, but the legal concept of ownership is not relevant if the concept is to be used in deciding an ethical position on the justification of gene patents. This is because the way in which a country or an area assigns ownership may be quite patently unreasonable or unjust. In that instance the legislation or the conventions have no ethical foundation. In this case any criticism of the legal practice surrounding ownership must necessarily be based on ethical reasoning, otherwise there is no platform from which to level criticism at this practice: The patent rules cannot be used to criticize the patent rules.

If the awarding of patents is actually rooted in specific ideas about ownership, it is therefore necessary to relate to the time when a person or institution has or has

obtained *ethically justified* ownership of something. Only on the basis of this *ethically defined* concept of ownership can a critical stance be taken on the established patent system and patents already awarded.

Several theories exist as to when ethically justified ownership of something is obtained.[70] What is characteristic of these theories, however, is that the different readings of justified ownership are just as vague and imprecise as the actual concept of ownership.

An example of this might be the classic theory[71] that any person has ownership of his or her own soul and body as well as the work produced by the organism as a whole, and since this work is involved in producing various products and, as it were, is mixed in with the rough material in the raw state, the person also achieves ownership of the product (provided there is no over-exploitation of the raw material).

Even this succinct description of the classic theory of ownership demonstrates the great difficulty of using it to discuss the patenting of genes. Firstly, it is unclear from the theory whether a person is entitled to transfer ownership of their genetic material to others, for if transfer results in a gene patent, this may restrict *others'* scope for action in relation to *their* genes (more about this later).

Secondly, it is unclear how great a value to place on the work a person or company performs to develop a particular product. For it is not just this work that is involved in developing that product. The knowledge already assimilated and the technologies developed in the field are also necessary to develop it. In principle, all players who have contributed to developing the relevant knowledge and the relevant technologies should be rewarded for their labours too. It is unclear, therefore, whether the work of developing the patentable product is extensive enough for it to reasonably result in a patent.

Finally, the aptness of describing a person's relationship with his or her own organism as a condition of ownership can also be queried. One criticism of this

70 For a more detailed description of relevant theories, see e.g. Lars Bergström. 2000.

71 The theory was developed by the philosopher John Locke (1632-1704) and defended more recently by others including Robert Nozick. 1974, in *Anarchy, State, and Utopia* (Baic Books, Inc.).

line of thinking might be that the individual has not become what they are entirely unaided. The society around has also made its contribution, including education, culture and material resources. But if the individual cannot be said to have ownership of their own organism, nor of course can they pass that ownership on to others. Nor, then, can a company acquire justified ownership of an invention that has been developed against a background of research in genes merely because the individual has agreed to take part in the research.

Similar criticisms can be formulated and levelled at other theories of justified ownership. All in all, therefore, these deliberations on ownership demonstrate the problematic nature of using the concept of ownership to discuss the acceptability of patenting genetic material. Instead, other concepts may be central, for example concepts such as scope for action or bodily integrity. In the following, some of the arguments concerning ownership more often put forward will be discussed. At the same time, reference is made to some of the concepts that may be more fundamental to the problem issues involved.

Property rights or self-determination in relation to one's own genes

With reference to the concept of property rights it can be attempted to argue in favour of patenting by asserting that the single individual has ownership of his or her own genetic material. The material can therefore be passed on to others, who assume those property rights and become entitled to act and transact the results achieved in connection with research or development.

One objection to the argument is that the individual cannot be said to have ownership of his or her own genes if this ownership interferes to any material extent with others' scope for action in relation to their genes. That this would actually be the case, however, can be illustrated by the following quotation from an article written by Margaret Everett, a woman with a mutation in her family:

> *I joined GRAC [the Genetic Research Advisory Committee] probably with the notion that I was there to defend the property clause, which I felt underscored individual and family rights to retain control over the use of one's own DNA. By the time the GRAC completed its work, however, I was less certain of the benefits of declaring DNA to be the property of individuals. I was troubled by some suggestions that individuals should share the profits of discoveries made using their DNA, or even that*

> *individuals might be allowed to accept payment in exchange for consent to use their DNA. How could such benefits be distributed when family members share even rare mutations?* [72]

The point, then, is that a single individual in a family should not be able to have sovereign disposal of his or her own genes because their particular mutation belongs in equal measure to the other members of the family. They all have the same mutation, after all. Correspondingly, it can be said that the individual genes must belong to all human beings, if collective genetic material is involved. In that sense, then, it would seem more justified to speak of collective property rights than individual property rights.

The question is, however, whether the intuitions and experiences used as a basis for talking about individual ownership are actually best captured by the property rights concept. An alternative interpretation, rather, might be that the issue has to do with personal autonomy or personal integrity. That is how Margaret Everett interprets it in the article mentioned, referring to a case in which a family with Canavan's disease agreed to allow tissue samples from the children to be used for research. The family hoped that they could thus be instrumental in developing a prenatal diagnostic test for the disease. They felt deeply offended, therefore, when the outcome of the research was a patent on the relevant gene, which was later used to charge a fee for every test for that gene. According to Margaret Everett, the example is illustrative:

> *The controversy over the patenting of this particular mutation is especially significant, because it indicates that while the subjects of DNA research are quite often not interested in getting a share of the profits, they are concerned about retaining some control over the use of their DNA through informed consent procedures.* [73]

In Margaret Everett's view, the individual's scope for selling his or her genes is not of fundamental importance to the debate. Rather, it is the possibility of using the information from the genetic material in a way that is consistent with the person's

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72 Everett, Margaret. 2003. *The social life of genes: privacy, property and the new genetics*. Social Science & Medicine, Vol. 56, Issue 1, January. pp. 53-65.

73 Ibid

own views and values. At minimum, this requires the person's autonomy or integrity to be respected by having the individual give informed consent for the research as well as any patenting to come out of it later on.

Of course, avoiding the discussion about ownership to take considerations of personal autonomy or personal integrity as a basis instead does not resolve all the ethical problems. For example, it is still necessary to decide whether respect for the individual's autonomy can be overridden in some cases by concerns for the interests of the community.[74]

Drawing the correct dividing line between respect for the individual and regard for more general interests is a question that remains controversial and unresolved, though some will certainly claim that, whatever happens, a person should have the opportunity to opt out of any form of research that involves tissue or data relating to that person, if either the research as such or the application of the research results is not compatible with the person's values or views. An example of one such clash between the interests of research and the relevant person's values might be the use of genetic material from a person to develop a prenatal diagnostic test for the aforementioned Canavan's disease, even if the person is a vehement opponent of prenatal testing even being performed, on religious grounds. It is also possible to envisage the research results being used, for commercial reasons, in such a way that they do not benefit the people the person wished to favour etc. In such instances, it can then be asserted with all reasonableness that the person is being used as a means to promote the interests of the research rather than as an end per se.

Product development and ownership

One last issue regarding ownership needs to be clarified briefly, i.e. whether one should be eligible to own those products requiring substantial work and/or great creativity. If this is the case, there is a good ready-made argument for accepting gene patents in many instances, since great creativity or resources may have been used to develop such products. This seems to be the philosophy behind the formulation of the Patent Directive since, as previously mentioned, patents can only be obtained if an invention involves sufficient inventive step etc. This

74 As, for example, has happened in Iceland, where every citizen is assumed to have accepted that his or her DNA and medical journals be used for research unless that citizen has explicitly opposed it.

provision reflects the need for the patentholder to have in some way invested an effort reasonably proportional to the procedure of acquiring the patent.

In theories about justified ownership, importance will certainly be ascribed to whether effort of some kind was expended in connection with the "original" acquisition[75] of an item. As mentioned, this is a crucial element in the classic theory of ownership. But it is essential to realize that, whatever the circumstances, ownership can only be said to be justified if the attribution of ownership is not inconsistent with other, more essential ethical considerations or principles that also apply in the particular context; and there is much to advocate that there are essential considerations of this kind to be taken into account with regard to patenting genetic material.

Firstly, as previously mentioned, it may be felt that genetic material is a resource over which the whole of humanity already has collective property rights or right of disposition as a basic working premise. If this is the case, however, then of course an individual or company cannot appropriate ownership of a product that has been developed on the basis of the resource merely by spending time, money or creative energy on the development work. For one thing, the developer must first be authorized even to use the resource in his work, and for another the resource-holder can lay down the ground rules for exploiting the resource with relative sovereignty, precisely because it is his property.[76] In principle, therefore, you might say that mankind is well within its rights to lay down the ground rules for the use of genetic material in absolute terms. If individual companies or researchers cannot accept those ground rules, they must refrain from working in the field. They have neither a claim nor a right to obtain anything before a set of binding rules has been laid down. It is quite a different matter, of course, that laying down ground rules that do not prevent the development of treatment options of potential benefit to everyone is in the interest of humankind. But based on this philosophy,

75 "Original" acquisition should be understood as the moment an object is owned by someone for the first time. Subsequent assignment of property rights is subject to ground rules other than this first acquisition. For example, the owner can freely assign the owned item if he feels like doing so. For the purposes of the discussions in this report, however, it is the original acquisition that is relevant, since it involves material not previously patented.

76 Basically, for example, A.P. Møller had no claim or right to make a profit from extracting oil from the Danish subsoil. On the contrary, the company was authorized to extract the resources on the basis of a set of rules that had to be acceptable to the Danish government in order to be valid.

the ground rules are purely a means of assuring optimal access to new treatment options.

Secondly, a major problem in terms of acquiring ownership of the products manufactured is that the patents in this particular context have to do with health services, which in large parts of the western world are distributed according to a different logic than most other services.[77] Thus, in a Danish setting, it is not the case that the only health services accessible are those that are affordable. On the contrary, the public health system, as the reader may know, makes health services available free of charge to everyone on the basis of needs assessment on a case-by-case basis. In that sense, Danish society could be claimed to be based on a principle that health needs[78] have special ethical weight or significance, which imposes an obligation on others to try to satisfy them.

If satisfying health requirements is ascribed special ethical weight, this regard must be a competing consideration in regard to the principle that ownership is granted according to effort. This follows from the fact that the awarding of patents does not necessarily ensure either the most effective development or the most equitable distribution of health services. In ethical terms, therefore, making different adjustments to the allocation of ownership may be justified if it enables more effective or equitable development to be achieved. The existing patent systems already include a number of "internal" special provisions that can be said to accommodate this. For example, research activities that have no commercial aim are never covered by a patent.

One conclusion to the above considerations might be that neither researchers nor companies have any weighty claim either to be rewarded for their efforts or to be rewarded in some way equivalent to the actual efforts deployed in the form of creativity, work and investment. But this does not mean that the relationship cannot be ascribed some weight, based on ethical considerations too. The point is, though, that no commercial companies will embark on taxing research or

77 See, for instance, ACOG committee opinion. 2003. *Patents, Medicine, and the Interests of Patients: Applying General Principles to Gene Patenting*. International Journal of Gynaecology & Obstetrics, 80, 93-98, for a critique of the patent system, based on the special nature of health services.

78 A number of other needs are also equally significant: for example, the need for food, clothing and a place to live.

development work unless there is a well-founded expectation of netting a satisfactory return. It is an open question, therefore, whether patents can be dispensed with altogether if the development of treatment options is to proceed satisfactorily, or whether they can be narrower and of more limited duration than at present without hamstringing developments.

Equitable distribution

In Chapter 5 it was mentioned that a possible reason for accepting patents on genes etc. is that patents promote research and development of treatments in the medical field. On the face of it, this argument appears to be entirely straightforward. It might even be maintained that there is actually an obligation to establish a patent system if it does not already exist, because the individual is entitled to receive optimal treatment under the health service.

Nonetheless, it is debatable whether the patent system actually promotes the interests of public policy, since most of the therapeutic options developed will not be accessible to everyone. In particular, many people from the third-world countries will not have access to them because they are too expensive. But citizens in other parts of the world, too, may be precluded from them because they cannot afford to pay for them and do not have access to them through a public health system. This, some think, creates a problem of equity[79]: Is it reasonable that all human beings do not have access to health services that have been developed as a result of research on our common gene pool, the provision of which is monopolized by a single patentholder? On the face of it, the system seems exclusively to favour the well-to-do part of the world's population.

Two very different answers can be given to the question posed. One possible view is that the patent system is completely unreasonable if its outcome is as described. An argument in favour of this view is that genetic material is a common resource, for which reason everyone ought to have access to the therapeutic options made possible by research in this field.

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79 See, for example, Nils Holtug. 1995. *Patents on human genes: Is there a moral problem?* Monash Bioethics Review, Vol. 14, No. 2, April, pp. 26-38. See also Peter Kemp and Niels Mattson Johansen. 2001. *Rapport om patent og etik* ["Report on patents and ethics"] (for the Danish Ministry of Business and Industry, for a number of reflections on social justice and patenting. The report also adopts a position on the relevance to the patent debate of key ethical concepts like autonomy, dignity, integrity and vulnerability.

Another possible view is that the uneven distribution of health services is not problematic if the existence of a patent system as a whole brings about an enhanced quality of life by comparison with realistic alternatives. One might think that that is precisely the situation in this case, because it is not detrimental to those who are worst off if those who are better off are given access to new therapeutic options. In that sense, developing new therapeutic options is useful in a global perspective too: it enhances life opportunities for those who are best off without worsening them for those who are worst off in the process.

However, it can also be asserted that the uneven distribution of health services that results from the patent system cannot be used to criticize the patent system as such. After all, the uneven distribution of the health services will exist irrespective of whether there is scope for patenting or not, because the health services are provided in a system piloted by market-economy considerations anyway. Anyone critical of an uneven distribution of health services, then, ought perhaps to level their criticism not at the patent scheme but rather at the social systems that fail to assure adequate redistribution of resources. For the critics, however, this philosophy is naturally no argument for omitting to redress the imbalances in the distribution of health services which the patent system is instrumental in clinging on to or exacerbating.

By way of conclusion to the above discussion about promoting research and development of therapeutic options through the patent system, it should briefly be mentioned that these deliberations can be framed in an even broader perspective. It is thus possible to claim that the possibility of obtaining gene patents generally promotes economic growth and as such is in the interest of the common good, i.e. serves a clear purpose in terms of public utility. That line of reasoning will not be pursued further here; it should merely be mentioned as a counterargument that if the possibility of taking out patents actually generates economic growth, it cannot be inferred from this that the patent system is a benefit. That depends partly on whether such economic growth benefits the many or serves altogether different public utility purposes, which in no way can be taken as read, and depends partly on whether the patent system is ethically acceptable from other points of view as well.

7. OUR VIEW OF HUMANITY, APPROACH TO NATURE AND PATENTING

This chapter will present a number of the most central arguments against patenting genetic material from human beings—all of which have in common that they characterize patenting as an infringement or an impermissible reduction of something vested with its own sovereign integrity. It can be nature. It can be man's dignity as a species being. It can be man's individual identity. And it can be God's creation.

These four arguments are examined separately below.

a) Gene patents are a violation of nature

Historically, the patent debate does not start with human DNA, it starts with plants, which have been patentable in the USA since the 1970s.[80] So although some debaters would like to claim that something decisively new happens the moment patenting of human genetic material is permitted, it can also be argued that the landmark ethical dilemma arises with access to the patenting of genes in general.

The view can further be supported by the fact that, as previously mentioned, only a minor proportion of man's genetic material is unique to homo sapiens. For instance, man shares approx. 50% of his genes with a banana. In other words: if a patent is taken out on a human gene, in many contexts that patent will also include genes or gene sequences from animals and plants. Conversely, a patent on an animal or plant gene will often include genes or gene sequences that occur in man

80 In the history of genetics the patent debate can be traced back to 1970. That year, US Congress passed the Plant Variety Protection Act—a law (still in force) permitting patents on genetic sequences in plants and on methods of modifying such sequences.

as well. In that sense it is not possible to conduct a detached discussion of whether it is ethically acceptable to patent human genetic material. The discussion must be framed in a broader perspective, where the decisive question is whether it is ethically acceptable to permit patenting of genetic material from living nature, whence we humans originate and with which we are constantly enmeshed.

The view can be regarded in relation to a number of profound changes to the economic system of the capitalist world since the beginning of the 1980s. The theories concerning the background to this economic transformation will not be examined in greater depth here, but its consequences for the status of nature in the life of the community and the public dialogue need to be stressed.

Firstly, from the beginning of the eighties, a wave of public service privatization occurs, such as train services, and power and water supplies. But this wave does not stop on the verge of what was hitherto national property—natural deposits that have hitherto been common property are now transferred and brought under the financial control of private companies. The example par excellence is the world's drinking-water supply. Whereas groundwater and spring water were once regarded as belonging to "mother nature" and were therefore freely available to everyone—on condition that the water was not contaminated or the supply spoiled for others (the common stewardship of nature)—it looks as if large multinational companies, with the aid of parties including the World Bank and the International Monetary Fund, are now gaining control of all potential drinking-water across large parts of the globe.[81]

Secondly, with the development of computer technology, the Internet and other digital communication tools follows a transition from the so-called industrial economy, in which the basis of the economic cycle was mechanical processing in production halls, to the new information economy, in which the crucial economic resource becomes knowledge and access to knowledge. Economic power is now linked increasingly to knowledge-based patents, copyrights, brands, data-processing methods and so on. [82]

81 E.g. Maude Barlow & Tony Clarke. 2002. *Blue Gold*. And Ottawa and Jacques Leslie. 2001.Bis zim letzten Tropfen. In du, March edition.

82 This is the background against which the enormous importance attributed by all the major players in the WTO to the talks on and adoption of the so-called TRIPS agreement (Trade Related Aspects of Intellectual Property Rights), which came into effect from 1995, must be understood.

There is probably no field where the two changes to the economic system mentioned—the privatization wave and the dissemination of intellectual property rights—interact more powerfully than the global biotech industry itself. By way of example, four of the world's largest companies, whose financial position rested for decades on the petrochemical industry (oil), have disposed of large parts of their chemical operations since 1996 in order to concentrate on genetic research instead, developing new genetic engineering technologies and derived products—they are Monsanto, Novartis, DuPont and Aventis. These and other companies have devoted colossal resources to finding and patenting useful genes and gene strands in the hope of being able to find an application in the future production of food, medicine, synthetic fibres, communications equipment, energy sources etc. In one way it may look as if the globe's total gene pool is in the process of taking over the role of minerals and fossil fuels as the principal raw material of the New Economy. In the debate on the integrity of nature in general and on gene patents in particular, there are gigantic financial interests up for grabs, in other words.[83]

Apart from the global equity problems raised by this development, it can also be described as a violation of nature that such essential parts of it—from genes to groundwater—have been expropriated in the space of a few decades and, having once "belonged" to nature (i.e. been a sort of common property), now belong to private financial interests that operate with the aim of securing the greatest possible return for shareholders.

In a sense this development can be viewed as a provisional culmination of our view of nature (and man's position in it) that has gained ground over the past 400 years. In brief: The human intellect is the observing subject; nature and the universe are merely the object of our systematic analysis and flair for technological manipulation. During the 20th century, particularly the latter part of the century, this perception of nature as a raw material or a resource for man's self-fulfilment brought about ecological destruction, threatening not only nature itself but possibly also mankind's continued existence.

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83 In 2000 the American social critic Jeremy Rifkin ascertained that ten biotech companies controlled 32% of the whole world's trade in seed grain (calculated at USD 23 billion)—Monsanto alone had 33% of the soya market, 15% of the maize seed market and 85% of the American cotton market (Jeremy Rifkin. 2000. *The Age of Access: How the Shift from Ownership to Access is Ttransforming Capitalism*. London, pp. 66-67). The seed involved here is genetically modified; it is protected by the supplier's patent rights—and both Monsanto and other biotech companies have made it clear that they intend to sue peasant farmers who take the liberty of reusing their patent-protected crop as seed grain next season.

But even if the spiralling destruction of nature in the form of the greenhouse effect, water pollution, desertification etc. were to be successfully halted, the continued commercialization of nature in the form of patents on life forms might still threaten the future of Earth anyway. For if man is never confronted with nature as anything other than the product of our own genetic engineering skills, then man is being robbed of an essential mental guiding principle: the encounter with that which lies beyond our power, the free and the alien, the absolutely not man-made. The consequence of this might turn out to be a self-centred person who is incapable of living in freedom and shaping human civilization.

The outline given of the development in the global economy may speak in favour of mankind adopting a different perspective on the world around than is presently the case. Nature is entitled to be embraced with respect, and in the final analysis the display of such respect also benefits mankind itself. In the longer term, the present way of dealing with the world at large, in our urge to control everything, may pose a threat to the existence of mankind.

It is open to discussion, however, whether that line of thought constitutes a separate argument against gene patents or, rather, whether it can be understood as a general argument against the social engineering model adopted by the western world. Arguments could feasibly be put forward to prove that exploiting genetic information, in particular, is especially problematic. For example, it can be asserted that the entire biotech industry comprises a particularly potent area—in terms of both globalization and future significance for humankind, qua species—an area that crucially needs regulating early on in its development. Or it can be stated that genetic data patents constitute a kind of violation of the actual idea or spirit of the living world because, as previously mentioned, the information concerned is in many cases common to all living things.

b) Gene patents are a violation of human dignity

It can be asserted that nature does not have integrity worthy of protection in its own right but exists for the sake of mankind.[84] To the extent that nature has to be taken into account, it is ultimately derived from consideration for mankind. For example, the environment and the species must not be protected for their own

84 The view is in harmony with the biblical account of creation.

sake but because a clean environment and a suitable variety of species can benefit mankind.

The process of civilization that has helped produce affluent modern democracies is built on the perception of man as a unique and valuable creature. Man is unique and stands out from every other being—whether that uniqueness is rooted in man's intellect, his creative capacity, his ability to build society or in other merits and assets. European humanism and the respective human rights declarations have made this perception a foundation stone of the pillars on which our society is shaped. Constitutions, judicial systems, civic and constitutional rights etc. are built on this.

An altogether central notion embodied in western culture is that no person can be regarded purely as an end for anything other than themselves. Working from this philosophy, it can be claimed that biotechnology oversteps a crucial frontier the moment you move from patent rights on genetic material in plants and animals to patent rights on genetic material (genetic information processes) in human beings. For in that same instant, man is largely rendered an end or a tool for other interests, e.g. commercial interests. This can also be referred to as *commodification* of man and our perception of man—not necessarily because genetic material is anything special, anything peculiarly problematic to patent, but because any form of commercialization of human tissue and cell processes potentially has this consequence; commercialization ineluctably changes the understanding of the object commercialized:

> *… patents themselves do not commodify in a narrow sense, they "raise the issue" in the way that they contribute to a change in the terms of the discourse and thus a change in the way we value the patented subject matter.* [85]

As a result of patenting, genes become something that can be traded in and bargained over, because they become a means of achieving financial gain and are thus made the object of a financial consideration. In this sense, patenting may be felt to contribute to a commodified view of mankind based on the consideration

85 Mark J. Hanson.1997. *Religious Voices in Biotechnology: The Case of Gene Patenting.* Hastings Center Report, Vol. 27, no. 6, Suppl., p. 11.

that the more human parts are subject to economic logic, the greater must be the commodification, all other things being equal. Furthermore, however, it can be asserted that the very ability to patent can in some contexts have an adverse effect on forms of human interaction and intercourse. By way of example, it has been suggested that people who make their genes available for research with a commercial bent must have some financial reward. This, of course, would have some bearing on the self-knowledge of the person involved and on the contact with researchers, just as it could have a bearing on the perception of the individual's right of disposition over the body.

The commodification argument is a difficult one to dismiss, but on the other hand the amount of weight to attach to it is debatable. Some will think that accepting gene patents has far-reaching consequences, partly because it affects linguistic usage and our perception of the genes in many contexts, just as it can presumably alter forms of social interaction, e.g. in health contexts. Moreover, it can be claimed that patenting genetic material from either the human being or living nature in a broad sense will invariably lead to a reduced sense of human self-knowledge, in which the genetic is attributed greater weight than hitherto.

One example is the large number of gene tests already available on the private market today, in many cases linked to the spread of patents. In principle, of course, it is an individual person's free choice whether or not to undergo such a test. But as the testing market grows (and marketing possibly becomes more aggressive) social pressure to be tested can very easily arise—for instance, from biological relatives, from employers for job interview purposes or from insurance companies. Some critics fear[86] that such a development can lead to a kind of *geneticization* of our perception of mankind, in which the person, to a much greater degree than previously, is perceived in the light of his or her gene pool. The risk is further compounded by the prospect of sophisticated biotech companies being able within a foreseeable number of years to offer any customer whatsoever a complete survey of his or her entire individual genome. It can be claimed that the problem of geneticizing our view of mankind will be there regardless of whether or not

86 Thus the molecular biologist Regine Kollek in an interview with DR (Danish State Radio and Television) in a programme called Agenda on P1 on 30.11.2003. Regine Kollek is professor of biomedical technology assessment at the University of Hamburg and vice-chair of Germany's Council of Ethics.

patenting genetic material is feasible. But there can scarcely be any doubt that the possibility of patenting intensifies the problem.

Others will think that patenting does not have that many consequences because the effects are rather limited and localized, making it impossible to detect any more general change in our view of humanity on that account. If the latter is true, there may be no reason to be sceptical about patenting genetic material, let alone attempt to restrict patenting possibilities on those grounds.

Another reading of the argument about dignity is that man's genetic material is particularly crucial to his uniqueness. What makes a human being is determined by its genes to a far greater degree than, say, any single organ like the liver or the spleen, or the brain for that matter. The genes generally have to be treated with special respect, therefore, ruling out any form of patenting. In a report from 1993, The Danish Council of Ethics' most pivotal argument against patenting genetic material was exactly of this nature:

> *It is, as it were, the whole of the human genome, its special genetic content, the special control processes and the siting of the genes in relation to one another as well as their mutual interaction via the gene products which is relevant and which differs from that of other species. ... Suppose for the sake of argument that parts of the genome that are carriers of feelings, language and suchlike were to be patented; one might say that the peculiarly human aspect—the thing to which human worth attaches—had been subject to commodification.* [87]

The argument outlined could be criticized by stating that the presence of specific genetic material is never the only, nor possibly even the most essential, condition for developing the qualities that are specifically human and hence merit special respect (see the critique of genetic reductionism under pt. c) on identity). It is not the genes as such which are the essential, significant component of the characteristics that give mankind his special status and value. Whether the nature of mankind is to be a free moral agent, to have been created in the image of God or something entirely different, therefore, it is not man's genes one should be guided

87 The Danish Council of Ethics. 1993. Pp. 33 and 34.

by in order to gain insight into man's nature. Instead, it is the concrete linguistic expressions, the individual person's convictions and faith, the emotions felt by the person, the decisions taken etc., depending on what it is felt makes up the specifically human. But the best way of expressing one's respect for these characteristics is not to refrain from patenting genes. Rather, it is by creating the right conditions for all human beings to be able to develop their potential to realize the specifically human, for example by providing everyone with the best possible conditions for growing up and acquiring an education etc.

c) Gene patents are a violation of man's identity

The idea behind this line of thinking can be illustrated with statements by Nobel prize winner Walter Gilbert*: "The total human sequence is the grail of human genetics … the ultimate answer to the commandment, "Know Thyself"!" "Three billion bases of sequence can be put on a single compact disc (CD), and one will be able to pull a CD out of one's pocket and say "Here is a human being; it's me!""* [88]

The view, therefore, is that the individual's total genetic material determines his or her identity. For that very reason alone, the genes must be ascribed special importance. But this allocation of importance is further supported—according to a number of observers—by the rhetoric frequently surrounding any talk of genes. Thus, Dorothy Nelkin and M. Susan Lindee maintain that:

> *The gene has become a way to talk about the boundaries of personhood, the nature of immortality, and the sacred meaning of life in ways that parallel theological narratives. Just as the Christian soul has provided an archetypal concept through which to understand the persona and the continuity of the self, so DNA appears in popular culture as a soul-like entity, a holy and immortal relic, a forbidden territory.* [89]

Together, these views of man's genetic material entail a kind of genetic essentialism, in which the gene set represents the unique features of being both an

88 Walter Gilbert. 1992..A Vision of the Grail. In D.J. Kevies & L. Hood (eds.) *The Code of Codes*. Harvard University Press, , p. 96 (quoted here from Nils Holtug. 1995.)

89 Nelkin, Dorothy & M. Susan Lindee. 1995. *The DNA Mystique: The Gene as a Cultural Icon*. New York, p. 41. Quoted here from Mark J. Hanson. 1997. P. 4.

individual and a person. For this reason, patenting genetic material is unacceptable, since it confers a right of disposal over that which constitutes the innermost core of man's existence.

It is obvious that the line of thought described includes a potent element of (genetic) reductionism—mankind is reduced to what is prescribed in its gene stock. The claims of genetic reductionism are allegedly flawed, however, because the individual's characteristics and personality attributes are not laid down by the genes alone. To an equally great extent they are laid down by a number of other factors which, interpreted very broadly, can be described as environmental influences or perhaps as chance. For example, from the outset it is quite vital for the individual's development that it receive the right nourishment and the right stimuli from the world around. The individual's personal characteristics are also laid down largely by events in the surrounding world that take place independently of the individual's own qualities and potential, such as the individual moving and starting a new school or becoming disabled as a result of a traffic accident.

Further on in life, too, the individual's identity will be characterized by a whole series of conditions and factors with no direct link to the genetic equipment. For instance, the meaningful relations established with others—parents, children, boyfriends/girlfriends and friends; or the roles assumed and the skills acquired—did the individual train as a cabinet-maker or did (s)he become a university professor?

So it is difficult to justify why exactly human *genes* must be treated with such special respect. They are just one of many factors of significance to the individual's development. It may even be difficult to know whether they are of the most essential importance.

Whether the genes are of great significance to the development of the individual or not, however, genetic essentialism is especially problematic for other reasons. For if genetic information makes up the innermost core of the individual's identity, surely there is no particular reason to have respect for the identity or to ascribe any special dignity to the individual. The whole thing, after all, can be measured and drawn and burned onto a CD.

d) Patenting is a violation of the creation

The fourth and final argument against patenting human genetic material is based on the religious notion of creation. According to this, man was created by God in His image and ordained by God to manage the creation respectfully and in keeping with His purpose. According to many debaters, this precludes any patenting of genetic material taken from human beings:

> *Human beings are pre-owned. We belong to the sovereign Creator… Yet, the patenting of human genetic material attempts to wrest ownership from God and commodifies human biological materials and, potentially, human beings themselves. Admittedly, a single human gene or a cell line is not a human being; but a human gene or cell line is undeniably human and warrants different treatment than all nonhuman genes or cell lines. The image of God pervades human life in all of its parts. Furthermore, the right to own one part of a human being is ceteris paribus the right to own all the parts of a human being. This right must not be transferred from the Creator to the creature.* [90]

Others will undoubtedly maintain that since the creation is different to and more than the genes, gene patents cannot be regarded as a violation of the creation.[91] In the final analysis, part of this theological debate derives from more profound disputes between different religious persuasions and faith communities—and of course, they cannot be commented on here. But it is presumably no coincidence that religious communities in the USA have been far more active in their criticism of human gene patents than, despite everything, has been the case here in more secularized Western Europe. Thus, Richard D. Land, quoted above, was the *prime mover* (amongst others) in the Joint Appeal against Human and Animal Patenting, which religious leaders representing more than 80 different communities across the USA (including Roman-Catholic, Jewish, Protestant, Islam, Hindu and Buddhist) circulated on 18 May 1995. In the words of the appeal:

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90 Land, Richard D. & C. Benne Mitchell. 1996. Patenting Life: No. *First Things*, 63, May, pp. 20-22; quoted here from Mark J. Hanson. 1997. P. 8.

91 See e.g. Ted Peters. 1997. *Playing God? Genetic Determinism and Human Freedom.* New York. Ted Peters is professor of systematic theology at the Lutheran Theological Seminary at Berkeley.

> *We believe that human beings and animals were created by God, not by human beings, and that as God's creatures they cannot be patented as human inventions.* [92]

For the sake of good order it should be noted that the appeal is perfectly aware that patent applications and patent awards do not cover original DNA (or mRNA) from human beings and animals, only synthetic copies (cDNA). The argument is that since the copy represents processes already found in nature, a patent can never be awarded.[93]

It may be objected that the religious argument addresses only broad patents, because only this type of patent covers concrete human material (this objection, incidentally, can also be used in connection with the arguments on identity and dignity above). The argument does not seem to exclude narrow application-based patents, therefore.

A completely different view of the violation of creation and man's nature is that all human knowledge and all scientific discoveries have invariably generated more questions than answers. The power of human knowledge (and history) to surpass itself has never led to a final realization, nor is there anything to suggest that that is about to happen. Nature (and history), you might say, are constantly evading a final clause in a constant withdrawal from the most recent advances made by knowledge. Human knowledge is like an island amid uncharted seas. The island of knowledge grows. So too does the island's contact with the unknown.

Both nature and human existence, which cannot then be determined as unspoilt nature, rest on a fundamental and preceptive indeterminability. That has always been known, at any rate since the Greeks, and modern society—despite plentiful attempts—has not been able to change that fact. Philosophically, it leads to metaphysics; religiously, to God. To take metaphysics or religion seriously is to develop an eye for the ever indeterminable remainder.

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92 http://www.counterbalance.net/genetics/hugo-body.html

93 Known in the USA as the *Douglas principle*, after Judge Douglas, who in the Supreme Court ruling on "Funk Brothers Seed Co. v. Kalo Inoculant Co." (1948) wrote, inter alia: "Patents cannot be issued for the discovery of natural phenomena … [Such] are merely manifestations of the laws of nature, freely available to all human beings and cannot be reserved exclusively for anyone."

The philosophy of the indeterminability of nature and human existence *can* lead to a basic cheerfulness in relation to genetics as such and hence also the patenting of genes. Patenting is becoming a question of common sense, reasonability and the balanced use of genetic knowledge more than one of man's craving for power, violation of nature's integrity etc. In other words, there is no question of letting things take their course, but the patenting of genes does not stand out as an exclusive problem.

8. STEM CELLS—KNOWLEDGE AND EXPECTATIONS

Stem cell research is a new field that has also been surrounded with great expectations in recent years. For some time now it has been possible to use adult stem cells for therapeutic purposes, particularly in connection with bone marrow transplantation. But recent years have seen a rapid growth in researchers' knowledge of stem cells, altering previous notions of what the body's cells are capable of. Many findings indicate that cells can be reprogrammed to a greater extent and in more ways than was previously known, and a way has even been devised of isolating human stem cells from fertilized eggs, the so-called embryonic stem cells, and cultivating these in a tissue culture.

But although progress has been great, we are still a long way off understanding or being able to control the processes that cause cells to specialize. So there is still a long way to go before, say, a part of an arm or a kidney can be engineered from stem cells. Amongst other things, we still lack a great deal of knowledge about the role of the genes, signal pathways and factors that promote or prevent cell development.[94]

As mentioned, there are high expectations of the potential for using stem cells to treat disease, even though hands-on results are few and far between. Consequently, stem cells have also become a goal for patenting, and the patent offices in Europe, and particularly in the USA, have begun granting patents on human stem cells.

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94 Sainsbury of Turville, Lord. 2002. *Opportunities and Challenges - Research and Health*. Speech from the conference: Stem cells: prospects for research and therapy. London, 11 September 2002. See: http://www.dti.gov.uk/ministers/speeches/sainsbury110902.html#top

What are stem cells and what can they be used for?

Cells are the basic unit of any biological system and thus the common basis for all life: microorganisms, plants, animals and human beings. Each cell in an organism contains the complete set of that organism's genes.

Two types of cells exist; *gametes or germ cells* (egg and sperm cells) and *somatic cells*. Among the somatic cells there are many different cell types, each one individual in size and shape. The size and shape of cells are related to the functions they have in the body. Higher organisms consist of many different more or less specialized cells, all of which have developed from a single fertilized egg cell through cell division. But in the developed organism, too, there are collections of stem cells—that is, non-specialized cells that can divide into more specialized cells. These stem cells play a part in the body's normal development processes and the repair of damaged tissue. They do so by virtue of their ability to divide and develop into cells which are either identical to themselves or to other types of cells in the body.

Owing to these characteristics, the scientific community has held out hope in recent decades that stem cells will be able to be used to treat a number of different diseases, with tissue-degradation damage forming part of the progress of the disease.

There are different types of stem cells

Embryonic stem cells

The stem cells thought to have the greatest potential for developing into all of the body's cell types are the embryonic stem cells found in the early phases of the fertilized eggs, the embryo. In an embryo up to about six days old, all the cells can develop into all cell types during the development of the fetus, including fetal membranes, placenta etc. and are therefore what is known as *totipotent*.

On about the sixth day the germinal disc is formed, which turns into the actual fetus. The cells from this are also stem cells and can turn into all tissue types in the actual fetus, but not into the tissue around the fetus, i.e. fetal membranes etc. These stem cells are said to be *pluripotent*. Such stem cells can be cultured and can possibly be used in treating disease. That is to say that the embryonic stem cell lines we are now capable of culturing outside of the body are no longer totipotent and are therefore no longer capable of becoming a fetus if inserted into a woman's womb.

For much of the research that has been undertaken with embryonic stem cells, stem cell lines from animal embryos have been used and, as mentioned, there are very great similarities between different mammals. In 1998, however, embryonic stem cells from human fertilized eggs were successfully harvested and cultured.[95] Here use is made of fertilized eggs that are left over from in vitro fertilization, but research is also being done into creating animal embryos using the cloning technique called nuclear transfer.

Embryos left over from in vitro fertilization:
In 2003 Denmark permitted embryonic stem cell lines to be developed from fertilized eggs produced as a result of in vitro fertilization of childless couples. More eggs may be fertilized for this therapy than prove necessary during the actual infertility treatment. The couple can choose to donate these eggs to stem cell research.

Embryos created through nuclear transfer:
When cloning by means of nuclear transfer, a nucleus is taken out of the cell of an individual and transferred to an egg cell from which the nucleus has been removed (an enucleated oocyte). The cell nucleus is then "reprogrammed" so that it begins to function as if it were the nucleus of a fertilized egg. That is to say that the new cell begins dividing and developing an embryo which, if placed in a womb, could become an individual virtually identical to the individual who donated the cell nucleus. Dolly the sheep was created in this way. The intention of stem cell research is not to create new individuals but only embryos that can be used to develop embryonic stem cells.[96] In February 2004 a team of South Korean researchers succeeded in creating human embryonic stem cells by means of nuclear transfer. The method would be banned in Denmark, however, where embryos may not be manufactured for research purposes only.

Adult stem cells

Researchers can isolate adult stem cells, for example from blood and bone marrow.

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95 Danish Ministry of Science. 2002. *Fremtidens bioteknologier – muligheder og risici.* ["Future Biotechnologies—Possibilites and Risks"].

96 See a more detailed description of the techniques in: The Danish Council of Ethics. 2000. *Cloning—Statement from The Danish Council of Ethics.*
http://etisk.inforce.dk/graphics/03_udgivelser/engelske_publikationer/kloning_/INDEX.HTM

These cells are more specialized than the embryonic stem cells but can still become several different cell types—they are *multipotent*. Recent research further shows that these stem cells have the potential to become more types of cell than originally assumed—possibly even all the body's cells. Multipotent stem cells also exist as:

Stem cells from umbilical cord blood:
The cord blood of neonates contains a large quantity of stem cells highly reminiscent of the stem cells found in bone marrow—i.e. multipotent stem cells. It is still unclear how great the potential for stem cells from cord blood is.

Fetal pluripotent stem cells:
Stem cells can be isolated from the human genital tissue of aborted fetuses that are 5-8 weeks old. These cells are pluripotent.

Fetal multipotent stem cells:
From aborted fetuses the so-called adult stem cells can also be extracted; fetal tissue is generally richer in these cells than adult tissue.

Somatic cells reprogrammed without the use of nuclear transfer:
In the longer term it is seen as an objective to be able to reprogramme cells from the adult body into entirely original stem cells, i.e. equivalent to totipotent embryonic stem cells. This would then be done without the use of nuclear transfer, i.e. without first creating an embryo.

Stem cells can be used to treat disease

At the present point in time, stem cells can be removed from people or animals and cultured in laboratories. Work is in progress to enable development of the cells to be controlled and to get them to develop into particular specialized cell types. In the process, the researchers hope to refine the targeted ability to develop spare cells and tissue for use in treating diseases where specific types of cell are degraded or destroyed. Work is underway to enable "healthy" stem cells or tissue culture to be introduced from stem cells outside the body to replace sick or dead tissue, or to enable the remaining cells and tissue to survive. One hope is to devise new forms of treatment for Parkinson's and Alzheimer's as well as diabetes.[97]

97 Danish Ministry of Science. 2002.

In the even longer term it may be possible to culture whole organs in this way.[98] This would provide an alternative to harvesting fully-developed cells or organs from living or dead donors, with all the involved problems of: organ shortages, compatibility, voluntariness, organ trading and so on.

One of the points of using stem cells is to develop spare tissue or repair tissue. But stem cells are also expected to be serviceable in other contexts, for example conveying healthy genes into the body as part of gene therapy and as models for testing newly developed drugs.[99]

Relations between genes and stem cells, particularly in a patent context

Whereas genes can be produced synthetically and consist of a biochemical (dead) material, stem cells are alive and too complex to be manufactured synthetically. So there is a more direct connection with the person from whom the stem cell has been taken.

It may therefore be felt that stem cells are more "specifically human" than the genes. If a number of embryonic stem cells are lying together in a petri dish, it is possible, for instance, to measure electronically that they are communicating with one another. If the cells are allowed to lie in the dish undisturbed, they can begin to specialize and develop certain types of tissue, for example heart muscle tissue, capable of contracting rhythmically.

Patents on stem cells

As in the field of genes, a practice has gradually arisen of the patent offices awarding patents on stem cells from human beings. Patents on adult stem cells have been routinely granted in both the USA and Europe in recent years, without causing any particular sensation.[100] An in-depth survey conducted in autumn 2001 showed that at that point 727 stem cell patents and 134 embryonic stem cell patents had been issued in the USA and Europe.[101] The patents cover the entire

98 See a more detailed description of the technique in: The Danish Council of Ethics. 2000. http://etisk.inforce.dk/graphics/03_udgivelser/engelske_publikationer/kloning_/INDEX.HTM

99 European Group on Ethics in Science and New Technologies. 2002. *Study on the patenting of inventions related to human stem cell research.* Luxembourg: Office for Official Publications of the European Communities. (See: Study on the patenting of inventions related to human stem cells <http://Europe.eu.int/comm/european_group_ethics/docs/stud-vanoverw.pdf>)

100 European Group on Ethics in Science and New Technologies. 2002.

101 Ibid, p. 23

gamut of human stem cell research. Thus patents have been awarded on pluripotent embryonic stem cells, pluripotent fetal stem cells, multipotent adult stem cells and multipotent fetal stem cells. Both product and process patents have been awarded, so broad patents too. [102]

In the USA both process and product patents are still being awarded on all forms of human stem cells, whereas the EPO has been reluctant to award patents on human embryonic stem cells since 1999.[103] This is due, as mentioned in Chapter 2, to the commotion that ensued after the so-called Edinburgh patent, which was awarded in 1999.

The EPO interpreted the Opposition Division's ruling against this patent to mean that patents on human embryonic stem cells cannot currently be awarded in Europe, as the Directive fails to take an explicit stand on whether embryonic stem cells can be patented. In Denmark, too, current practice is that human embryonic stem cells have been barred from patenting because stem cells are seen as being ethically commensurate with embryos. By contrast, stem cells isolated from adults are not excepted from patenting.[104]

102 Ibid, p. 34
103 Ibid, p. 36
104 Danish Patent and Trademark Office. 2003. *Redegørelse om etiske aspekter i patentpraksis som følge af gennemførelsen af direktivet om beskyttelse af bioteknologiske opfindelser.* Pp. 10-11.

9. ETHICAL DELIBERATIONS ON STEM CELL PATENTING

This section sets out the special issues associated with patenting stem cells. Many of the problems connected with patenting genes are also issues in patenting stem cells. This applies, for instance, to the question of whether stem cells should be regarded as common property, whether patents constitute a violation of man's identity and dignity, and what types of patents are best for promoting the development of new knowledge and new therapeutic options. Those questions will not be taken up in this section.

The following four problems concerning patents, all of which relate specifically to patenting stem cells, are discussed below:

- Embryonic stem cell patents are made possible by research on embryos, and these cannot be divested of ethical status.
- Stem cells can be regarded as living human tissue that should not be commercialized.
- Stem cells contain one individual's unique and total genome.
- There may be great therapeutic potential linked to stem cell research.

Patenting and research in stem cells

There has been—and continues to be—great debate on the ethics of using embryonic stem cells for research purposes. The Danish Council of Ethics has twice taken a position on whether this type of research constitutes an unacceptable violation of the embryo on the grounds of its ethical status. One point of view might be that the embryo has such great ethical status that there can be no question of using it for research, because such an application is disrespectful. Treating the embryo with respect demonstrates that it is, in some sense, a human being with ethical status and a right to be protected. That applies whether or not the embryo has the possibility of developing further into a person.

A different point of view might be, conversely, that the embryo should not be attributed the same ethical status in connection with research as a more developed fetus or a born person, even though it must still be treated with greater respect than other tissue. This has been the working basis for the majority of Council members both times the Council has formalized its views on the problem, the majority having found that regard for the embryo can be weighed against consideration for the seriously ill who may possibly be able to benefit from the treatments whose development is being researched. From this point of view, therefore, it should be permitted to use embryonic stem cells from fertilized eggs left over from infertility treatment for research into therapies for severe disorders, on certain conditions.[105] This has also been authorized in Denmark, having been passed by Danish parliament on 27 May 2003, thereby amending the Act on Assisted Reproduction to permit experiments with fertilized eggs and stem cells from the same, where their purpose is to obtain new knowledge that might enhance the scope for treating disease in humans.

The European countries display great differences in their attitude towards whether it should be permitted to research into embryonic stem cells. Hence, in Denmark, Belgium, Finland, Greece, the Netherlands, Great Britain and Sweden, such research is permitted, whereas France, Ireland, Spain, Austria and Germany have a ban, and Luxembourg and Portugal have no specific rules on this.[106] In Italy research is not possible, after a highly restrictive law on assisted reproduction was recently enacted. The various national outlooks are partly reflected in the countries' adoption of the EU's sixth framework programme for research, which for several years now has been blocked by discussions as to whether the EU can subsidize research in embryonic stem cells.

If embryonic stem cell research cannot be accepted because it involves a violation of the embryo, nor can the patenting of embryonic stem cells normally be accepted either. The reason for this is presumably twofold.

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105 See The Danish Council of Ethics. 2002. *Etisk begrundet stillingtagen til Genteknologiudvalgets spørgsmål om reguleringen af forskning i og anvendelse af stamceller* ["An ethically reasoned position on the Danish Committee on Gene Technology's question about regulating stem cell research and applications"], http://www.etiskraad.dk/sw454.asp; and Council of Ethics. 2000. *http://etisk.inforce.dk/graphics/03_udgivelser/engelske_publikationer/kloning_/INDEX.HTM*

106 European Commission. 2003. *Survey on opinions from National Ethics Committees or similar bodies, public debate and national legislation in relation to human embryonic stem cell research and use.* Volume I in EU Member States. Ed. Line Matthiessen-Guyader.

Firstly, patents are obtained on the basis of research because patents can only be granted for embryonic stem cells that are isolated and form part of an invention with some industrial application. And since the possibility of patenting creates a financial incentive to conduct this research, the existence of patents will therefore help to maintain or boost research on embryos. It is possible to imagine a kind of pressure—financial, for example—arising to donate embryos to research. Taken to its logical conclusion, this might result in more "surplus embryos" being developed than would otherwise have materialized without the possibility of patenting.[107]

Secondly, it may be thought that embryonic stem cell patents entail more extreme violation of the embryo than that which takes place in the course of development work and research that cannot be patented. By being patented, the cells from the embryo are thus made into a commodity and objectified, because it is subjected to commercial logic.

One may wonder whether it is fair to regard stem cell *commercialization* as a more extensive form of commodification than that associated with stem cell *research*, for in both instances the embryo is used as a means to ends other than oneself. Some will respond that the commercialization of patenting is more problematic because the embryo here may be used as a means of economic gain to a greater extent than for research purposes.

It is not certain, however, that a prohibition of stem cell patenting would eliminate an ethically problematic form of commercialization. Stem cells, of course, can perfectly well be involved on the commercial market without patents; so if it is only commercialization that poses a problem, preventing patenting may not help. Instead, research in embryonic stem cells should be refrained from or should take place entirely independently of any economic interests.

To summarize, it can be said that there is not necessarily anything inconsistent about acquiescing to embryonic stem cell research and at the same time opposing

107 A foreign research group used 286 embryos to create and describe 17 new embryonic stem cell lines (compare The New England Journal of Medicine, 25 March; 350 (13): 1353-1356). In a Danish context, a research group has developed three cell lines from 345 donated eggs (personal communication with Moustapha Kassem of Odense University Hospital). The quality of the eggs is largely a determinant of the number of cell lines it is feasible to produce.

patenting of these cells. A more far-reaching conclusion to the discussion might be that the research is acceptable, but patenting stem cells and stem cell lines is unacceptable.

It is worth mentioning that new possibilities for developing embryos have come about because adult stem cells can be "embryonified" by means of nuclear transfer. Since these embryonic cells may assume the same potential as a normal embryo for developing into a person, it would be obvious to opine that they have the same ethical status as any other embryo.[108] Based on this line of thought, therefore, stem cells and stem cell lines developed from such cells should be treated in accordance with the same guidelines as those that apply to embryos that have come about as a result of fertilization.

Stem cells viewed as living human tissue

The point of the above argument is that patenting embryonic stem cells is incompatible with the respect due to the progenitor, i.e. the embryo from which the cells originate. So it is not the stem cells as such that must be taken into consideration; that consideration originates from the embryo's ethical status. A similar argument can be advanced in connection with adult stem cells, i.e. non-embryonic cells that are living and have been taken or developed from cells from a fully developed person. In this case once again, it is not the individual cells as such that must be taken into consideration; the consideration originates from the respect for the progenitor: in this case, the person from whom the cells originate.

The argument exists in several versions, but only two will be mentioned here. In the first version, patenting is regarded as conferring a form of ownership that is incompatible with the person's dignity:

> *… human beings should always be treated as having intrinsic value or worth and should not be treated as have only extrinsic value or worth. But to treat something as property, according to this argument, is to treat it as having only extrinsic value or worth. We value pieces of property not for their own sake but for their*

108 For a more detailed report on this view, see The Danish Council of Ethics. 2003. *The beginning of human life and the moral status of the embryo.* (http://www.etiskraad.dk/graphics/03_udgivelser/engelske_publikationer/moral_embryo/engelsk_embryo.pdf)

> *commercial value. Thus, it is immoral to treat human beings as property. Furthermore, since human cells, tissues and organs are parts of human beings, treating human body parts as property is equivalent to treating human beings as property. Hence, it is immoral to treat human body parts as property.* [109]

The argument can be supplemented, if need be, by the observation that stem cell patents involve living human cells, which can carry on developing and, entirely unaided, form complex tissue structures. Patents on genetic material in general, on the other hand, can be thought of as something pertaining to ”inert” chemical compounds, which can even be said to be synthetic copies of the actual gene. This difference may explain the fact that some people find patenting stem cells more problematic than patenting human genetic material in general. It may perhaps be said that such stem cells, being alive and able to divide and develop into other human cells, will symbolize the human being to a greater extent than the original stem cell. These potentials form one of the basic prerequisites of human lifestyle.

One argument against the above line of thought might be that the commercialization of the human body may well be justified in some individual case, partly because it never involves complete commercialization of either the individual or mankind as such. If the individual, for instance, has to give consent for the use of cells originating from him or her, it may be thought that commercializing stem cells will lead to an extremely limited ”disparagement” of the human being. In that case the individual person is appreciated for what makes human beings people, and their ability to govern themselves and make independent decisions will not be challenged. If the person has to give consent for the use of the stem cells, it may therefore be felt that the problem of commercialization carries less weight.

In the second version of the commercialization argument, it is formulated slightly differently. This version recognizes that commercialization may not be so problematic in each individual case, but that the long-term consequences of

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109 David B. Resnik. 2002. The Commercialization of Human Stem Cells: Ethical and Policy Issues. *Health Care Analysis* **10:** 127-154, p. 139-140. It should be noted that bans on the commercialization of human parts can be found in many places. Article 21 of the Council of Europe’s Bioethics Convention, for example, says: ”The human body and its parts shall not, as such, give rise to financial gain”.

permitting stem cells and other human tissue to be commercialized are difficult to take in and may potentially be particularly negative. To start with, for example, such commercialization can undermine more altruistic forms of donation known today, blood and organ donation, for instance. And in the slightly longer term, it may contribute to a change in our collective view of mankind, so that the special dignity or value of the individual is not apportioned the same weight as it is now in the way we engineer our social practices.

It is hard to decide whether the slippery slope argument concerning commercialization is a good argument against patenting stem cells, owing to the fact that the argument involves evaluating the way any commercialization will affect our perception of mankind in the future.

There are also other problems associated with the commercialization argument, in both the first and second versions. Firstly, as in the preceding section on embryonic stem cells, one may ask whether the argument is directed at all forms of commercialization or just patenting. Here again, one reading might be that patenting subsumes a more extensive form of commodification because it assigns a greater form of ownership. Seen from this point of view, it is quite possible to be against patenting without necessarily being an opponent of all forms of commercialization. A different and more ambitious reading might be that the argument addresses all forms of commercialization. Seen from this point of view, it would only be acceptable to carry out research and development work in connection with stem cells if this were to take place on a non-commercial level.

Another problem with the commercialization argument is whether it can also be used in connection with modified stem cells. Since the cells are modified, they are no longer human cells in the true sense. On the contrary, they are processed human cells. For some people this will certainly make a difference, because the cells no longer represent a particular person. Others will ascribe less significance to the fact, partly because the bulk of the genes in the cell still originate from a person and partly because it is still a living cell that can function in the human organism.

One last problem regarding the commercialization of stem cells should be mentioned here, i.e. that in principle it is no longer just embryos and embryonic

stem cells that have the potential to develop into a complete and finished person. As already mentioned, there is much to indicate that the new cloning techniques will make it possible to repurpose adult stem cells into embryonic stem cells with the aid of nuclear transfer. But if the potential to become a fully developed person is the rationale behind embryos and embryonic stem cells having a special right to be treated with respect, one may well ask whether any adult stem cell ought not to be shown the same consideration? For these cells, after all, may possibly have the potential to turn into a fully developed person, although this presupposes the use of various techniques. But the fact that techniques need to be used in order to realize that potential is not, perhaps, a clinching argument that the cells need not be treated with respect. A fetus that has been placed in a petri dish cannot become a person, either, without a variety of techniques being taken into service. Yet no one would dream of divesting the embryo of its ethical status on those grounds.

As has been shown, the new technologies can risk undermining the distinction between those human cells that have the potential to become a person and those that do not. It can be difficult to say anything about the conclusions to be drawn from this. For some, however, the problem issue outlined will certainly bring home the fact that the question of patenting stem cells is not coterminous with the question of when the patented cells are embryonic. The essential thing, instead, is whether human tissue ought to be able to be commercialized, since it has special status at any rate.

Stem cells contain one individual's total and unique genome

Stem cells represent the person from whom the cell has been extracted and contain that person's total and unique genome. On that account, the individual can be said to be more entitled to dispose over the cells without taking the interests of the general public into account. In connection with stem cells, therefore, it may be possible to demand even more categorically that each individual consent to the specific use of his or her stem cells, including any patenting that may arise from research on the cell. So there is an argument in favour of stem cell patents requiring more rigorous demands in terms of consent from the person the cell originates from, including consent for patenting. The fact that such rigorous consent is necessary is underscored by the absurdity of a person having to learn that his or her cells had formed the basis of a patent without having had any influence in the matter.

Patenting stem cells and treating disease

The above arguments seem to affirm that accepting patents on stem cells is more problematic than accepting patents on genes. However, you might also think it would be *less* problematic to patent stem cells than genes. That may be because it will involve a far greater inventive step (cf. previously) than simply determining a gene and its function, with many scientists predicting that it will be a very difficult and highly specific task to align stem cells and marshal them into developing in one particular direction, to become liver cells, for example, which can then be used as "repair tissue". For that reason, then, it may appear more acceptable to allow provision for patenting such stem cells.

Also, it is only fair to mention that the arguments in favour of accepting patents on stem cells might, for some other reason, possibly be more powerful than the corresponding arguments for accepting patents on genetic material, i.e. if the scope for using stem cells to treat disease was considerably greater than the equivalent scope for using genetic material in general for treatment. In some researchers' opinion, the stem cells can be expected to offer huge therapeutic potential and in the longer term an ability to be incorporated in the fight against a raft of major diseases, such as Parkinsonism and Alzheimer's. If that turns out to be right, the situation might perhaps be described thus: both the arguments *for* accepting stem cell patents and those *against* accepting stem cell patents are weightier than the corresponding arguments pro/contra the patenting of other genetic material.

Stem cells' potential for therapeutic applications can also be used as an argument against patenting, however. Thus, in a debate article from a conference, it states that:

> *We and others consider that it would be contrary to the concept of ordre publique to give anyone a broad monopoly over what may prove to be an entirely new way of treating a wide range of otherwise incurable human diseases. It would not be in the public good for any one organization to have control over the use of the basic techniques to provide replacement cells.* [110]

110 *Human Stem Cell Patents would be Unethical,* A discussion document of the Working Group on Bioethics, Church and Society Commission, Conference of European Churches, p. 3. (www.srtp.org.uk/stempat1.htm)

This approach can scarcely be used as a general argument against stem cell patents, but it does advocate the avoidance of broad patents, particularly during this period, when it is still unsure what the individual patent may ultimately be used for. If broad patents are awarded owing to lack of knowledge, these may also end up obstructing further developments in stem cell research.

10. MEMBERS' RECOMMENDATIONS ON GENE PATENTS

In this section The Danish Council of Ethics presents its views on patenting human genes. The first section contains members' overall ethical evaluation of the patent system, setting out both collective and individual points of view. This is followed in the subsequent section by some specific recommendations as to how the rules for granting and applying patents should be.

Ethical evaluation of the patent system

As made clear in the section "What *is* being patented?", it is open to discussion whether it makes any difference in ethical terms whether patents on human genes include the actual genes or just synthetic copies. This relates to the fact that the information content of the genes is what makes obtaining a patent interesting, and that information also concerns the original genes, of course. So even if the patentholder is not given the right of disposition over any humans' actual genes, the way it works in practice is that most methods of handling the specific gene are covered by any existing patent on the "synthetic copy". For example, broad patents on particular genes can prevent people other than the patentholder carrying out diagnostic examinations on the gene under consideration. This demonstrates that the distinction between the original genes and the synthetic copies is hardly of great importance for an ethical evaluation of the patent system. It is also questionable whether it makes sense to operate with this distinction when the information content linked to, respectively, the concrete genes and the synthetic copies may be completely identical.

In the stance taken by the legal profession on concrete patent applications and the patent system in general, the distinction between actual genes and synthetic copies seems to play a crucial role. Many consider the fact that these are copies to constitute essential grounds for allowing gene patents to be issued. Many,

however, think that such a view fails to take into account that an essential aspect of the genes is their information content, being common to mankind for the most part and at the same time containing a small part that is unique to each and every individual. This information content, as mentioned, is identical in naturally occurring genes and synthetic copies, and that can give rise to ethical problems.

In the light of these reflections on the general information content of the genes, members of the Council of Ethics wish to submit that the provisions of the Danish Patents Act, Section 1a, subs. 1 and 2, appear to be full of incongruities. Section 1a, subs. 1 shows that the human body, including a sequence or partial sequence of a gene, cannot constitute patentable inventions. Accordingly, Section 1a, subs. 2 establishes that it is perfectly possible to patent a part of the human body that is isolated from it or in some other way produced by means of a technical process. In the members' view, it cannot be said with any reasonableness that a sequence or partial sequence of a gene ceases to be part of the human body merely because an identical copy of the sequence is isolated from or produced outside of the human body.

In keeping with the view just voiced, the members further wish to draw attention to the fact that the distinction between discoveries and inventions, which is vital to the Danish Patents Act, may currently appear unclear to a general observer of the patent system. There is no such lack of clarity in the history of the patent legislation, however. Before the biotech industries came along, it was an occurrence of extreme rarity, and generally regarded as unacceptable, to award a patent on phenomena and processes occurring in nature.[111] That kind of thing was an "invention of nature". Only methods for extracting and isolating natural phenomena and natural processes could be patented. For the emergent and expanding biotech industry, however, this was an unacceptable barrier. And it has since transpired that the legislation on this point has now been tailored to the wishes of industry—there are many examples in the gene field of the original distinction in patent law between inventions and discoveries having been

111 In the USA this is sometimes referred to as the Douglas Principle, after Judge Douglas, who in the Supreme Court ruling "Funk Brothers Seed Co. v. Kalo Inoculant Co." (1948) wrote, amongst other things: "Patents cannot be issued for the discovery of the phenomena of nature … [Such] are mere manifestations of the laws of nature, freely available to all human beings, and cannot be made the exclusive preserve of anyone." In 1873, however, Louis Pasteur obtained a patent on isolated yeast in France and the USA, and patents have been issued on vitamin B12 and on the hormone adrenalin.

obliterated. Within genetics, many so-called inventions are in a sense mere ascertainments of particular causalities or information processes in the cell—in other words, discoveries, properly speaking. This applies to both broad product patents and narrow use patents. The problem is certainly smaller, however, if the patent relates to a DNA sequence that has been decisively modified and is now no longer a discovery of something already occurring in nature.

Although many patent lawyers claim that the distinction between discoveries and inventions is still manageable, members of The Danish Council of Ethics find current practice in the field dubious. It might be seen as a violation of common morality that private interests can secure copyright or property rights over phenomena or processes that were 'discovered' by nature long before mankind was technologically capable of identifying (i.e. discovering) them.

The Danish Council of Ethics wishes to submit that every possible safeguard should be taken to ensure that new knowledge and new therapeutic options in the field of medicine benefit all individuals (compare point 5, also, in the recommendations on rules for patents below). In part, the Council would justify this view with the argument that man's genetic material should be regarded as common property, for which reason everyone should have a share in that knowledge and the therapeutic options developed on the basis of the material (compare the chapter containing ethical deliberations on patents). Furthermore, access to health services is seminal, as it can be crucial to a person's survival and health. The members do not consider, therefore, that health services should be allocated purely on the basis of financial wherewithal.

The rationale behind the view that genetic material should be regarded as common property is that it involves general information usually contained in the genetic material of many different individuals. Human, animal and plant genes, it might be said, are just one of several expressions of the wisdom of "the Creation", and that wisdom should be freely available to all human beings for the purpose of ethically defensible applications. Amongst other things, therefore, it should not be possible to take out broad patents on genes.

The Danish Council of Ethics feels that there are many problems attached to the patenting of human genetic material. One such opinion is that patents allow the living world as such to be monopolized and financially controlled, thereby

reducing man as a person and failing to accord nature the respect it duly deserves. Moreover, scope for patenting leads to commercialization, which can have undesirable consequences. For example, research environments can become more closed, and companies can attempt to exploit their patents to optimize earnings in inauspicious ways.

Nonetheless, the members take the view that these problems must be weighed up against the possible advantages of patenting genes from human beings, particularly the development of new knowledge and new therapeutic options in the medical field. In the judgement of the members, however, doubts may be voiced as to whether human gene patents are actually necessary to promote developments in medicine. This cannot be corroborated by, for example, the historical experiences of economies that have not acknowledged patents,[112] so it is open to discussion whether patenting human genes is even acceptable, appropriate and/or necessary.

The Danish Council of Ethics thinks that although human genetic material enjoys different status to traditional materials, the differences involved are not so significant per se as to preclude the material from being patented. The special status of genes as carriers of data about the individual as well as all living beings does mean, however, that patenting needs to be done with greater consideration for both the individual and the common good than when patenting traditional materials.

Recommendations on the rules for patenting

The members of The Danish Council of Ethics agree on a number of recommendations concerning regulation of the patent field *on condition that* it will also be possible to obtain human gene patents in future. The recommendations are presented point by point below, though to some extent they should be thought of as a whole. Given the Council of Ethics' mandate, these recommendations-in-principle take a relatively basic form. [113]

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112 See inter alia Eric Schiff. 1971. *Industrialization without National Patents: The Netherlands, 1869-1919, Switzerland 1850-1907*. Princeton University Press. The book demonstrates how companies like Philips, Unilever, Nestlé, Ciba/Sandoz/Novartis (et al.) built up their market position by clever exploitation of the absence of patent rights.

113 The text therefore makes reference to other reports concerning a more detailed description of recommendations that adopt a stance on concrete practice in the field.

Some of the recommendations concur with pre-existing legislation, but the Council's judgement is that there may be a need to emphasize stringent enforcement of these requirements in the particular patent award under review. Amongst other things, this is a consequence of biotechnology apparently evolving more quickly than the patent system. Developments quickly turn certain processes into sheer routine, so that the patent offices are constantly having to adjust the patentability criteria. Unfortunately, there is some inertia in the system, so that by the time the patent offices and the courts of appeal have gathered sufficient experience to adapt their requirements to a particular technology, that technology has often become outdated and has been overtaken by developments. [114]

1) All members of the Council of Ethics recommend that it **should not be possible to award broad gene patents** where the patentholder is given sole rights over several possible applications of a particular gene.[115] This is because broad patents can have an outright inhibiting effect on the development of new treatments and diagnoses utilizing the characteristics of the relevant gene sequence other than the one on which the broad patent was based.

The members further consider broad patents to be reminiscent of actual property rights over a gene, and consider that in principle no one should have the possibility of owning genes.

The Council is aware that, as a result of international criticism[116] and technological developments, the award of broad gene patents may possibly even become a rarity in future anyway.

2) The Council of Ethics finds that only narrow gene patents should be issued, which is to say that a precise, detailed description must be available of the uses to which the patent will be put. The patent must only include that part of the genetic

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114 See, for example, Gold, Richard. 2002. *Biotechnology patents: strategies for meeting economic and ethical concerns*. In Nature Genetics, vol. 30, April. http://www.utoronto.ca/cip/Gold.pdf

115 In patent legislation, consideration should possibly be given to distinguishing between patents on the physical DNA molecule and the information contained in this molecule. Patents should not include the actual DNA sequence, so that a patentholder, for instance, can prevent a laboratory from reproducing a person's DNA with a view to examining the person's risk of disease. See e.g. Gold, Richard. 2002. http://www.utoronto.ca/cip/Gold.pdf

116 Inter alia from the Nuffield Council, 2002.

information required for the industrial application stated in the patent application.

The benefit which the intended use is expected to provide must also be specified, since patents can only be issued on new inventions of substantial general beneficial value and inventive step.

3) All members of The Danish Council of Ethics recommend that **more emphasis be given to granting compulsory licences** than is currently the case, where such awards are a matter for the courts. A compulsory licence can be considered if a company enforces its patent in a way that unreasonably prevents others from developing new diagnoses and therapies. For example, it should not be possible for an enterprise to have a monopoly on carrying out a particular diagnostic test, as such a monopoly can prevent others from developing adequate know-how in the field. And of course, it should not be at all possible, purely for market strategy reasons, to prevent others from marketing a treatment or diagnostic test that utilizes a characteristic of a gene sequence patented in a different context. This is in keeping with the fact that a compulsory licence can currently be granted "When required by important public interests"[117]. The Council is informed of the fact that the possibility of a compulsory licence is rarely exploited, but would urge this route to be taken more often in cases where enforcement of a patent is at odds with the interests of the general public in the way described.

The Council further wishes to draw attention to the provisions of the Norwegian Patents Act, which also provides for the issue of a compulsory licence if "patent rights are being exploited in a way that may materially restrict competition".[118] Following on from this, the Norwegian Competition Authority has also been authorized to issue compulsory licences in Norway.[119] Such a provision seems appropriate in terms of preventing a patentholder from exploiting his or her monopolistic position to prevent others from developing new treatments.

4) The Danish Council of Ethics recommends that, wherever possible, the rules on patents be formulated so as **not to prevent research,** research being defined as

117 Danish Patents Act, Section 47.

118 Section 47 of Act No. 127 of 19.12.2003: Norwegian Act to amend the Patents Act and Plant Breeding Act (implementation of EU Patent Directive in Norwegian law etc.).

119 Ibid, Section 50.

activities not being commercially exploited at the time concerned. On the other hand, its objective may certainly be to develop treatments that can eventually be exploited commercially. Exactly when research can be said to be being exploited commercially is difficult to determine in many cases, but a description should be formulated detailing when this is deemed to be the case.

The Danish Council of Ethics suggests that profound measures are taken to neutralize the restrictions on research that may be implied by the patent system in the field of biotechnology. They refer to the shorter distance between basic research and application effective in this field, and to the order issued to university researchers to patent their research results as soon as they are considered capable of assuming commercial value. Although this provision is not found in the Danish Patents Act, but in *The Act on Inventions at Public Research Institutions,* The Danish Council of Ethics would call for this obligation to be done away with and would urge the introduction of endeavours to keep basic research exempt from patenting.

5) The Danish Council of Ethics finds that **the monopoly comprised by gene patents should not be exploitable to the detriment of the common good**. For one thing, a large part of the products are manufactured on the basis of information common to mankind, and for another it may be a life-saver for the patient. The high prices of patented biotechnological treatments may thus pose a strain on the individual patient and a great problem for any publicly financed health system.

Despite the practical difficulties involved, therefore, society should work to find models to counteract unreasonably high monopolistic prices in this field. Possibly, this should not be controlled exclusively through the Danish Patents Act, but members feel that society, for example, should take on board whether a new, patented product has sufficient public utility to warrant receiving public subsidization or whether such subsidies should possibly be retrenched. Technology assessment of new, patented medicines should be undertaken to establish whether they are substantially better than existing products which are cheaper (for example, because the patent on them has expired).

6) The members of The Danish Council of Ethics recommend that people whose genes are used in the research that leads to applications for patents should **give their written consent for the research activities**. That consent, however, must not

only include the actual research activity; it must also include acquiescence to the research results being used in development work that may possibly result in patents. If the aim of the research is known beforehand, this should be made clear in the consent documents used.

7) The members of The Danish Council of Ethics take the view that the present rules on human gene patents are too opaque and complex. This creates both a democratic and a practical problem. The democratic problem is brought about by the fact that, realistically speaking, common citizens have no way of acquainting themselves with the significance and implications of the rules. For that same reason, citizens have no way to form their own opinion on gene patents or the reasons officially given for their legitimacy. The practical problem arises from both researchers and companies having difficulties predicting how the rules will be interpreted in a particular case. This not only engenders uncertainty, which may deter some people from taking initiatives in the field, but will inevitably lead to a number of lawsuits incurring extra expense and, whatever happens, favour the big companies, who have the resources to take on such lawsuits.

The members are sensitive to the difficulty of finding a complete solution to this problem, but in the Council's opinion one possibility may be to **set up independent bodies at national and European level that undertake an ethical and legal evaluation of specific patent applications relating to both genes and stem cells.** Such bodies would be mandated to enforce the provisions of the Patent Convention stipulating that inventions whose exploitation is at variance with ordre public or morality cannot be patented. That is to say, to prevent patents being administered in a way that is inconsistent with the values of the relevant country or overarching ethical or political norms.

In addition, such bodies could ensure that uniform and clear-cut practice is established with regard to the administration of patents awarded.

Again, the Council's members wish to refer to the recent implementation of the Patent Directive in Norwegian legislation, Section 15a of which provides that the Norwegian Patent Office shall confer with an ethical committee if in doubt as to an invention's compatibility with Norwegian provisions on ordre public and morality. The committee shall consist of five members with recognized credentials within philosophy (ethics), medicine, biotechnology and animal welfare, and shall rank

alongside the scientific ethical committees that already have experience with the ethical evaluation of concrete research applications.

8) Some members of The Danish Council of Ethics (Klavs Birkholm, Ole Hartling, Nikolaj Henningsen, John Steen Johansen, Anette Roepstorff Nissen, Ragnhild Riis, Katrine Sidenius, Ellen Thuesen and Peter Øhrstrøm) feel that gene patenting reflects our growing urge to control all our dealings with nature and that by allowing natural resources to be taken over by multinational companies, we are subjecting them to a commercial logic that does not respect nature. This is the case with gene patenting, but presumably only very few of those who consider gene patenting to be a violation of nature harbour any illusion that it would be possible to call for the repeal of tens of thousands of patents already issued. The politicians and policy-makers in relevant organizations like the WTO, EU or UN are urged to work on a moratorium on gene patents, for five to ten years, say. This would be done with a view to creating the time and space for a global debate on whether mankind has "lost the plot" in its craving to master nature and reduce it, technologically, to a resource for our own self-expression.

11. MEMBERS' RECOMMENDATIONS ON STEM CELL PATENTS

The members of The Danish Council of Ethics take the view that many of the problems that manifest themselves with regard to the patenting of human genes are also present in the context of stem cell patents. A number of the deliberations presented in the previous chapter containing members' recommendations on gene patents are therefore readily transferable to the question of stem cell patents. Inter alia, this applies to the consideration that it can be difficult for a general observer to distinguish between inventions and discoveries, and that new knowledge and new therapeutic options in the field of medicine should benefit everyone, wherever possible. That applies equally to the concrete recommendations on patenting rules, including emphasis on the possibility of issuing compulsory licences (pt. 3), patents not preventing research (pt. 4), making commercially unreasonable exploitation of an awarded patent impossible (pt. 5), countering the democratic problem of opaque legislation and setting up ethics committees to assess DNA patents specifically (pt. 6).

As is clear from the preceding chapter 9., however, it may be thought that there are more far-reaching ethical problems associated with patenting stem cells than with patenting human genes. In the following, then, members' positions on the actual possibility of obtaining patents on stem cells will first be presented here, omitting any arguments not specifically related to stem cells. Instead, reference is made to the recommendations under ethical evaluation of the patent system. Following this an account will be given of the specific recommendations on the rules governing the patenting of stem cells as endorsed by the members.

Ethical evaluation of stem cell patents

The members of The Danish Council of Ethics consider all forms of stem cell patenting problematic. The members base this view first and foremost on the

argument that patenting stem cells involves commercializing and commodifying the human organism, which cannot be combined with respect for the dignity of mankind.[120] Such commercialization turns stem cells into an object that can be used as a mere channel for brokering financial agreements. The members are aware that stem cells can become commodities, even where the possibility of patenting does not exist. Nevertheless, the members do feel that patents open the way for a form of ownership that renders commercialization more problematic.[121]

Some members find it particularly unacceptable to patent embryonic stem cells and stem cell lines as well as embryonic stem cells formed by nuclear transfer. Some of these members think that embryos should be viewed as human life with ethical status equal to that of born human beings.

The Danish Council of Ethics would point out that although it may be acceptable to do research into embryonic stem cells if this is done with a view to developing new knowledge and new courses of action that may be of benefit in preventing and treating disease, patenting these inventions need not necessarily be acceptable. The reasons adduced for this are that acceptance of patenting leads to more extensive commodification of the embryo than acceptance of the research as such.

Some members (Klavs Birkholm, Ole Hartling, Anne Marie Morris, Anette Roepstorff Nissen and Katrine Sidenius) find it easier to accept patents on stem cells than on genes. They take their stand based on one or both of the following arguments: It can be reasoned that in the case of stem cells the involved information originates purely from and represents a single individual. It can also be argued that most stem cell patent cases will involve greater inventive step than is the case with gene patents, since the stem cells are developed specifically for use in treating disease. These members also accept the patenting of embryonic stem cells which can be used to treat severe disease, as the cells involved are undifferentiated and modified.

Others members (Kamma Bertelsen, Asger Dirksen, Thomas G. Jensen, John Steen Johansen, Morten Kvist and Ellen Thuesen) accept patenting of stem cells. Some of

120 For a more detailed report on this view, reference is made to the Danish Council of Ethics. 2003 *(http://www.etiskraad.dk/graphics/03_udgivelser/engelske_publikationer/moral_embryo/engelsk_embryo.pdf)*

121 Compare the deliberations in the preceding section on ethics and stem cells as well as the deliberations on ownership in Chapter 6.

them, however, do feel that patenting stem cells is more problematic in principle than patenting human genes, as stem cells are alive.

Still other members (Mette Hartlev, Nikolaj Henningsen, Lisbet Due Madsen, Ragnhild Riis and Peter Øhrstrøm) agree that patenting stem cells is more problematic than patenting genes, but would not dismiss every form of patenting of stem cell applications. These members would, however, reject all forms of *embryonic* stem cell patenting.

One member (Kathrine Lilleør) considers narrow patents on stem cells acceptable but rejects all forms of *embryonic* stem cell patenting.

Special recommendations on the rules for stem cell patents

On the proviso that society elects to permit patenting of both embryonic and adult stem cells, the Council's members recommend the following supplement to the recommendations on patenting human genes.

1) The Council does **not think it should be possible to issue broad patents**, giving the patentholder sole rights to more applications of a particular stem cell than are covered by the invention described. Use or process patents should only be awarded on stem cells where a precise, detailed description is available of that covered by the patent. In keeping with this, The Danish Council of Ethics recommends the following in respect of patenting stem cells:

Isolated stem cells which have in no way been **modified** should not be patentable. Apart from the patent application having to describe precisely what **function** the patent covers, it should also outline the **benefits** of the intended use, since patents are only to be awarded on inventions with **substantial utility value and inventive step**.

There is reason to be cautious in issuing broad patents, but in the context of stem cells there may be special reason to display reticence, since we are still in the early days of stem cell research. It may therefore be difficult to gauge what a particular patent may entail in the longer term. Perhaps, then, consideration should be given to imposing tougher requirements on specifications detailing the intended use of stem cell patents, as compared with human gene patents. Alternatively, in this field, thought might be given to whether it would simply be **easier to revoke a**

patent already awarded. Today, it is both costly and time-consuming to have a patent invalidated through the legal system, which may delay or entirely prevent the invalidation of even an overtly unreasonable patent.

2) Under pt. 6 of the general recommendations on the rules for gene patents, the Council of Ethics stated that **written consent must be given for research** that may result in patents. The members feel that there are even weightier arguments for this recommendation in relation to stem cells. This is because stem cells can be said to represent the very individual they originate from, since the cell houses the individual's total and unique genome. Where research involves embryonic stem cells, written consent, in the members' view, should be available from the couple who have parented the embryo.

GLOSSARY

Base pair (bp) – The four bases A (adenine), T (thymine), C (cytosine) and G (guanine) are the building blocks of DNA. The bases are located opposite one another in pairs, and depending on the sequence the bases are positioned in, they form a specific code. To sequence a gene thus means to determine the sequence of bases.

Central dogma – The central dogma refers to the view that there is a simple linear correlation between DNA, RNA and protein, where information always proceeds from DNA to RNA and thence to protein – never the other way around.

Chromosome – A structure in the cell nucleus consisting of DNA bound to protein. Every species has a specific number of chromosomes. Man has 46 chromosomes or 23 chromosome pairs – 44 autosomes and 2 sex chromosomes.

Compulsory licence – A licence that restricts the patentholder's sole right to exploit the patent. By means of a compulsory licence, a court can grant another party permission to exploit the invention.

DNA – Deoxyribonucleic acid. The genetic material.

Embryo – The stage of an organism's development directly following fertilization and zygote formation.

Embryonic stem cells – Stem cells taken from the embryo.

Enzyme – Proteins with catalytic activity that regulate biochemical processes in organisms.

EPC – The European Patent Convention.

EPO – The European Patent Office.

Gene – Functional part of the hereditary material. 'Function' means that the gene codes for (results in or originates) RNA and or protein.

Gene therapy – Treatment based on the transfer of DNA or RNA.

Genetic determinism – A view that there is a simple correlation between a gene and its function, that is to say that a given gene always codes for a given protein.

Genome – Term denoting the total genetic material in an individual, organism or species. The human genome thus refers to mankind's total DNA.
Germ cells – Egg or sperm cells (gametes). Contains only half the number of chromosomes found in the rest of the body's cells – 23 in man.
Intron – Most protein-coding genes contain areas, introns, that are transcribed into RNA and then cut out before the transcription into protein.
Inventive step – The invention must differ substantially from that already known (the art) and the quality must be superior to that which is perceived as trivial within the field.
Monogenic hereditary disorder – Disorder due solely to a fault in a single gene.
Mutation – Process that alters the hereditary material in an organism. In some cases it will affect a single gene; in others, it will affect part of a chromosome. Most mutations have no functional significance. The damage can be due to e.g. environmental factors like radiation and may be the cause of severe disabilities or diseases like cancer.
Neurotransmitter – Molecule or chemical compound responsible for actuating the transfer of signals between nerve cells.
Nuclear transfer ("Dolly Technique") – Transfer of a cell nucleus from an individual to an egg cell from which the nucleus has been removed. The new, combined cell can then be made to behave as if the egg were fertilized. Under the right conditions – as with Dolly – nuclear-transplanted eggs from animals have been made to develop into cloned animals. But the early embryo can also be used for extracting embryonic stem cells.
Nucleic acid – The building blocks of DNA. SEE also under base pair.
Patent – Patent protection confers on the inventor a time-limited right of a maximum of 20 years to prohibit others from manufacturing, using or selling the patented invention within the geographical area where the patent has effect. Exploitation of the patent by the patentholder, however, can be hindered by other laws prohibiting the activity in question.
Prenatal diagnosis – Diagnosis of embryos and fetuses.
Process patent – Grants a patent of the process or production of the substance or gene.
Product patent – Grants a patent on the actual substance and is therefore very far-reaching because it prevents all conceivable potential applications.
Protein – Group of organic compounds found in all living organisms and entirely central to the chemical life processes. The proteins are formed on the basis of the DNA code.

RNA – Ribonucleic acid. RNA is formed from the structure of DNA and amongst other things acts as a linkage when information in the genetic code forms the basis for protein formation.

Sequencing – Mapping the sequence of bases on a given DNA sequence.

Stem cell – Most cells are specialized to perform the functions characteristic of the tissue type they are in. Stem cells, on the other hand, are cells that have not yet specialized, but have the capacity to divide and develop into a wide range of specialized cells. They therefore have a central function in the body's natural development processes and in repairing damaged tissue.

Use patent – Grants a patent for a specific industrial use or application of a substance or gene.

WIPO - The World Intellectual Property Organization.

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Klavs Birkholm, journalist
Professor Asger Dirksen, MD, consultant
Professor Thomas G. Jensen, MD
Mette Hartlev, PhD (Law), associate professor
Dr Ole Hartling (Chairman), MD, consultant
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