
# The True Cost of Gene Patents

The Economic and Social Consequences of Patenting Genes and Living Organisms

A Greenpeace Documentation

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Patents

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## Introduction and Summary

The patenting of living organisms continues to be extremely controversial in Europe. Whereas the German Association of Research-Based Pharmaceutical Manufacturers (Verband forschender Arzneimittelhersteller, VFA) accords the highest priority to implementing EU Biotech Patents Directive 98/44, large sections of the general public and politicians continue to reject the patenting of genes and living organisms. The reasons that speak against the patenting of living organisms can be grouped as follows:

- Ethical reasons: Living organisms should not be placed on the same level as human technical inventions.
- Scientific reasons: A gene sequence is not a conventional chemical substance, but more like an information code with many different functions. The holder of a patent that describes *one* commercial use should not receive a monopoly on *all* possible functions.
- Social and economic reasons: Patents may make access to genetic resources more difficult and in some cases block that access altogether. Research and development are hindered, and in many cases the resulting costs are disproportionately high. These problems are of particular relevance to health systems and medical research, but their consequences can also be seen in agriculture and plant breeding.

This documentation mainly deals with the third aspect. The costs of gene patenting are demonstrated by means of actual cases. The documentation covers three areas: The patenting of microorganisms, human genes and seeds.[1]

The present documentation is one in a series of various topical publications that all demand substantial restriction of or a complete end to the patenting of genes and living organisms. The corresponding demands were recently made in a study by the French Council of Economic Analysis. Here too, the authors come to the conclusion that no further patents should be granted on genes. [2]

Meanwhile, more and more scientists are taking action against too far-reaching patents. In a joint letter of July 2003 to the World Intellectual Property Organisation (WIPO) in Geneva, human geneticists (including Nobel prize winner John Sulston), computer specialists and economists (among them Joseph Stiglitz, Nobel prize winner for economics) state their opinion that free access to knowledge may make a more effective contribution to research

[1] Greenpeace already set out in detail the negative economic consequences of the patenting of animals used for experiments, in particular the "OncoMouse", in a previous study (Onco-Mouse. Eine Recherche zur medizinischen und kommerziellen Bedeutung der Harvard-Krebsmäuse von Benno Vogel, Greenpeace Study, 2001).

[2] Intellectual Property, Claude Henry, Michel Trommetter and Laurence Tubiana, 1. 07 2003, www.cae.gouv.fr

and development than exclusive copyrights. They call on the WIPO to hold a conference on this subject in 2004. [3]

In the face of all experts' reports, the German government represents the view that the EU Biotech Patents Directive should be implemented exactly as it stands. According to a government draft of October 2003, the German government does not expect any additional costs to arise from the patenting of genes and living organisms. This documentation shows how far removed from reality that position is.

The thesis stipulated in several quarters, namely that the biotech branch in general will benefit from patents on genes and living organisms, is obviously equally erroneous. Although some start-up companies or big pharma corporations may reap short-term profit from the discovery and patenting of genes, this documentation shows that no generally beneficial effect of gene patents can be deduced from these instances.

It would also be wrong to dismiss the problems documented here by pointing to the general effects of patents or the law on competition. The harmful consequences documented here really are the specific and systemic consequences of gene patents, as can be seen from the following facts:

**The real innovation that is to be promoted by the patent is usually not on the level of gene sequencing**, but is downstream from this. As with the manufacture of pharmaceuticals, this is where the major capital expenditure is made. The granting of patents on genes entails unjustified and unnecessary costs for the downstream areas, and in some cases innovation is blocked altogether.

**Genes are not ordinary chemical substances.** Human and other genes must be presumed to have very different functions. As became known with the deciphering of the human genome, several hundred thousand biological proteins are governed by only about 30,000 genes. Genes must therefore be considered far more as encoded information than as patentable chemical substances. Present patenting practice, where the statement of just one commercial application of a gene is enough to claim a monopoly on all uses of that gene, leads to gross overcompensation and considerable impediments to research.

Through the biological ability of living organisms to reproduce and be crossed, and the extension of gene patents to all biological material in which protected properties exist, **the effect of patents may accumulate in individual forms of life (such as seeds, for example),** like toxins in the food chain: Just one grain of rice may already be covered by up to 70 patents. For medium-sized breeders and farmers, this represents an impenetrable minefield of monopoly rights and royalty claims.

[3] Nature 424, 118 (10 July 2003); "Drive for patent-free innovation gathers pace", Declan Butler

The negative consequences of gene patents described in this documentation can be summarized as follows:

- considerable increase in the burden on patients and health insurance funds
- protracted litigation that may also severely impede research and development
- a blockade of research and development by whole bundles of patents to be observed for individual technical innovations
- hindrance to medical institutions, particularly in the field of diagnosis
- obstruction of current proteomics research by hastily granted and too extensive gene patents
- impediment of research and development, particularly in the field of infectious diseases
- unacceptable dependence of patients with hereditary diseases on individual companies
- danger to world food supply owing to the exorbitant cost and monopolization of seeds
- new systematic dependence of medium-sized plant breeders
- considerable financial risks and direct dependence of farmers
- stepping up of international concentration process in the seed industry
- new dependence of food industry on agrochemistry

Only a fraction of these problems can be theoretically reduced by tightening up the law on competition or granting compulsory licences. Greenpeace threfore demands patent law provisions to counteract this development. These demands are also underpinned by patent law literature. Fears have arisen that the legitimation of patent law in general might suffer from the negative effect of gene patents:

“The above-mentioned aspects of the unrestricted and absolute (chemical) product protection in gene patents show the cumulation of risks entailed by the economic exploitability of exclusive rights. As a result, companies are less willing to invest. If, however, as must be presumed, the unrestricted and absolute (chemical) product protection in gene patents (which also covers every non-recognized function of the gene sequence) has a negative effect on the willingness to invest and thus impedes the will to innovate, patent law loses its last remaining foothold on the legitimation level. The principles of freedom of research and societal restrictions on individual property rights laid down in our constitution preclude the justification of unlimited patent protection at the point where further technological development is obstructed.” [4]

Greenpeace demands the renegotiation of Directive 98/44/EC on the legal protection of biotechnological inventions. Should it be implemented, patents for plants and animals must be restricted to technical processes. Genes can only be included in patents with relevance to individual technical applications. Moreover, the general social and economic consequences of granting patents must be given greater consideration.

[4] Niclas Kunczik, GRUR 2003, No. 10, page 845 ff

# 1. Gene Patents on Pathogens:

## 1.1 Patents on genes of AIDS and hepatitis pathogens (Chiron/ Hofmann-La Roche)

A fierce controversy has raged for years over the rights to gene segments of HIV (AIDS) and hepatitis C pathogens, on the one side between pharmaceutical companies, and on the other between the pharma industry and blood banks. This dispute particularly concerns Hofmann-La Roche and Chiron (USA). The gene sequences are of great economic interest because they are the basis for the examination of blood samples sometimes prescribed by law. After years of argument, the companies finally reached an agreement, but the result was utterly unacceptable to patients and blood donor services. The German Red Cross lodged a complaint with the European Commission over demands for excessive royalties. Greenpeace looked through the examination files of the European Patent Office and was also allowed to study the statement of the blood donor services. This case is a classic example of how ruthlessly patent proprietors and licencees pressurize health systems and disregard the interests of doctors and patients, and of how gene patents may cause problems related to the law on competition. Moreover, the case shows how protracted patent disputes may be. Even ten years after the patent was granted, the health insurance funds and blood donor services had no legal certainty. The dispute concerns two patents: EP 318 216 (HCV) and EP 181 150 (HIV).

Patent EP 318 216 was first granted by the European Patent Office (EPO) in 1993, and covers the genes and proteins of hepatitis C. The patent was hotly contested on an international level, also in Australia and the USA. After lengthy litigation involving several thousand sheets of paper, the EPO considerably reduced the scope of the patent and reissued it in different form in 2001.

Hoffmann-La Roche is one of the users of the patent. Originally, the company challenged the patent on several legal levels and tried to topple it altogether. At the same time, the company brought an action against Chiron to obtain a licence to use the patent. In proceedings before the Higher Regional Court in Düsseldorf, concerning the use of the patent in Germany, Hofmann-La Roche submitted a pleading in Sept. 1999 that sharply criticized the competitive practices of the Chiron company: "the refusal ... to grant a licence for the opposed patent is an abuse of the law for several reasons. An abuse of the law is already constituted by the fact that the opposed patent is misused far beyond its protected scope to oust the defendants as competitors from the market for the immunological testing of blood preparations in general." A co-inventor of the patent reproaches Chiron for "breach of the cooperation agreement, unjustified enrichment, organized money-making through robbery and extortion ... private conspiracy, misappropriation of the inventive ideas of the plaintiff ..."[5] The court rejected the motions by Hofmann-La Roche.

[5] Statement of grounds for appeal by Hofmann-La Roche, to the Higher Regional Court in Düsseldorf, 2nd division for civil matters, received on 21.9.1993

Patent EP 181 150 was also granted by the EPA in 1993, and covers the genes and proteins of the AIDS (HIV) pathogen. It was opposed with equal vehemence and was reissued in slightly modified form in 2003 after lengthy legal proceedings, but the claim to gene sequences of the HIV pathogen continues to be part of the patent.

Again, Hoffmann-La Roche was one of the opponents. In a letter to the European Patent Office dated 24 September 2001, the lawyers refer to the fundamental importance of the patent: "The disputed patent concerns a field of extremely great importance for public health, namely the diagnosis of possible AIDS infections, with enormous economic significance because all blood samples have to be examined for possible AIDS infection. This also affects a wide range of laboratory diagnoses, particularly those pertaining to blood banks."

As a result of the fierce opposition by Hoffmann-La Roche to the Chiron patents, an agreement was finally reached between these two firms. They subsequently took joint action: Hoffmann-La Roche as licensee tried to levy extortionate fees for the examination of blood samples for hepatitis and HIV infections. According to the Red Cross, the cost of the examination of blood samples threatened to go up by 3,000 per cent.

On 8 October 2001, the German Red Cross (DRK) therefore lodged a complaint with the European Commission, Director General for Competition: "The present complaint is directed at the behaviour of the appellees in the sector of blood tests, particularly with regard to HCV (hepatitis C) and HIV (AIDS). ....It [Chiron] charges exorbitant and legally inadmissible royalties in this context. ... The exorbitant royalties and the threat of a market block in the event of non-payment constitute a major risk to the supply of blood test agents."

According to the complaint, Hoffmann-La Roche paid 300 million $ US to Chiron for the use of the patented genes and test processes. In its complaint, the DRK lists in detail how the claims of Chiron and Hoffmann-La Roche push up the costs for legally prescribed blood tests.

The DRK fears that "the costs ... will therefore rise dramatically to the detriment of end consumers or social insurance systems." The consequences are serious – whereas the HIV test cost €0.43 and the HCV test €0.28 per tested donor in 2001, in future the DRK says the prices may be around €9.20 per sample (Page 24 of the DRK complaint). The additional costs for the health system are enormous. The DRK calculates them to be €84 million per year.[6]

Extensive agreements were also signed with Bayer. According to an agreement with Chiron, Bayer offers virtually identical and much less expensive test methods for examining patients.

[6] Volker Macke, 29.8.2003, in: Freitag 36, "Unbezahlbare Blutkonserven"

But the agreement with Chiron prohibits Bayer from offering these tests to blood donor services.[7]

In 2003, the European Commission declared the trading agreements between Chiron and Hoffmann-La Roche to be void, owing to the abuse of a dominant position on the market. Nevertheless the DRK believes that considerable additional costs must still be feared[8]. The negotiations had still not been concluded by January 2004[9].

Obviously, extensive basic patents are the central problem in this case. Although the appeal procedure is now concluded, patent EP 181150 still lays claims to the gene sequences themselves. The problem of this dispute is made clear by the Hoffmann La-Roche statement: "We don't think it's right for someone to decode genomes, perform no research and then be able to make outrageous claims“, a spokesperson of the company is quoted as saying in the German weekly newspaper *Die Zeit* 36/2001.

Based on the patents, Chiron was able for ten years (from 1993, the first granting of the patents until 2003, decision of the EU Commission) to obstruct competitors, oust some of them from the market, and levy extortionate royalties. Even after the decision by the EU Commission, it is still not clear how high the costs for the blood tests will finally be, but according to experts they are sure to rise.

Since the genes of pathogens may also be patented according to the EU Biotech Patents Directive, the risk of a similar monopoly also exists with regard to other major pathogens. In fact, patent applications have long been filed for the pathogens of tuberculosis, meningitis and malaria, and some have already been approved.

## 1.2 USA: Dispute over the rights to microbes

In 1997, the dispute between TIGR (The Institute for Genomic Research) and HGS (Human Genome Sciences) over the patenting of the genome of a common pathogen (Haemophilus influenzae) came to the public eye. HGS wanted to delay publishing the genome data until the patent specification had been submitted. TIGR, by contrast, was in favour of publishing the analyzed genes immediately so as not to impede drug development[10]. The genomes of viruses, bacteria and other pathogens are in generel high up on the shopping list of patent strategists. The American company Incyte, which also played an important role in the mapping of the human genome, already had the blueprints of at least 40 different pathogens in its database back in 1999.
The Staphylococcus aureus bacterium caused an international stir in 1999. This pathogen that causes wound infections and pneumonia, among other diseases, was the first pathogen

[7] Statement of grounds for appeal by Hofmann-La Roche, to the Higher Regional Court of Düsseldorf, 2nd division on civil matters, received on 21.9.1993
[8] Volker Macke, 29.8.2003, in "Freitag“ 36, "Unbezahlbare Blutkonserven“
[9] Elke Brüser, 14.1.2004, Süddeutsche Zeitung, “Das Geschäft mit den Bluttests”
[10] Science, Vol. 275, 7.2. 1997, pages 777f

to become resistant to all antibiotics. A woman in Hong Kong therefore died in 1999 as a result of a staphylocuccus infection. It is feared that this resistant pathogen might spread all over the world. Modern medicine would then be completely powerless to fight a disease that might cost more human lives within a short time than the immunodeficiency syndrome AIDS.

In an article in the Los Angeles Times in February 1999[11], the genome companies are also made responsible for this development. Their secrecy and patenting strategy delays the development of new medication by four to five years, according to experts' estimations. Although the entire genetic makeup of the bacteria is known, the data have not been made accessible to the public. "Without this information, we don't have the insights we need. It's like keeping the map of the city of Washington secret." (John La Montagne, Deputy Director of the US National Institute of Allergy and Infectious Diseases, NIAID). Incyte is one of the companies that have systematically collected information on the genome of the pathogen, and sold it for millions to companies like Eli Lilly, Abott Laboratories and Johnson and Johnson. These then file successful patent applications with the help of the genes. Free research has no access to the databases. The NIAID invests millions of dollars in research projects to investigate information that has long been available in private databases.

The rights to the genome of the SARS pathogen have long been embattled in the USA. Meanwhile, the numerous patent applications filed for the genome may, according to an article in the Washington Post, lead to a situation where research is systematically impeded: " 'If people think they are going to have liability down the road for patent infringement, they may be reticent to invest' in SARS tests, said Michael J. Shuster, an intellectual property lawyer with Fenwick & West LLP in San Francisco. 'There could be a chilling effect.'" Representatives of the US health authorities are particularly concerned that access to the genome of the virus might be blocked, and that is might not be possible to adequately control the epidemic: "In a briefing with reporters last week, CDC Director Julie L. Gerberding said that U.S. public health officials fear they could be blocked from researching the virus if it is patented by foreigners. 'From our standpoint, it's a protective measure to make sure that the access to the virus remains open,' she said."[12]

### 1.3 Malaria, barriers due to overpatenting:

During a comprehensive investigation of the consequences of patent law for developing countries, a high-profile commission in the U.K. discovered that research was hindered by overpatenting. A specific protein (MSP-1) of the malaria pathogen, which may be especially important for developing vaccines, is affected by up to 39 different patent families (different types of patents). Most of these patents are technically irrelevant for current research, but since they cover gene sequences and proteins, and therefore all modern technical

[11] Biotech Battlefield: Profits vs. Public, Sunday Report, 21.2.1999

[12] "Over Patents, Another Outbreak, U.S., Foreign Diagnostic Firms Compete for Rights to Virus Tests", The Washington Post, USA, by Michael Barbaro, http://www.washingtonpost.com/wp-dyn/articles/A57444-2003May14.html, May 15, 2003

applications of these biological materials, they nevertheless affect the research presently being conducted. The Malaria Vaccine Initiative (MVI) now fears that excessive fees and royalty stacking may severely hamper malaria research.[13]

"The Malaria Vaccine Initiative (MVI) has identified a particular protein antigen (MSP-1) which may be crucial to the development of an effective vaccine for malaria. The ownership of patents relating to this protein was investigated, uncovering some surprising findings: The patenting of the DNA sequences for the antigen is very complex. There are up to 39 patent families that are potentially relevant in developing the vaccine from MSP- (...) Faced with such a situation, a commercial research organisation might decide to shift to another area of research."[14]

## 2. Patent on Human Genes

### 2.1 Myriad and patents on breast cancer genes

The U.S. company Myriad Genetics, Inc. owns several international patents on BRCA 1 and BRCA 2. The European Patent Office also granted several comprehensive patents for the breast cancer gene BRCA 1 and 2 to the company based in Salt Lake City, Utah. In the patents on BRCA 1 (EP 0705 903, EP 0705 902), Myriad lays claim to about 80 human gene segments of different lengths. These contain genetic mutations typical of hereditary breast cancer. The patent moreover comprises diagnosis techniques and the rights to the use of the gene for therapy and drug manufacture. These comprehensive claims are based on very slight technical performance by Myriad. Prior to discovery by the company, it was already known on which chromosome and in which chromosome segment the mutations had to be looked for.

Myriad Genetics came under fire because the company consistently imposed its monopoly and made use of its exclusive right. Based on its patents, it claims to be the only company worldwide capable of performing the relevant tests. It prohibits all other laboratories from offering these or similar genetic tests for breast cancer.[15]

After receiving the first patents for the BRCA 1- and BRCA 2-genes in the 1990s, Myriad Genetics successfully prevented almost all U.S. laboratories from offering different tests. Only a handful of American laboratories received a corresponding licence, all others had to stop their tests.[16]

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[13] (Integrating Intellectual Property Rights and Development Policy, CIPR Commission on Intellectual Property Rights, http://www.iprcommission.org)

[14] see 11

[15] Westphal, S.P., New Scientist, Vol. 175, issue 2351 – 13 July 2002, page 29 ff

[16] Cornish, Llewelyn, Adcock, "Intellectual Property Rights (IPRs) and Genetics", A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector, July 2003, ww w.phgu.org.uk

As a direct consequence, the tests for the breast cancer genes became much more expensive. In the USA, a test now costs US$2,700[17]. In other countries too, the royalties demanded by Myriad are twice or three times as high as the costs charged by independent laboratories. The costs are so high that the 'Hereditary Cancer Program' in British Columbia, for instance, suspended its in-house testing in 2001 after receiving a corresponding letter from Myriad Genetics.

The British science journal New Scientist[18] warns against the foreseeable consequences: "With a new generation of patents making the prize more easily attainable, the rewards for pharmaceutical companies may be too tempting - and all the more disastrous for society. It would raise the spectre of, say, a company not just 'owning' one drug for treating Alzheimer's disease but also governing any progress in that field for the 20-year lifetime of its patent. What would governments do then?"

European doctors also oppose this patent because it will directly affect themselves and their patients. Corresponding demands from Myriad have already been announced. According to these, examinations for breast cancer in the U.K. will go up to double the present cost of £750 per patient[19]. In Switzerland, the price is to rise from the present level of about 950 to 4,020 Swiss francs. Clinicians in Germany fear costs may increase fourfold.

Human geneticists from various EU member states, research institutions like Institut Curie and several EU governments have joined in the opposition to the patent. The European Parliament itself has spoken against the patents[20].

It is particularly interesting that representatives of patient groups are also taking a stand against the patent. Carriers of the genes are in danger of depending to a large extent on the commercial intentions of Myriad, the only company able to decide freely on developments in diagnosis and therapy. The organisation Europa Donna, which represents patients with breast cancer, therefore demands a complete ban on the patenting of human genes: "We call upon the European Parliament .... to establish a ban on patents on the human genome." [21]

Since the patent also lays claim to the non-mutant form of the BRCA gene, the patents are of significance for any use of the gene, also in connection with non-hereditary forms of breast cancer. According to the results of clinical research, the BRCA gene also plays an important role in these forms of breast cancer that are not inherited, but acquired in the course of a woman's life, i.e. the majority of cases. (see Venkitaraman, A.R., Cell, Vol 108, 171-182, January 25, 2002).

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[17] some sources state US$ 2,400

[18] see 13

[19] The Guardian, 17.1.2000

[20] European Parliament, resolution on the patenting of BRCA1 and BRCA2, 4.10.2001

[21] Europa Donna – European Breast Cancer Coalition, 19 October, 2001

The UNESCO also warns against the consequences of these patents: "Industry is naturally interested in human genetic data as well. The legal battle between several European institutions, including France's Institut Curie, and the US firm Myriad Genetics shows this. It concerns screening for breast cancer and ovarian cancers both of which are linked to the presence of the BRCA1 gene. The Europeans are challenging Myriad's patents that give it an unofficial monopoly. The Europeans also say that because the firm refuses to grant manufacturing licences, all DNA samples will have to be sent to the Myriad Genetics headquarters in Salt Lake City for processing, providing the company with a unique databank about people at high risk." [22]

In fact, Myriad intends not only to demand royalties for the use of the genetic tests, but also to stop all test methods in Europe, as it does in the USA, and to examine all blood and tissue samples itself in that country. Institut Curie points out that Myriad's BRCA test does not cover newly discovered mutations and may therefore constitute a risk for patients. It is estimated that 36 per cent of all diseases connected to BRCA are affected by this mutation, which is not detected by the Myriad test. There are fears that it may not be possible to use the improved test due to Myriad's patents[23].

The government of Ontario, Canada, has taken legal action to topple the patent. Moreover, the government intends to launch its own test system without paying royalties to Myriad: "In April, Ontario will offer its own test, which uses the same gene in a different process. The province says its test provides results quicker than Myriad's and costs two-thirds less than the approximately $2,300 that Myriad charges for its test. Alberta is also offering its own test." Cancer research facilities in Canada share the government's concern: "Groups that oppose gene patenting, like the Canadian Cancer Society, say that as more genetic therapies come into use, gene-patent owners may stop others from making new, possibly better tests. 'It really puts a chilling effect on research,' says Society president Julie White." [24]

## 2.2 Impediments to diagnostic institutions in the USA

The patents granted to Myriad are no exceptions. The negative effect of patents, particularly in the field of diagnosis, can be empirically proved. Mildred Cho of Stanford University presented her study "Effects of gene patents and licenses on clinical genetic testing" at the OECD Workshop on Genetic Inventions from 24 to 25 January 2002 in Berlin. According to this study, 25 per cent of the interviewed laboratories suspended their test processes because of claims by patent holders, and 53 per cent declined to develop their own improved diagnostic processes because relevant patents had been granted. She concludes:

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[22] Ethical Guidelines Urgently Needed for Collecting, Processing, Using and Storing Human Genetic Data, Source: UNESCO, Press Release No. 2002-93, http://www.unesco.org/bpi/eng/unescopress/2002/02-97e.shtml, DATE: Nov 25, 2002

[23] Balter, M., Science, Vol 292 8. Juni 2001, Seite 1818

[24] "Ownership of genes at stake in potential lawsuit", in: The Christian Science Monitor, USA, by Ken Ernhofer, http://www.csmonitor.com/2003/0227/p07s03-woam.html, Feb 27, 2003

"Laboratory directors in the US believe that patents and licenses have had a negative impact on access, cost, and quality of testing, and on information sharing between researchers."[25]

This statement is confirmed by Merz, J.F. et al, in Nature dated 7.2.2002[26], who also established negative consequences for patients and clinical laboratories. The Nuffield Council on Bioethics[27] harbours grave reservations about gene patenting, particularly in connection with diagnostic procedures.

### 2.3 General problems of gene patenting:

One example of the situations the patenting of genes may lead to was given in SCIENCE in 1997, under the title "HIV Experts vs. Sequencers in Patent Race". The article describes the discovery of the CCR5 receptor, which caused a great stir in the international scientific community because it plays a major role in the penetration of the AIDS virus into the cell. After many scientists had already looked into the CCR5 receptor and its possible therapeutic implications, they found that Human Genome Sciences had already filed a patent application for the corresponding gene sequence in 1995 (WO96/39437). Although the patent specification does not even mention a connection with the HIV infection, Human Genome Sciences also claims the rights to this gene in the framework of AIDS research. Jorge Goldstein, the company's attorney, declares: "Whoever is first to patent a DNA sequence - for any use - can lock up subsequent uses." [28]

A major part of the problem stems from the transfer of patent law from the sphere of chemistry and physics to the living world. In connection with chemistry, so-called product patents can be granted. These cover all properties of the patented substances, independently of whether they are described in the patent specification or not. Only one single commercial application needs to be stated in order to receive exclusive control of the substance and all its properties. This model was transferred to the genetic code. If one commercial application is described, the patent protects all biological functions of the gene inasmuch as they can be commercially exploited.

Now that the human genome has been decoded and it has become evident that genes usually perform several and often very different functions, this type of patent appears completely inappropriate. Genes now appear to be much more like encoded information than like active chemical substances. The genes that govern the laying of eggs in the threadworm may be responsible for Alzheimer's in human beings. Genes that cause breast cancer may also play an important role in diseases of the colon or prostate gland. Moreover, under this kind of patent protection, a company that receives a patent connected with a diagnostic procedure also has the rights to the gene if it is used to develop a much more complex

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[25] htttp://www.oecd.org/EN/document/0,,EN-document-617-1-no-21-24552-617,FF.html
[26] "Diagnostic testing fails the test", Nature, Vol 415, February 2002, S. 577
[27] The ethics of patenting DNA, ISBN 1 904384 02 1, July 2002
[28] Science, Vol 275, 28.2.1997 p. 1263

therapy or medicine. This monopoly makes no sense either in scientific or in economic terms, since it does far more to hamper research and development than to promote it.

The Nuffield Council on Bioethics therefore states quite clearly[29]: "We note, further, that the fact that DNA sequences are essentially just genetic information distinguishes them from other chemical compounds, with regard to the patent system.“

In the modern view, a gene is therefore not a precisely defined unit of DNA, but a set of DNA sequences that may recombine continually in a new way and interact in a complex manner with other gene sequences or their environment. It is still not known exactly how the synthesis of several proteins may be induced by one gene. Initial knowledge exists of some mechanisms that lead to this variety of proteins, but it now appears impossible to transform the dynamic and constantly changing set of gene sequences into a patentable object with a precisely defined structure and function. All that is patented is an intellectual construct that has little to do with reality.

An additional factor is that, unlike with chemical substances, it is rarely possible to circumvent a patent on genetic information by inventing a new chemical substance, particularly because the number of human genes is finite. Once these have been analyzed and patented, the blockade effect is much more extensive than in the case of chemical substances, whose number can be constantly increased by means of variations and experimental modifications.

The negative consequences also become apparent for small companies that not only sequence genes, but also handle scientifically more complex problems such as gene therapy. Thus, an employee of Mologen in Berlin has repeatedly voiced public criticism of gene patenting. The company itself has filed numerous patent applications, but fears dependence via patents on genes that are upstream of gene therapy. "Sequencing, the technology by which a gene can be recognized, 'read', and then patented, has meanwhile become an automated process. Robots, one would think, cannot make inventions, and it should therefore not be possible to patent genes ", says Claas Junghans of Mologen AG[30]. In the newspaper “transcript”, Junghans also expresses grave reservations about too extensive gene patents: “If we are being asked in 30 years, why the development of a drug against AIDS took so long, then patent law should not be the answer.”[31]
Finally, the hasty patenting of human genes really does affect the entire development of drugs and vaccines, which are mainly based on protein technologies. When both are concentrated in one company, as is the case with the large pharma corporations, difficulties can be skimmed over. But as soon as different patent owners are involved and there is a risk of royalty stacking, research and development are considerably impeded. "This could lead to

[29] The ethics of patenting DNA, ISBN 1 904384 02 1, July 2002
[30] quoted acc. to Gen ethischer Informationsdienst, GID No.143
[31] magazine “transkript – biotechnology and the economy, research and politics”, issue September 2000

a situation where there will be a need to obtain multiple licenses in order to complete diagnosis. In addition, where a company acquires a bundle of patent rights over different, yet related, aspects of any given invention the resulting thicket of patents could make further research work difficult as the morass of patents to work around could be perceived to be impenetrable."[32]

## 3. Gene Patents on Plants

Beyond the problem of the patenting of gene segments, patents on living organisms and seeds lead to an extremely critical accumulation of patents. Patent protection extends to all living organisms that are technically modified or into which the patented genes are inserted, or even when only their "normal" molecular properties are analyzed. The patent applies to living organisms inasmuch as these can be put to economic use in the described manner, as well as for all subsequent generations that have the patented properties.

The absurdity of this system becomes particularly apparent when one considers the ability of living organisms to reproduce and to be crossed. Various breeding steps and technical processes may lead to the accumulation of several dozen patents on one single seed. Patents can thus become almost insuperable barriers to plant breeders. Access to genetic resources that also provide the basis for the world's food supply is severely restricted.

For agriculture, the patenting of seeds represents a change of system in several ways. It fundamentally alters the economic framing conditions for plant growers and farmers. Varieties so far freely accessible via other growers are greatly restricted. Farmers may be directly subject to access by the patent proprietors, i.e. the latter can directly influence agricultural practice via licensing agreements.

The possible consequences also depend on the individual case. In the USA, seed patents are not only used to sign licensing agreements with growers, the farmers are also told which pesticides they should use. In the case of the Flavr Savr tomato, the patent proprietors even controlled crop sales.

At the same time, the patenting of seeds has greatly accelerated the worldwide process of concentration on just a few seed-growing companies, i.e. the growers have largely been bought up by agrochemical companies. In many cases, patent holders often own the plant variety rights as well. The result is increasing economic control of agriculture, because choices are limited and no negotiations take place between variety growers and patent owners. This restructuring of the market is also expected to speed up in Europe and Germany owing to the change of system (patent protection of plant varieties).

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[32] Cornish, Llewelyn, Adcock, “Intellectual Property Rights (IPRs) and Genetics”, A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector, July 2003, www.phgu.org.uk

### 3.1 Syngenta's genome bank

According to a recent study in the U.K., access to the rice genome is subject to similar restrictions as those that apply to Celera's data acquired during mapping of the human genome. Syngenta, which analyzed large parts of the rice genome, only allows access to this information under extensive conditions. Thus, the data is only available on Syngenta's home page, not in public databases. Under certain conditions, researchers are granted access to the database, and scientists performing commercial research have to negotiate special access rights. Sir John Sulston, Nobel prize winner for medicine and co-founder of the Human Genome Project, criticizes this practice. In his opinion, the information should be compiled in large databases, be freely accessible and in particular allow comparison between different data records. On top of the growing number of different databases with different access rights, there are the patent claims that may make it impossible for an entire field of research to work in a meaningful manner.[33]

### 3.2 Vitamin A rice

The case of vitamin A rice shows how rice plants in particular have been smothered in patent claims. The Swiss researcher Potrykus, who wanted to genetically modify rice to produce additional vitamin A, found that he had to deal with up to 70 patents held by 32 different owners[34].

### 3.3 Systematic effects of seed patents in the agricultural sector

Over 300 patents have already been granted in Europe that expressly contain plants and seeds. Besides these, there are a large number of further patents that are only worded to cover processes, but which also extend to the cultivation and breeding of useful plants. Companies have long begun to claim plants as their invention even without genetic modification. In the case of patent EP 744 888, all DuPont had to do was analyze the oil content of corn grain in order to receive a monopoly on all maize plants with a specified oil quality. The government of Mexico, among others, objected to the patent. Maize with the described oil quality has been cultivated in Mexico for centuries. Monsanto analyzed the genes of certain soy varieties from China and in 2000 filed a patent application on all plants that naturally carry these genes (WO 0018963).

The inroads made by patent law in the seed sector have been accompanied for several years by an intensive and comprehensive concentration process from which only a few agrochemical multinationals have emerged triumphant: DuPont, Monsanto, Syngenta and Bayer are all companies that originated in the chemical business and now stand right at the

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[33] see 29

[34] Kryder, R., Kowalski, S. & Krattinger, A. (2000) The Intellectual and Technical Property Components of Pro-Vitamin A Rice (Golden Rice): A Preliminary Freedom-to-Operate Review", ISAAA Briefs No.20, International Service for the Acquisition of Agro-biotech Application, New York.

top of the multinational seed corporations. Only these big players can survive in the million-dollar-league of patent litigation. Only they are able to accumulate the required exclusive rights by buying up competitors and also wield sufficient patent rights as a basis for negotiation in their battle with other companies.

These groups generally control access to seeds on a large scale, independently of whether genetic engineering was involved or not, whether the seeds are new varieties or were simply collected years ago. What these companies have collected in their gene banks or propagate in their nurseries is withdrawn from the public and only launched on the market once patented genes have been introduced and the cultivation, propagation and harvesting of the seeds can be controlled via exclusive rights.

In its study "Integrating Intellectual Property Rights and Development Policy", the UK Commission on Intellectual Property Rights recognizes the key role played by patents: "Apart from the problem of incentives for research relevant to poor farmers, there is evidence that patents, and to some extent PVP, have played a part in the major consolidation of the global seed and agricultural input industries. The consolidation appears to be driven by technological change, with an objective of vertical and horizontal integration so that the appropriability of investment in research can be maximized through better control of distribution channels, including those of complementary agricultural inputs (such as herbicides).
Companies acquire patent rights to protect their own investment in research, and to prevent the encroachment of others. But by the same token, other companies' patent rights can impede one's own research. .... And the major multinational agrochemical companies, with their growing control over essential proprietary technologies, also represent a formidable barrier to the entry of innovative start-ups. In the 1980s, the university and public sector accounted for 50% of the total of granted US patents relating to Bt. By 1994, independent biotechnology companies and individuals held 77%, but by 1999 the big six companies (which became five with the merger of the agricultural arms of AstraZeneca and Novartis to form Syngenta) held 67%. Moreover, the growing control of these companies was demonstrated by the fact that 75% of their Bt patents in 1999 had been obtained by the acquisition of smaller biotechnology and seed companies."

The study says this trend can also be observed in developing countries. Monsanto, for instance, meanwhile holds a market share of 60 per cent of the trade in (ordinary) maize seed in Brazil. Only a share of five per cent is left over for Brazilian companies.

The authors come to the following conclusion: "Thus, the speed of concentration in the sector raises serious competition issues. There are considerable dangers to food security if the technologies are overpriced to the exclusion of small farmers, or there is no alternative source of new technologies, particularly from the public sector. Further, the increase in

concentration, and the conflicting patent claims when both the public and private sectors have patented plant technologies, may have had an inhibiting effect on research.“ [35]

The UK Commission on Intellectual Property Rights therefore explicitly advises developing countries to completely ban patents on plants and seeds.

Until recently, free access to genetic resources was a prerequisite for breeding plants, and a special intellectual property system was developed in Europe and elsewhere. This system protecting plant variety rights presumes that access to genetic resources must remain free from exclusive claims so as not to inhibit research and development. Although owners of the protected variety have the exclusive right to sell the seed they have bred, this so-called reservation of ownership enables a permanent innovation process. Every breeder who wants to grow a new plant variety has free access to the protected seeds. If the new breeder's variety really shows new properties, the right of the previous grower lapses, and the new variety can be marketed by the new breeder. Unlike plant variety protection, patent law replaces free access with the possibility of imposing wide-ranging blockades on the activities of plant breeders with the patented plants. Moreover, the patents cover all levels of added value, from field to food (see below). Plant breeding by medium-sized companies, such as still exists in Germany, has little hope of survival against this backdrop. In 2002, Bayer and BASF together held a 50 per cent share in the field of "green gentech", and the traditional plant growers had a share of nine per cent[36].

Also the vice president of the "International Union for the Protection of New Varieties of Plants" (UPOV), observes with concern, that the patent claims increase on crops and thus the entrance to seeds is blocked also for the plant breeders:
"The rapid progress in the development of genetic engineering raises the prospect that, in the foreseeable future, an ever increasing number of plant varieties will contain patented inventions. Furthermore, the varieties may contain several patented genetic elements. The practical consequence of this development would be that the breeder’s exemption, which is an essential principle in the UPOV system of plant variety protection, would be lost or greatly weakened." [37]

The Rockefeller Foundation and the UNEP are among those who warn against the consequences of patenting, especially for the poorer countries. A publication in the February 2003 issue of Nature[38] also views the situation as dramatic. Parallel to the extension of

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[35] Integrating Intellectual Property Rights and Development Policy“, UK Commission on Intellectual Property Rights, http://www.iprcommission.org

[36] Herrlinger, Jorasch, Wolter in Baumgartner and Mieth (Ed.),"Patente am Leben?", mentis Verlag, 2003

[37] (Rolf Jördens, Oktober 2002, http://www.upov.org/en/documents/Symposium2002/pdf/wipo-upov_sym_02_2.pdf)

[38] "Crop improvement: A dying breed" Knight, J., Nature 421:568-570, Feb 6, 2003

private copyrights, the funds for public research have been drastically cut. At the same time, patenting has made access to genetic resources more difficult. Seeds are becoming too expensive, especially for developing countries: "If this trend isn't halted, some experts claim, tomorrow's supercrops may end up like many of today's medicines: priced out of the reach of much of the developing world's growing population. 'We are headed down the same path that public-sector vaccine and drug research went down a couple of decades ago,' says Gary Toenniessen, director of food security at the Rockefeller Foundation in New York."

### 3.4 Prosecution of farmers

Reports from the USA and Canada show that companies also impose considerable financial demands directly on farmers in industrialized countries. According to an Associated Press report dated 26.11. 2002, a "court of appeal in Washington State ruled that a soy farmer from Pontotoc County had infringed a patent owned by the biotech company Monsanto for a certain kind of seed. The court ordered the farmer in question, Homan McFarling, to pay US$ 780,000 to Monsanto because the farmer had supposedly retained roundup-ready soybeans from his harvest for the next sowing".

According to press reports in the USA, Monsanto has instituted legal proceedings in more than 73 cases against farmers and other members of the agricultural trade. Other companies like Syngenta have also instituted corresponding court proceedings. In one case, a farmer was sent to prison because he had burned the evidence, i.e. seed samples[39].

The case of Percy Schmeiser caused a particular sensation. This farmer's alleged patent infringements are now to be heard before the Supreme Court of Canada. He was ordered in 2000 to pay about US$175,000 to Monsanto. The latter accuses Schmeiser of sowing seed with patented genes without Monsanto's permission. The farmer says these genes constitute undesired contamination of his seeds and fields.

### 3.5 Consequences for food production

The consequences of seed patenting for food production have met with little notice so far. By contrast, it is striking how consciously agrochemical companies are expanding their claims via patent law to the downstream areas of food production. Apart from the Dupont patent (EP 744 888) mentioned above, which covers not just corn grain but also "the use of the oil ... in food, animal feed, cooking or industrial applications", a Monsanto patent for (ordinary) soft wheat is particularly interesting:

Patent EP 445 929 patented wheat in which certain genes are naturally absent or inactive. Besides these, it explicitly lays claim to:

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[39] Seed makers' suits sow hostility, David Mercer, Arkansas Democrat Gazette, 18 May 2003, http://www.nwanews.com/adg/story_Business.php?storyid=30426

"flour prepared from wheat...
dough or batter prepared from flour...
an edible product made by cooking dough or batter...
biscuits or the like prepared from flour ...“

In view of these patents and the existing concentration of just a few agrochemical companies in the seed market, the influence of agrochemistry on the food production market may be expected to grow in coming years. The agrochemical sector will be able to manoeuvre itself into a new key position because EU patent law was specifically tailored to this branch of industry. Patents are granted on the basis of relatively slight inventive activity (such as the isolation of genes), but with a wide scope. The life industry's aim to cover the complete range from field to consumer can thus be supported and realized by means of patents. Like the plant breeding and agriculture sector, the food industry is one of the branches that may become directly dependent by this way.

The OECD report on biotechnology and food safety (1994, p. 23) already describes a corresponding strategy on the part of companies. Under the heading "Industrial Strategies and Constraints", it states: “The main focus of attention in this sector has been the reorganization of the seed market, leading to a greater integration with the agrochemicals sector." It continues: "Among the marketing strategies for new products, the tradtional gene technology supplier option has become vulnerable and is giving way to the strategy of controlling seed markets, or, more importantly, to strategy of moving further downstream into crop output markets, in order to capture the industrial value added."

Against this backdrop, the advent of genetic engineering to agriculture must be seen more as an economic strategy than a solution-oriented technology.