OPINION

# Genes and patent policy: rethinking intellectual property rights

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Concerns about human gene patents go beyond moral disquiet about creating a commodity from a part of the human body and also beyond legal questions about whether genes are unpatentable products of nature. New concerns are being raised about harm to public health and to research. In response to these concerns, various policy options, such as litigation, legislation, patent pools and compulsory licensing, are being explored to ensure that gene patents do not impede the practice of medicine and scientific progress.

Although gene patents have been granted worldwide for several years, the wisdom of this action is now being questioned. Lawsuits, proposed legislation, international protests and even patent-office proposals have recently been initiated to eliminate, undermine or otherwise challenge the scope of patents on human genes. The challenges come from various interested parties — people from whom patented genes have been isolated, researchers who wish to undertake genetic epidemiological studies or to develop gene therapies, clinicians and health-care providers who cannot afford expensive licensing fees for genetic tests and policy-makers who want to ensure that the patent system actually meets its goal by encouraging invention. Evidence is mounting that gene patents are inhibiting important biomedical research, interfering with patient care and provoking criticisms from international trading partners.

So far, the US Patent and Trademark Office (USPTO) and the European Patent Office (EPO) have treated isolated and purified nucleotide sequences as if they were the same as man-made chemicals[1] (BOX 1). Although many believe that human genes should not be viewed with such a cavalier attitude[2,3], recent challenges to gene patents have moved beyond the initial moral concerns about making a commodity out of a part of ourselves. Now, the concerns are being expressed in terms of harm to public health and research. These concerns have generated debate and the exploration of policy options to ensure that gene patents do not impede the practice of medicine and the progress of science.

In my view, the decision to allow patents on human genes was inappropriate, both legally and as a matter of sound policy. The useful properties of a gene's sequence (such as its ability to encode a particular protein or its ability to bind to a complementary strand of DNA for diagnostic purposes) are not ones that scientists have invented, but instead, are natural, inherent properties of the genes themselves. Moreover, in my opinion, gene patents do not meet the criteria of non-obviousness, because, through *in silico* analysis, the function of human genes can now be predicted on the basis of their homology to other genes. In addition, as a matter of policy, human nucleotide sequences should not be patentable, even if their function is known, because such scientific information should be available to all.

## The foundation of patent law

Industrialized nations worldwide share a belief in the importance of a strong patent system. Such a system was put in place in the United States two centuries ago in the US Constitution to create incentives for technological innovation. Article I of the US Constitution gives Congress the power "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries". Because the constitutional provision is vague, the US Congress determines the types of incentive that are necessary to encourage invention and ensure that the public receives a sufficient benefit from the temporary monopoly granted to the inventor.

Under US federal patent law, an inventor has the right to exclude others from making, using or selling his or her invention for 20 years from the date of the application. For a gene to be patented, the patent applicant must show that his or her invention is useful, non-obvious and novel. The usefulness of the inventions must be specific, substantive and "credible". The patent application must also be adequately "enabling". That is, it must describe the invention fully, in a way that would allow another person who is skilled in that field to reproduce the invention. This requirement is particularly important because one of the purposes of patent law is to ensure that the public gets information in exchange for the monopoly granted to the patent holder. When a patent is granted, the information in it becomes public. Other inventors can then use that information to further their own research. Other inventors, however, cannot make or use the patented invention itself without the permission of the patent holder. In the United States — unlike in Europe — the inventor has no duty to actually "work" (use or develop) the invention.

The US patent laws are designed to ensure that the public benefits from a new invention in exchange for the monopoly. The laws do



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**Box 1 | The legal basis for gene patents**

Although products of nature are not patentable, various courts have upheld patents on isolated and purified natural substances. The 1912 case of Parke-Davis versus H. K. Mulford[38] upheld a patent on adrenaline, a natural hormone that was found in animal glands. The patent applicant identified, isolated and purified the active ingredient — adrenaline. This created a product that did not exist in nature in that precise form and that could be used for medical treatment.

The US patent office holds that a human gene as it occurs in nature cannot be patented. However, if a DNA sequence is purified and isolated in the form of a cDNA or is part of a recombinant molecule or vector, then this 'invention' is patentable under the precedent of the adrenaline case[1].

not allow patents on products of nature because the public would not be gaining anything new. Also, patents are not allowed on scientific formulas. As the US Supreme Court has pointed out, "The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of … nature, free to all men and reserved exclusively to none'"[4].

Genes straddle the boundary between patentable and unpatentable substances. As Rebecca Eisenberg, Professor of Law at the University of Michigan, USA, notes, "DNA sequences are not simply molecules, they are also information. Patent claims to information — even useful information — represent a fundamental departure from the traditional patent bargain"[5]. That bargain originally allowed a patent on an invention in exchange for the disclosure of useful information in the application to spur on other inventors.

### Effects on diagnosis and treatment

Gene patents have attracted capital investment to the biotechnology industry. That makes business sense, but not, in my view, policy sense. The very exclusivity of a patent — the monopoly power of its holder — has created problems in medical and scientific fields. For 20 years from the date that a gene patent was filed, gene-patent holders can control any use of 'their' gene; they can prevent a doctor from testing a patient's blood for a specific genetic mutation and can stop anyone from doing research to improve a genetic test or to develop a gene therapy based on that gene.

For example, Athena Neurosciences, Inc., which holds the patent on a gene that is associated with Alzheimer disease — the apolipoprotein E (*APOE*) gene (US Patent No. 5,508,167) — will not allow any laboratory except its own to screen for mutations in that gene[6]. Doctors and laboratories across the country face a lawsuit if they try to determine whether one of their patients carries this genetic predisposition to Alzheimer disease, even though testing can easily be done by anyone who knows the sequence of the gene, without using any product or device made by the patent holder.

In 2001, the US company Myriad Genetics was granted a European patent related to the *BRCA1* breast-cancer-associated gene. The patent (EP699754) covers all methods for diagnosing breast cancer by comparing a patient's *BRCA1* gene with the *BRCA1* gene sequence that Myriad describes in its patent[7]. Myriad is now asserting that no French doctor or scientist should be allowed to test for *BRCA1* gene mutations; instead, the company requires that all samples be sent to Myriad's laboratory[8]. However, French physicians are concerned that such a mandate compromises patient care. They allege that Myriad's test only assesses 10–20% of potential *BRCA1* mutations[9]. Indeed, a French physician has recently identified a mutation in an American family that the Myriad test had missed[9]. Moreover, geneticists in France can offer genetic tests for breast cancer for less than the US $2,680 fee per test that is charged by Myriad. It is both the breadth of Myriad's *BRCA1* patent and the company's refusal to grant licenses for *BRCA1*-mutation detection that has led to concerted and international opposition.

Exclusivity in diagnosis can also impede research. Various mutations in the same gene can cause a particular disease. But companies that do not let anyone else screen a gene sequence that they have patented for other mutations lessen the chance of other disease-associated mutations being found, as often occurs when many laboratories screen the same gene. In countries where the *APOE* gene that is associated with Alzheimer disease and the *HFE* gene that is associated with haemochromatosis have not been patented, researchers have found previously unknown mutations[10,11], which can be used to diagnose people who would not otherwise be diagnosed.

Companies now also sequence and patent the genes of disease-causing bacteria and viruses. This gives them the power to prevent others from introducing inexpensive public health genetic testing for a common infectious disease, for example, or from undertaking genetic research on the disease. The possibility of patenting human genes and the genomes of disease-causing bacteria and viruses has led Tufts University policy professor Sheldon Krimsky to comment that "the intense privatization of biomedical knowledge that has evolved since the 1980s threatens the entire edifice of public health medicine"[12].

Gene patents also hamper pharmacogenomic research. Many drugs work on only a percentage of patients who use them. Genetic testing can help to distinguish those patients for whom a drug will work from those for whom it will not. But such tests will also reduce the market for certain drugs. For example, a pharmaceutical company, GlaxoSmithKline, Plc, has filed for a patent on a genetic test to determine the effectiveness of one of its drugs, but will not develop the test, or let anyone else develop it, possibly because such a test would cause the company to lose customers[13].

Research to find additional genes that are responsible for diseases is also impeded by gene patents. In one reported example, the search for a gene that is related to autism was impeded because researchers from several prominent American universities would not share DNA samples from affected children and their families; each university wanted to capitalize on being the one to discover and patent the gene that is associated with the disease[14]. In response, families of patients with autism founded Cure Autism Now (CAN), which, through its fundraising efforts, has raised US $5 million to create a DNA bank, called the Autism Genetic Resource Exchange, that is available to all scientists who are willing to work on finding the gene or a cure for autism.

Gene patents also undermine the scientific method. Researchers who discover and patent genes have financial incentives to promote the use of those genes for diagnostics as rapidly as possible, sometimes before sufficient data are available to assess how well a test predicts future disease. The patent examiner has to take what the applicant says as correct, and there is no Food and Drug Administration review in the United States when a company offers a genetic test as a service. If a patent holder states that one in three people in the population have the gene



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mutation that is covered by its patent, the patent holder can actually prevent others from duplicating the patent holder's research and evaluating it. In one survey, 14 out of 27 gene-patent holders said that they would require a license for researchers to study the prevalence of mutations in the patented gene in the population[15]. Even if the patent holder allows research by other scientists, the licensing costs might prevent other researchers from doing the necessary epidemiological studies to determine, for example, the proportion of people in the general population who carry a gene mutation and who will actually develop the disease. Some entities that offer patented genetic tests have already apparently exaggerated the prevalence of certain diseases, possibly to scare people into being tested[16].

### Economic effects on research

Patenting genes can impede invention and health care in other ways too. Gene patent holders have prevented some researchers from searching for cures for genetic diseases. A researcher who wants to find a cure for breast cancer would have to negotiate with not only the patent holder for the full wild-type *BRCA1* and *BRCA2* genes, but with all of the other patent holders who have discovered and patented any of the hundreds of other mutations in these genes.

The granting of patents on parts of genes or different alleles creates a tangle of rights that can impede innovation. It is the policy of the USPTO that the discoverer of a gene should not be able to undertake mutation testing or the development of a product that is based on that gene without the permission of the holders of any patents on expressed sequence tags (ESTs) created from that gene[1]. The EST patent holder could withhold consent entirely or charge a fee. According to John Doll, Director of Biotechnology Examination at the USPTO, "The USPTO views this situation as analogous to having a patent on a picture tube. The picture-tube patent does not preclude someone else from obtaining a patent on a television set. However, the holder of the picture tube patent could sue the television set makers for patent infringement if they use the patented picture tube without obtaining a license"[1]. But I find this analogy troubling. Other inventors can create alternatives to the picture tube, and a consumer can do without a television. There are no alternatives to the patented human genes in genetic diagnosis and gene therapy — and these inventions might mean the difference between life and death to the consumer.

> "'Patent claims to information — even useful information — represent a fundamental departure from the traditional patent bargain' … [that] allowed a patent on an invention in exchange for the disclosure of useful information in the application to spur on other inventors."

Michigan law professors Michael Heller and Rebecca Eisenberg have discussed how patents can deter innovation in biomedical research by stifling research innovations early on in the product development process[17]. Economist Carl Shapiro elaborates on the problems created by a 'patent thicket'. Using traditional economic analysis, he has shown how, when several monopolists exist that each control a different raw material needed for development of a product, the price of the resulting product is higher than if a single firm controlled trade in all of the raw materials or made the product itself[18]. However, the combined profits of the producers are lower in the presence of complementary monopolies. So, if there are several patent holders whose permission is needed to create a gene therapy (and any one of them could block the production of the gene therapy), inefficiencies in the market are created, potentially harming both the patent holder and the patent users.

Gene patents do not seem to be necessary to encourage technology transfer in the move from gene discovery to the availability of a genetic diagnostic test. As soon as information about the discovery of the haemochromatosis gene was published, laboratories began testing for mutations in the gene. After a patent on the gene was granted 17 months later, 30% of the 119 US laboratories that were surveyed reported discontinuing or not developing a genetic test for the disease[19]. The patent holder was asking for an up-front fee of US $25,000 from academic laboratories and as much as US $250,000 from commercial laboratories, plus a fee of US $20 per test[19]. The patent interfered with clinical use of the test and potentially compromised the quality of testing by limiting the development of higher quality or lower cost testing methods[19].

Professional organizations, such as the American College of Medical Genetics[20] and the College of American Pathologists, oppose gene patents as threatening medical advancement and patient care[21]. The World Medical Association considers human genes to be part of "mankind's common heritage" and urges medical organizations around the world to lobby against gene patenting[22]. This mounting concern about gene patents has lead to policy initiatives through litigation, legislation and administrative action.

### Litigation

In the United States, the patent system is a three-way relationship among the USPTO, the courts and the Congress. All three have roles to ensure that the goals of the patent system are met and that the monopoly granted is not too broad. Most often, this means that the courts and the Congress reduce the breadth and scope of patents granted by the USPTO. For example, when Samuel Morse convinced the USPTO to grant him a patent on all uses of electromagnetic waves, the Supreme Court ruled that he could not patent every conceivable use of electromagnetic waves[23]. He could only patent his invention — the telegraph.

In addition, the Director of the USPTO has the authority to order patents to be re-examined. In the 1970s, the USPTO denied patents on software. When, in 1981, the US Supreme Court ruled that software was patentable subject matter[24], the USPTO lacked examiners with expertise in this area to evaluate these types of patent and, as a result, issued many patents that were criticized as being over-broad[25]. In response, the USPTO undertook more than 40 re-examinations of software patent claims that it had issued. These re-examinations resulted in the rescission of existing claims and the establishment of rules to narrow markedly the scope and breadth of these types of patent claim in the future.

There has yet to be a definitive legal case to address directly whether human genes are an appropriate subject matter for a patent in the first place. Rather than challenging the patenting of genes *per se*, the court cases on gene patents are generally battles between two entities (such as a university and a biotech company) about who has rights to a particular patent. There is no incentive for either side to challenge whether a gene patent is an inappropriate patent on a product of nature because each side wants to reap the financial rewards of a gene patent. The member of the public who could end up paying a high fee to learn genetic information about himself or herself — or be denied



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that information altogether — rarely has legal standing in the United States to bring a lawsuit to challenge the patentability of human genes. Although a physician, researcher or laboratory could challenge the patentability of human genes, various financial and institutional constraints have generally acted against this. Legal challenges against patents are financially expensive. A physician challenging a patent can expect to pay upwards of US $500,000 in attorneys' fees alone[26]. For a laboratory, it might be cheaper to pay for a license to use a gene — and pass that cost on to the patients who are tested — than to initiate a legal challenge.

Consequently, it is quite remarkable that any court challenges to gene patents are taking place. However, recently, legal assaults on gene patents were launched on two fronts. The first type of case was brought by patients against researchers and their institutions in cases in which the defendants did not specifically disclose their intentions to patent a gene that they isolated from their patients. The patients rely on precedents that require physicians/researchers to disclose potential financial conflicts of interest to the patient/research subjects in advance of undertaking the research[27]. One such suit, concerning the aspartoacylase gene, which is mutated in Canavan disease — a rare, genetic, neurodegenerative disorder that occurs most frequently in Ashkenazi Jewish families — is now pending in the federal court in Chicago. (I am a public interest (pro bono) attorney for the plaintiffs in this case.)

The second type of legal challenge, typified by that mounted by the French, contests aspects of the patentability of genes and raises policy concerns about the effects of gene patents. In October 2001, the Institut Curie in France challenged Myriad Genetics' European patent (EP 699754) on the *BRCA1* gene on the grounds of alleged lack of novelty (because predisposition tests for breast cancer on the basis of indirect methods were available before the Myriad patent); lack of inventiveness (as the gene sequence that was patented by Myriad was based, in part, on information from public genome databases); and inadequate description (because there were errors in the original sequence published by Myriad)[9] (see online link to the Institut Curie). On 22 February 2002, the Institut Curie initiated a challenge to another Myriad patent, EP 705903, on *BRCA2*. The governments of Belgium and the Netherlands intend to challenge that same patent as well (see online link to the Institut Curie). Geneticists in those countries issued a joint statement that, if gene patents were not narrowed or eliminated, "the monopolies on genes and genetic testing will wreck the reimbursement system and negatively influence health care."

Other challenges to gene patents might also try to narrow the claims that are made in patent applications. In some cases, the patent applicant has been granted rights not only to the mutations in a gene that he/she discovered, but also to any other mutations discovered later by other researchers. In other instances, the patent gives the applicant rights to all possible functions of the encoded proteins. In still other cases, patents have been granted on all methods of comparing the sequence of a high-risk individual with a known normal sequence, even though the patent has only described one method. The breadth of such patents could be challenged on the grounds that the patent has not sufficiently described all of the mutations, functions or methods that the patent holder has claimed rights to.

### Legislation

Because the US Constitutional provision encouraging inventors is quite general, the actual provisions of patent law are enacted by Congress and can be modified by that body. It is not uncommon for the US Congress to limit patent rights in the public interest[28]. For example, a statute gives the federal government 'march-in' rights[29]. When a federally funded patentee has not made the invention available to the public within a reasonable time or when "action is necessary to alleviate the health or safety needs which are not reasonably satisfied" by the patentee, the government can license the patent to third parties. In addition, under the Clean Air Act, courts can, when necessary, order compulsory licensing of patents on equipment or technology used in air pollution control on reasonable terms to ensure competition[30].

The US Congress is considering a proposed law (BOX 2), introduced by Members of Congress Lynn Rivers and Dave Weldon (a physician), which would amend the federal patent statute to exempt health-care providers that are involved in genetic testing from patent infringement liability, so that their ability to diagnose patients is not compromised by gene patents. Also, because there is no statutory research exemption to patent infringement in the United States (and because rare exemptions that have been recognized by the courts have been extremely narrow), the bill, if passed, would allow non-commercial researchers to be exempt from liability for the use of patented genes. It is quite common internationally to have exceptions to patent laws. For example, the European Patent Convention Article 53(a) prohibits patents for "inventions the exploitation of which would be contrary to 'ordre public' or morality." Other inventions that the European Union's Biotechnology Directive consider to be unpatentable include processes for cloning human beings; processes for modifying the germ line of human beings; and uses of human embryos for industrial or commercial purposes[31].

**Box 2 | US legislative initiatives to reform patents on genes**

On 14 March 2002, members of the US Congress Lynn Rivers and David Weldon proposed a new law that would exempt health-care providers who carry out genetic testing from being sued by holders of patents on genes. This proposed bill, the Genome Research and Diagnostic Accessibility Act of 2002 (REF. 39), aims to exempt two groups from patent infringement: first, medical practitioners and related health-care entities that provide genetic diagnostic, prognostic or predictive tests; and second, scientists that undertake non-commercial genetic research. The bill also requires that patent applications involving a genetic sequence discovered with federal funds are made public within 30 days of a patent application being filed[39].

Rivers and Weldon also introduced a companion bill — the Genomic Science and Technology Innovation Act of 2002. This proposed bill directs the Office of Science and Technology Policy (OSTP) to initiate a study of the effect of federal policies on the discovery and development of genomic technologies. This proposed bill is based on the presumption that federal intellectual-property laws and technology-transfer laws can stimulate the development of innovative genetic technologies by attracting commercial investment, but might also inhibit basic research and information sharing, thereby slowing innovation. Rivers' primary concern in drafting this bill was to assess whether gene patents are granted without an adequate understanding of their impact on innovation. The aims of this study are: to assess the impact of federal policies, including intellectual-property policies, on the innovation process for genomic technologies; to identify and quantify the actual and expected effects of patenting policy on genomic science and technology innovation; and to consider various alternatives for protecting intellectual property rights over genomic materials and their likely impact on genomic innovation.



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Exceptions in patent law to protect patients' access to health care and to protect doctors' liability have a historical basis in the United States. Originally, US patent law forbade patents on health-care inventions. Throughout the first 150 years of US history, the USPTO did not issue patents for methods used to diagnose and treat patients[26]. Such methods were not considered to be patentable subject matter by the medical profession, by the courts or by the USPTO because patents were granted for tangible inventions. Medical or surgical methods were not considered to fall in the scope of the statutory requirements until 1954, when the Board of Patent Appeals opened the door to patents on medical methods[32]. In the 1990s, such patents began to interfere with patient care. In 1996, the US Congress created an exception in the patent law so that health-care providers are not subject to patent infringement suits when they use a patented medical or surgical technique[33]. Eighty other countries already had such an exemption[34]. Until recently, many other countries did not even provide intellectual property protection to medicines and other pharmaceutical products[35]. Some developing countries had short periods of protection for such products (such as three years of patent protection in Thailand) to allow health needs to be met by the rapid introduction of generic drugs[35].

The Trade-Related Intellectual Property Rights (TRIPS) agreement of the World Trade Organization, promulgated in 1995, requires all of its international signatories to agree to provide a 20-year intellectual property protection for inventions (including those that are related to health care). But even TRIPS highlights how public health should be given greater weight than the commercial concerns of patentees. Article 27 of TRIPS specifically allows governments to exclude diagnostic, therapeutic or surgical methods from patentability. It also allows them to deny patentability of a particular invention to protect human life or health. Article 8 of TRIPS allows governments to take public health concerns into consideration in their national intellectual property laws, and Article 31 allows governments to ignore health-care patents in certain situations and to grant compulsory licenses (see next section) to third parties to produce a generic version of a health-care product. Under TRIPS, patents can be ignored in a public health emergency.

## Patent pools and compulsory licensing

Policy options based on traditional patent law are also being explored, such as creating a patent pool — an agreement between two or more patent owners to license one or more of their patents to one another or to third parties. Patent pools are voluntary agreements among patent holders in which they gather all the necessary tools to practice a certain technology in one place, rather than obtaining licenses from each patent owner individually. One model to base this on is the pool created by the American Society of Composers, Authors and Publishers (ASCAP), which handles the licensing of music under copyright laws. Instead of having to negotiate with each holder of a copyright for thousands of songs, a radio station or bar can buy a blanket license from ASCAP and play any song from the pool at any time. In a similar way, a gene patent pool could extend non-exclusive licenses to all for set fees.

> "…court cases on gene patents are generally battles between two entities (such as a university and a biotech company) about who has rights… [t]here is no incentive … to challenge whether a gene patent is an inappropriate patent on a product of nature because each side wants to reap the financial rewards…"

Patent pools are particularly appropriate when patent exclusivity is being used contrary to the public's interest. During the First World War, the Assistant Secretary of the US Navy, Franklin D. Roosevelt, pressured the aircraft industry to form a patent pool to facilitate the production of aeroplanes[18]. Previously, the Wright–Martin Aircraft Company and the Curtiss Airplane and Motor Company were able to block such production owing to their control of key patents.

Compulsory licensing is also being explored as a way to counter some of the problems of gene patents. This system has been advocated by the French Minister of Research, Roger-Gérard Schwartzenberg (see online link to Institut Curie). Compulsory licensing is the granting of a license by a government to use a patent without the patent holder's permission. This approach, which might be necessary if gene patent holders did not voluntarily create patent pools, would require gene patent holders to allow physicians, researchers and others to use the patented gene sequence for a reasonable fee. Laboratories would be able to undertake genetic diagnostic testing using their own, as well as patented, tests, which could lead to the discovery of new mutations. Furthermore, pharmaceutical companies would not be able to prevent pharmacogenomic testing related to their products. Also, researchers could not be prevented by gene patent holders from undertaking research on gene therapies (or discouraged from undertaking such research through high licensing fees).

Compulsory licensing is clearly permissible under TRIPS, and the mere threat of it sometimes serves to drive down the costs of pharmaceuticals. When the South African government passed the Medicines and Related Substances Control Act in December 1997 to authorize the compulsory licensing of drugs, 40 drug companies initiated a lawsuit to overturn the act[36]. Subsequently, the companies agreed that the law could be enforced, dropped the legal challenge and negotiated to sell their products at a lower cost[37].

## Conclusion

Whatever policies society develops for gene patents, policymakers will be influenced by the fact that the 'bio' in biotechnology — the genes in the gene patents — comes from people. Researchers need the trust of those whom they study to get access to their tissue for research into diagnostics and cures. Using the biological resources of the public (and a substantial amount of public funding), genes have been discovered and patented. Now, policy makers are being asked to ensure that the public receives the benefits.

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## Online links

DATABASES
LocusLink: http://www.ncbi.nlm.nih.gov/LocusLink
*APOE* | aspartoacylase | *BRCA1* | *BRCA2* | *HFE*
OMIM: http://www.ncbi.nlm.nih.gov/Omim
Alzheimer disease | Canavan disease | haemochromatosis

FURTHER INFORMATION
American College of Medical Genetics: http://www.acmg.net
College of American Pathologists: http://www.cap.org
Cure Autism Now: http://www.canfoundation.org
European Patent Office: http://www.european-patent-office.org
Food and Drug Administration: http://www.fda.gov
Institut Curie: http://www.curie.fr
Trade-Related Intellectual Property Rights: http://www.wto.org/english/tratop_e/trips_e/trips_e.htm
US Patent and Trademark Office: http://www.uspto.gov
World Medical Association: http://www.wma.net
World Trade Organization: http://www.wto.org
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SCIENCE AND SOCIETY

# Human genetic technologies, European governance and the politics of bioethics

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With human genetic technologies now an important area of European research and development, bioethics is becoming increasingly important in its regulation and future. As regulatory decisions are also statements about who should get what, bioethics cannot avoid political controversy. Can bioethics sustain its claimed role as authoritative adviser to decision makers, or will its attempts to reach a consensus on human genetic technologies be perceived as the actions of an ambitious interest group? What, in short, is its political future in Europe and elsewhere?

In a 2002 report that outlines a strategy for the life sciences and biotechnology in Europe, the European Commission recognizes a fundamental tension at the heart of its policy. On the one hand, Europe has the scientific and industrial potential to be a global leader in new biotechnologies, including human genetic technologies. On the other hand, it acknowledges that "public support is essential, and ethical and societal implications and concerns must be addressed" if Europe is to benefit from these technologies[1]. Given the European public's reaction to genetically modified food and crops, there is no guarantee that the problems that beset one area of biotechnology will not affect another. When it comes to human genetic technologies, such as pharmacogenetics, gene therapy, predictive diagnostics and therapeutic cloning, will the necessary public support be there? It remains to be seen whether the health applications of genetic knowledge will be perceived by the public as being an issue that is distinct from GM food and crops[2].

Traditionally, public support for new technologies has been assured through governmental regulatory arrangements that have relied heavily on scientific advice about the risks that are associated with a particular technology. However, the public response to the bovine spongiform encephalopathy (BSE) crisis in the United Kingdom (when conflicting scientific advice was withheld from the public until it was too late to quell the epidemic, resulting in a subsequent wide-scale inquiry) and to GM crops in Europe and Asia (where public protests about GM foods, including the occasional destruction of seeds and crops, have achieved results such as mandatory product labelling) is testament to the general decline in the public's trust in scientific authority[3–6]. Ethical and cultural concerns have been thrown to the fore and new forms of public opposition[7–9] have emerged to challenge the efficacy of what is sometimes called "the technocratic approach" to regulation. Given the uncertainties that therefore beset this science-based approach, 'red' biotechnology, as the health genetic technologies are sometimes known, could prove to be as contentious as the 'green' biotechnologies of food and crops.

With the European Union's plan to expand its investment in genomics and



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