

# ACOG COMMITTEE OPINION

Number 364 • May 2007

## Patents, Medicine, and the Interests of Patients\*

### Committees on Ethics and Genetics

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**ABSTRACT:** Many basic scientists and clinicians support the right to obtain and enforce patents on drugs, diagnostic tests, medical devices, and most recently, genes. Although those who develop useful drugs, diagnostic and screening tests, and medical technologies have the right to expect a fair return for their efforts and risks, current interpretations of patent law have the potential to impede rather than promote scientific and medical advances. Policies regarding the patenting of scientific inventions, discoveries, and improvements must balance the need for the open exchange and use of information with the need to make the pursuit of such knowledge financially rewarding.

New technologies and the translation of research discoveries into clinical medicine are essential for improvements in patient care. The increasing commercialization of medical discoveries, however, may hamper the dissemination of new knowledge and the ability of physicians and patients to benefit from applications of this knowledge. Many basic scientists and clinicians support the right to obtain and enforce patents on drugs, diagnostic tests, medical devices, and most recently, genes. Some primarily are concerned with recovering the costs they incur in developing new treatments and technologies. Others see patents in medicine as a legitimate means, within a society based on the principle of free enterprise, of protecting and enhancing intellectual capital.

Such patent protections may be regarded as necessary incentives for the development of new tests and treatments. Also, they may limit the ability of clinicians, patients, and researchers to obtain the right to use these discoveries commercially under reasonable conditions and at an affordable price. Furthermore, the issue of gene patenting

poses unique challenges to knowledge development and academic collaboration because a gene sequence, unlike previous technical advances, is both a tool for pursuing scientific knowledge and the basis for any diagnostic or therapeutic application.

### Patent Protections

The U.S. Patent and Trademark Office (PTO) is guided by federal statutes, regulations, and case law in granting patents. Patent protection is intended to promote research and discovery and to act as a stimulus to progress in science and the useful arts. The PTO evaluates an application for a U.S. patent to determine whether the claimed invention satisfies the following three conditions: the invention is a 1) “new” and 2) “useful” discovery or improvement that is 3) “not obvious” to individuals with ordinary skill in the art (1, 2). In evaluating patent applications, the PTO also assesses whether the specification adequately describes the invention and enables the skilled artisan to make and use it. A patent is granted for an invention that meets the three conditions and other requirements, such as being patentable subject matter. For example, “products of nature” can be patented if they are in an isolated form that does not occur in nature.



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\*Update of “Patents, Medicine, and the Interests of Patients” in *Ethics in Obstetrics and Gynecology*, Second Edition, 2004.

Patents that may affect the practice of medicine fall into four categories: 1) patents on medical and surgical procedures, 2) patents on surgical or diagnostic instruments, 3) patents on drugs, and 4) patents on genes and gene-based diagnostic or predictive tests. All of these types of patents raise ethical issues and may create conflicts of interest for physicians who contribute to the development of new products through research. The commercial potential of medical discoveries may motivate physicians to increase their own incomes in ways that may jeopardize the care of patients. Academic and research physicians may be offered incentives by their institutions to maximize the institution's extramural revenues through patent arrangements that restrict use by other researchers and, thus, act as barriers to further research discoveries.

### **Patenting Medical and Surgical Procedures**

Historically, physicians have taught and shared medical information without regarding this knowledge as trade secrets to be protected from others. Physicians have a fundamental obligation to provide advice to their patients about the most appropriate care, without being influenced by any profit they might gain through associated commercial ventures. Open communication of information gained from research and experience with medical and surgical procedures is essential if safety and efficacy are to be validated or refuted by colleagues. It is through further scientific work by one's peers that diagnostic methodologies and medical procedures are either validated, refined, and improved or discarded as ineffective or unhelpful.

Some corporate or individual business arrangements—including the patenting and licensing of medical and surgical procedures—can be adverse to the welfare of patients. These arrangements present barriers to the availability of the protected procedures to other physicians and patients. Moreover, they may inhibit new research that might otherwise be stimulated by open access to information about the procedures. Investigational use of patented procedures is permitted under the “experimental use doctrine,” which allows a patented invention to be used in a manner that does not interfere with the economic interests of the patent holder (ie, used with no commercial intentions).

For these reasons, the enforceability of patents covering medical and surgical procedures has been challenged, both ethically and legally. The American Medical Association asserts that it is unethical for physicians “to seek, secure or enforce patents on medical procedures” because such practices may limit the availability of new procedures to patients (3). In the 1996 case *Pallin v Singer*, Dr. Pallin was prohibited from enforcing his patent claims on a particular type of incision used in cataract surgery (4). As a result of this case, Congress enacted a 1996 statute making patents of medical or surgical procedures unenforceable (5). In the United States, medical and sur-

gical procedures are still patentable, but patent claims are not enforceable against a medical practitioner unless the practitioner uses a patented pharmaceutical, medical device, or biotechnology process. Thus, the U.S. legal system provides some support for the traditional ethic of physicians to share their knowledge and the use of advances in medical and surgical procedures. Other countries view the patentability of medical procedures differently than the United States. For instance, the European Union and Great Britain consider medical procedures to be nonpatentable subject matter.

### **Patenting Surgical and Diagnostic Instruments**

The U.S. patent system also permits medical and surgical devices to be patented, including surgical and diagnostic instruments. The U.S. patent protection permits the patent holder to exclude other individuals or entities from making, using, or selling the patented invention in the United States for a period of 20 years, thus providing market exclusivity to the patent holder. Both ethically and legally, physicians may obtain patents on surgical or diagnostic instruments that they have invented (6). However, out of concern for the welfare of patients, the patent holder should make the instrument available at a fair and reasonable cost.

### **Patenting Drugs**

The granting of patents to pharmaceutical companies for drugs that they have developed may appear to be relatively uncontroversial. Drug makers have successfully argued the need for patent protection to recoup the cost of their investment in drug research and to gain a profit before the makers of generic equivalent drugs are permitted to enter the market.

However, some techniques used by pharmaceutical companies to extend the terms of their patents and their products' market exclusivities have recently come under criticism. For example, companies have paid manufacturers of generic drugs to drop a legal challenge to a patent or to postpone the manufacture of a generic equivalent, they have developed minimally altered formulations or dosages that become eligible for new patents, and they have lobbied Congress for statutory and legislative patent extensions on highly profitable drugs. These techniques may allow the patent holder to continue to charge prices that are far higher than would be the case in a competitive market and to extend the government-sanctioned market exclusivity long beyond when the original patent term would have expired. As a result, the cost to consumers or patients may be inflated beyond providing a reasonable return on research investments and may, in fact, prevent some patients from using drugs that would be beneficial to them. As patients bear an increasing share of the cost of their prescribed drugs, the issue of drug pricing and extended market exclusivities should be of concern to physicians. Cost may influence patient compliance with physician recommendations.

## The Patenting of Genes

### Patent and Trademark Office Guidance

The PTO maintains that genes and gene sequences are patentable subject matter under existing U.S. federal statutes and case law. Since 1980, more than 20,000 patents on genes or other gene-related molecules have been granted, but this total includes gene patents for all organisms, not only humans. More than 25,000 applications for patents on genes or related molecules are pending (7).

Because of continuing controversy over the granting of patents on genes and gene sequences, the PTO has attempted to clarify its standards for granting such patents in its final guidelines on the written description and utility requirements of patents. The guidelines were issued after consideration of public comments on interim guidelines, and they are pertinent to gene patents. The PTO guidelines confirm that an isolated and purified gene (a chemical entity modified from its natural state) is not a naturally occurring substance. Substances that occur in nature in an unisolated form are not patentable.

Under U.S. patent law, the PTO regards a newly isolated gene or modified gene sequence to be a “composition of matter.” This is subject matter that is eligible for a product patent as long as the product satisfies all the statutory conditions for a patent. These conditions require that the patent specification describe an invention that is a new discovery or improvement (novel), that is not obvious to those with ordinary skill in the art (inventive), and that has utility (is useful) (1, 2). Product patents may be enforced broadly against a variety of uses of the claimed product. For example, a product patent claiming an isolated gene sequence can be used to exclude others from using the sequence for commercial purposes (ie, both the isolated gene sequence and the methods of using it in tests and treatments).

If the gene sequence is not new, it may nonetheless be eligible for a use patent (ie, a patent having claims directed to the product’s use). The enforcement of a use patent is narrower, being limited to the patented use. Although a use patent restricts the right to use a patented method using a product or composition, it does not restrict access to the product or composition itself.

A patent claiming an isolated gene covers the isolated gene but does not apply to the gene as it occurs in nature. Genes as they occur in the body are not patentable because they do not exist in an isolated and purified form. Therefore, individuals who possess such genes in their bodies would not infringe the patent.

In its final guidelines on the utility requirement for patentability, the PTO requires that the utility be “specific, substantial, and credible” (8). To satisfy this requirement, the inventor must disclose at least one way in which the purified gene, isolated from its natural state, may be used or applied, for example, for diagnostic or predictive genetic testing. However, if the applicant does not explic-

itly identify a specific utility for the isolated gene sequence, the guidelines permit the utility requirement to be satisfied if the examiner believes that an individual with ordinary skill in the art would recognize that the gene or sequence has a readily apparent “well-established utility.” Some commentators have suggested that this well-established utility may be simply a comparison with a structurally analogous gene or sequence that is known to have utility.

In the view of some commentators, the PTO guidelines do not set a high enough standard for establishing the usefulness of a gene or gene sequence and, therefore, may deem a product useful and allow a patent to be issued covering a gene or gene sequence before the applicant is able to identify a specific practical application (9). Allowing patents on genes and sequences to be issued before their function and purpose are adequately identified could create barriers to other researchers pursuing such studies or could lessen the incentive for them to do so. Moreover, researchers warn against relying too heavily on structural analogues to predict utility because minor changes in a gene sequence “may produce profound changes in biological activity” (10).

### Gene Patents and the Interests of Patients

Those who support the granting of broad patents believe that patent protection encourages rather than impedes research. It was the intent of Congress that the disclosure required to secure a patent and the limited exclusivity provided by the patent would stimulate progress in science and the useful arts. As the PTO notes, a patent application requires complete public disclosure of the invention, discovery, or improvement and, therefore, may promote dissemination of knowledge rather than secrecy. In the PTO’s view, gene patents foster scientific progress because other inventors are encouraged to discover new uses beyond the one specified in the patent application (8). Inventors who develop new and nonobvious uses for a patented gene may patent these inventions, according to the PTO, thereby rewarding researchers who develop the genetic information to the endpoint of a useful method or product (11, 12).

Opponents of broad gene patenting fear that the welfare of the patient, the traditional role of the physician, and the public trust are compromised by gene patents. According to opponents of gene patenting, the patenting of genes can impinge on the interests of patients in at least four ways:

1. By retarding the transmission of knowledge (possible if researchers choose to delay the announcement or the publication of their findings until after a patent application is filed)
2. By inhibiting other researchers from pursuing further investigation on the patented product (developing a subsequent invention often is difficult, complicated, or unprofitable because of the need to coordinate licensing with the original patent holder)

3. By establishing a monopoly on all diagnostic and predictive tests based on a patented gene (such action would limit the ability of practitioners and researchers to improve genetic testing by adding new mutations, devising new testing techniques, and developing national quality assurance programs [13])
4. By infringing on the interests of groups of patients who have provided the original genetic material on which the discovery of a gene or sequence is based (they may feel that their concerns are disregarded because of restrictions on access to tests and treatments made possible by their contribution of biologic material)

European challenges to the patent on the breast cancer gene *BRCA1* illustrate problems that arise when a patent holder claims that a patent on a gene precludes other researchers or organizations from developing their own tests for gene mutations. French researchers, supported by the European parliament, argue that such a monopoly could impede or even prevent the development and use of cheaper and more effective tests for *BRCA1* mutations, such as tests that cover a broader range of mutations (14, 15).

Similarly, in the clinical setting, experience has shown that patent holders may in effect deprive patients and physicians of reasonable access (eg, to a genetic test) by placing significant hurdles to its use. These hurdles can include substantial royalties or licensing fees and restrictions on the licensing of clinics or on the number of tests allowed, such as the conditions placed on prenatal and carrier testing for some autosomal recessive diseases (16).

Responses to the problem of restricted access to patented genes have led to several proposed solutions. One proposed solution is to develop a system similar to the music licensing system, where gene patent holders would be required to grant nonexclusive licenses for a reasonable set fee (17). Another proposed solution is that genes and genetic sequences should not be granted composition-of-matter patents because the market exclusivity of their patents extends beyond the use identified by the patent applicant and covers uses of the substance that may be discovered later. Instead, a patent would be granted to an applicant who identifies a specific function of a gene, but the patent would cover only the use or utility identified, such as a particular genetic test. Then researchers who later discovered additional applications for the gene would be able to patent these new discoveries (18).

Response to the issue of access to genetic tests has led some patient advocacy groups to take a proactive stance at the time that patients provide tissue samples to researchers. To ensure that any genetic tests that result from their participation will be inexpensive and widely available, these groups are seeking patents held jointly by the patient group and the researchers (19). Therefore, rather than objecting to the patenting of genes and genetic tests,

these patients are seeking to use the patent system to protect their own interests.

## Recommendations

Practitioners and researchers need to be aware of public policies that may jeopardize their ability to advance medical knowledge and provide the best tests and treatments to patients. Although those who develop useful drugs, diagnostic and screening tests, and medical technologies have the right to expect a fair return for their efforts and risks, current interpretations of patent law have the potential to impede rather than promote scientific and medical advances. Because the purpose of the patent system is to promote the public welfare, practices that are inimical to the public good and overly protective of commercial monopolies should be altered (18).

Policies regarding the patenting of scientific inventions, discoveries, and improvements must balance the need for the open exchange and use of information with the need to make the pursuit of such knowledge financially rewarding. Therefore, the Committee on Ethics and the Committee on Genetics of the American College of Obstetricians and Gynecologists suggest the following recommendations regarding the patenting of medical and surgical procedures, medical devices, genes, DNA sequences, screening and diagnostic tests, and gene-based therapies:

1. Patents on medical or surgical procedures are ethically unacceptable, and some are legally unenforceable. Physicians may obtain patents on surgical and diagnostic instruments that they have developed. However, the patent holders should make these instruments available at a fair and reasonable cost for the benefit of patients.
2. Because a patent claiming a gene as a composition of matter enables a patent holder to control future applications of the patented gene or sequence, such patents should not be granted. A patent should be granted only for the specified use or application of the gene or sequence (a "use" patent), thus enabling others to develop additional applications (18). Because case law and the PTO interpret a gene as being a patentable chemical composition of matter, such a limitation would require congressional intervention. The Committee on Ethics and the Committee on Genetics support legislation that would make composition-of-matter patents on genes unenforceable.
3. If composition-of-matter patents on genes continue to be enforceable, such patents on genes with clinical applications should be subject to federal regulation and oversight to ensure reasonable availability of the genes and their products for research and clinical use. Such regulation should include requirements on licensing arrangements to ensure access for the public good, including both the advancement of knowl-

edge and the clinical care of patients. Specifically, licensing agreements should permit reasonable but not excessive royalties and should allow unlimited access to tests by qualified laboratories, precluding exclusionary arrangements and quotas on the number of tests that may be offered.

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Patents, medicine, and the interests of patients. ACOG Committee Opinion No. 364. *American College of Obstetricians and Gynecologists. Obstet Gynecol* 2007;109:1249–53.

12345/10987

ISSN 1074-861X

