Life Sciences Series 1

Intellectual Property and Bioethics – An Overview

Consultation Draft

World Intellectual Property Organization

CONTENTS

INTRODUCTION[1]

Recent developments in the life sciences – genetic engineering, cloning, and manipulation of cell lines, exploitation of genetic resources – have sparked vigorous debate about the ethical dimension of these new technologies. The reasons are not hard to identify. Life sciences research literally touches on issues of life and death. Biotechnology

- aims to serve basic human needs such as human health, food and a safe environment,
- touches on fundamental values, such as human dignity and the genetic integrity of humanity,
- can raise human rights issues such as access to health and benefits from scientific progress,
- raises concerns over equitable access to the fruits of new technologies, the consent of those involved in research, and protection of the environment.

The ethical dimension of the life sciences touches many issues and policy communities, but one widely debated aspect is the ethical implications of protecting biotechnological inventions through the intellectual property (IP) system. This issues paper provides a systematic outline of the complex relationship between bioethics and IP:

- Part I gives an overview of the two fields of bioethics and IP.
- Part II sketches core principles in the interaction of IP and bioethics.
- Part III looks at the four main sets of issues that come up in debate.

These are challenging and complex issues. This paper does not offer any readymade or preferred solutions to today's difficult questions concerning bioethics, biotechnology and IP, but presents a way of clarifying the issues to assist those who wish to take an active part in an important set of debates. These issues are discussed more fully in a background study, which discusses some of the leading cases mentioned briefly in this paper.

[1] This overview has been developed in parallel with, but independently from, continuing co-operation within the United Nations system on bioethics issues. An earlier draft was presented to the UN Interagency Committee on Bioethics, and that draft was subsequently drawn on by that Committee as part of a collective process of co-ordinating policy resources to promote awareness. However, this publication is not linked in any way to that Committee. In addition, it does not express an official view of WIPO, its Secretariat or its Member States, and is provided only as a technical overview of the issues discussed.

Navigating the Issues

Some general principles can help to define ethical concerns and expectations in real-world contexts where IP may have an impact on the way biotechnology and biomedical technologies are developed and put to use:

- transparency and access to information
- prior informed consent
- access to the fruits of technology, or equitable sharing of benefits
- pluralism, or accommodation of different value systems.

Another way of navigating through this tangle of issues is to consider four distinct sets of ethical questions:

- What are the ethical aspects of a life sciences technology *as such* (e.g. should research on embryonic stem cells or human cloning be permitted?);
- What are the ethical aspects of a national authority *granting* exclusive IP rights over a technology (e.g. should patents be granted for DNA sequences or for genetically modified mammals?);
- What are the ethical aspects of an individual, a firm or an institution choosing to seek exclusive IP rights over a technology (e.g. should a publicly funded agency patent its research results on a new vaccine production technique?);
- What are the ethical aspects of how an IP right holder *chooses to exercise* its exclusive rights over a technology (e.g. should the holder of a patent over a basic research tool license it in an open or a restrictive way?).

These questions are not insulated from one another – but as the discipline of bioethics covers a wide range of issues, it can be helpful to focus on these distinct aspects and then to consider their interaction. Put simply: when does the bioethics debate concern the technology and its applications, and when does it concern obtaining or exercising exclusive rights over that technology?

I. BIOETHICS AND INTELLECTUAL PROPERTY

What is bioethics?

Ethics is the discipline concerned with what is good or bad, right or wrong. It has theoretical and practical aspects. Ethics seeks to establish norms or standards of conduct (normative ethics), and to analyze the basis of judgments about what is right and wrong (descriptive ethics). Applied or practical ethics is the application of theoretical ethical tools and ethical norms to address actual moral choices. Bioethics deals with the ethical implications of biological research, and the biological and medical applications of research. Specific bioethics issues arise in debates over the dignity of the human being, beginning-of-life and end-of-life issues, consent to medical treatment, freedom of research, the consent of the donor of human genetic material, access to health care and distribution of health resources, and equitable access to the outcomes of biological research, as well as animal protection and environmental ethics.

Ethics versus morality

'Ethics' and 'morality' are often used interchangeably, but they do have different aspects. For instance, practical ethics aims to guide right behavior; 'morality' refers to the underlying moral values that are used to assess what is right and wrong. In the field of IP, some patent laws refer to inventions the exploitation of which would be contrary to *ordre public*[2] or morality, and some trademark laws refer to trademarks that are contrary to morality. In this sense, ' morality' could refer to the shared values of a community, values that might differ from one community to another.

Law versus ethics

Law and ethics are closely interrelated, but they are not the same thing. Some acts that are legal might be considered unethical. As a simple example, it is normally unethical to tell a lie, but only in some circumstances is it a true crime. There can be strong commonality and consistency between the law of human rights, and ethical norms and expectations, but it would actually reduce the legal effect and status of human rights law to regard it as giving ethical guidance only. Sometimes legislators choose not to pass laws on certain issues, as a conscious choice to allow communities' ethical considerations to govern behavior, instead of legal rules. Certain forms of stem cell research may not actually break the law of a particular country, but some might still argue that it is unethical.

[2] "The term *'ordre public'*, derived from French law… expresses concerns about matters threatening the social structures which tie a society together, i.e., matters that threaten the structure of civil society as such." Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement, ICTSD & UNCTAD, Geneva, 2005. *'Public order'* is not an accurate English translation, so the term is generally left in its original language.

What is intellectual property protection?

Intellectual property refers to legal rights resulting from intellectual activity in the industrial, scientific, literary and artistic fields. IP systems protect certain well-defined subject matter by giving limited entitlements to eligible right holders to exclude others from certain uses of the protected material. But an IP right does not give the holder the entitlement to use or market a product.

IP rights are normally created, administered and exercised separately under the national jurisdiction of each country. Their legal effect is restricted to the territory of the states where they are granted. Several international treaties lay down general legal and administrative standards. But these international standards need to be implemented through national laws and may be applied in diverse ways. Some questions of potential interest to the bioethics community are barely dealt with at international level at all, but are left to national or regional authorities to determine. These include the definition of the core concept of 'invention', and the notions of 'morality' and *'ordre public'* that should apply in the interpretation and administration of patent law.

Patents protect eligible inventions, including some forms of biotechnological invention (the exact scope of protectable inventions varies from one national system to another). The patent is the form of IP most pertinent to biotechnology, and most often discussed in the context of bioethics. But a number of other forms of intellectual property may also be considered relevant, for instance:

- Plant breeders rights or plant variety rights systems give IP rights over new plant varieties, generally with an exception for further breeding.
- Copyright and *sui generis* database rights may have ethical implications for access to genetic information.
- Trademarks may help ensure honest commercial practices, for instance with regard to counterfeit medicines.
- Law of confidentiality and the protection of undisclosed information may have ethical implications, for instance concerning obligations to protect individual genetic information.
- Bioethics issues concerning clinical trials and informed consent questions may be relevant to the protection of test data concerning the safety and efficacy of chemical entities, because of the public

interest role of this information, and concerns about duplication of trials involving human or mammal subjects.

- Within the domain of unfair competition, international IP law includes a general requirement to suppress behavior 'contrary to honest commercial practices.'

The ethical basis of IP policy

In principle, appropriate IP protection aims to promote policy objectives that are consistent with widely accepted ethical principles. But there are different ways of analyzing the ethical basis of IP laws. Some IP laws and principles are argued to have a 'natural rights' basis, reflecting an inherent entitlement to just reward and recognition for one's intellectual and creative contributions.

On the other hand, there is also a strong utilitarian flavor to IP law and policy, as a conscious tool to promote social welfare. A utilitarian approach to ethics would assess moral value of a measure or an action according to its contribution to overall social utility or welfare. This utilitarian ethic is increasingly emphasized in current debate on IP as a tool of public policy. It is echoed in the TRIPS Agreement, which provides that the protection and enforcement of IP rights should 'contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.'[3]

The Human Rights dimension

IP and bioethics have bearing on international human rights principles. The Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights provide for

- *the recognition of the dignity of the human being,*
- *the right to the enjoyment of health,*
- *the right to food,*
- *the right to enjoy the benefits of scientific progress,*
- *the right to benefit from protection of the moral and material interests resulting from one's scientific productions.*

The Sub-Commission on Human Rights has called for provisions "in accordance with international human rights obligations and principles that protect the social function of intellectual property".
The Universal Declaration on Bioethics and Human Rights (discussed in the following section) also has relevance for how intellectual property rights in the life sciences are utilized.

[3] Article 7 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.

II. GENERAL PRINCIPLES

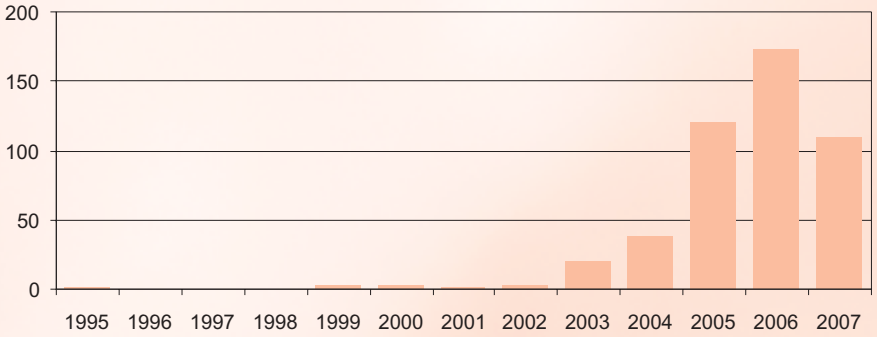
This section discusses the four broad principles mentioned above, namely: transparency, prior informed consent, equitable benefit-sharing, and pluralism.

Transparency

Transparency and access to knowledge are key principles that are both central to bioethical concerns and facilitate the ethical scrutiny of new technologies. The Universal Declaration on Bioethics and Human Rights (UDBHR) calls for the greatest possible flow and the rapid sharing of knowledge concerning medical, scientific and technological developments. As a matter of principle, the patent system is required to promote the flow of timely information about new technologies. It is often through the patent system that a new biotechnology is first, and most fully, disclosed to the public. Additionally, patent documents reveal the identity of inventors, commercial enterprises, as well as governmental and educational institutes that are involved in the creation and development of those technologies. Patent information systems shed light at an early stage on the development of technologies that may have important bioethical implications. They may be used to monitor:

- overall trends and patterns in the development of key technologies (for example, the trends in patenting gene sequences),

International patent activity covering undifferentiated human cells or tissues



PCT applications in class C12N-5/08 by year of publication as at 25.05.07 *(Source Patentscope)*
The rapid growth in patent activity relating to inventions that involve or are derived from human tissues can pose significant bioethical questions. The patterns of ownership and the ways such patents are used are likely to be subject to special scrutiny from a bioethics viewpoint.

- state of the art and recent developments in a particular technology area (such as recent technologies concerning stem cells),
- research and patenting activities of specific firms, institutes and individuals (for instance, the activities of government agencies or a university foundation).

The transparency of the patent system therefore supports ethical scrutiny of biotechnology and can help inform the bioethics debate. However, the sheer volume of information disclosed through the patent system can make it difficult for policymakers and other participants in the debate to make improved use of patent information. Policymakers and others concerned with bioethics issues may need further distillation and analysis of this raw patent data so that the broader implications can be assessed.

Access to information through the patent system does not, however, entail freedom to use that information in practice as technology – precisely because a patent gives exclusive rights over that technology in those countries where it has legal effect. How those exclusive rights are obtained and exercised can also have an ethical dimension, discussed below.

Consent

Consent to use certain inputs to biotechnological research has been a recurrent issue with bioethical implications. There have been cases where genetic materials taken from the human body have been used as inputs for research, leading to inventions, which were subsequently patented. This has raised questions about the need to obtain the prior consent of the human subjects concerned, and whether consent extends to the patenting of outputs from research.

Hairy cell leukemia

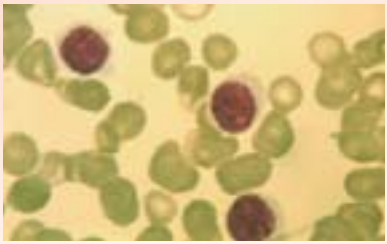


Photo: U.S. National Cancer Institute

Dr. Golde patented a cell line established from Mr. Moore's discarded spleen tissues. A court was confronted with some difficult legal issues. Does consent to have medical treatment imply consent to use of cells in research? Does consent to allow research entail consent to patenting the results of that research? How do legal obligations, differing forms of property, and ethical expectations overlap? The Court, in Moore v. Regents of the University of California, rejected Mr. Moore's claim to ownership interest in the patent, but ruled that a physician had a "fiduciary duty" to inform a patient of any economic or personal interest in using or studying his tissues.

Consent is a key issue in bioethics, and it can be helpful to explore the relationship and the boundaries between legal and ethical aspects of consent to use genetic inputs to research. The issue of recognition of the interests of the donor of human genetic resources may overlap with questions of research involving human subjects in general. It may be necessary to clarify whether consent to take part in medical research or to undergo medical treatment extends to consent to the obtaining of IP based on that research. Various texts state the importance of the consent of the persons involved in research. The UDBHR (Article 6 (II)) provides that "scientific research should only be carried out with the prior, free, express and informed consent of the person concerned".

A similar debate applies to other genetic resources, such as genetic resources obtained through bioprospecting, which are subsequently used in research to create new technologies for which patent protection may be sought. The Convention on Biological Diversity (CBD) makes prior informed consent a condition of access to genetic material of plant, animal or microbial origin. While the UDBHR sets prior informed consent in the context of human dignity and autonomy, the CBD links it to the sovereignty of nations over their resources, and the interests of indigenous and local communities.

Equitable sharing of benefits

A further theme is how the benefits of research should be shared, and what it means for the sharing to be equitable. This theme potentially has both legal and ethical aspects. Human rights law – as expressed in the

The Hagahai Case

The Hagahai are an indigenous community in Papua New Guinea. Many members of the tribe carried a retrovirus that normally causes T-cell leukemia (a disease caused when human immune cells themselves are infected with the virus), but they appeared immune to the disease. Researchers established a cell line of T-cells infected with the HTLV-1 virus which had potential use in screening for this form of leukemia and in developing a vaccine. A patent on the cell line was issued in 1995, in the name of the US Department of Health. But patenting a cell line developed from a blood sample from an indigenous donor raised bioethics issues that are still debated today, ten years after the patent was disclaimed and dedicated to the public domain in 1996. The patent sparked controversy on several issues: consent, including cross-cultural communication and recognition of diverse value systems, the ethics of patenting of inventions derived from human tissue, and equitable sharing of benefits.

Universal Declaration on Human Rights – accords everyone the right "to share in scientific advancement and its benefits" while affirming the everyone's right "to the protection of the moral and material interests" resulting from their scientific productions. This equitable balancing of interests finds expression in other legal instruments. For example, the CBD establishes as an international legal principle that the benefits of the use of genetic resources should be equitably shared. Similarly, explicitly in a bioethics context, the UDBHR calls for "equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries". The FAO International Treaty on Plant Genetic Resources for Food and Agriculture establishes a multilateral system of benefit-sharing for the use of plant genetic resources. As one means of generating benefits from biotechnological research, the IP system and in particular the patent system could have a potential ancillary role in helping to generate, clarify and equitably apportion such benefits. How to find this balance of interests – how to determine what is an equitable sharing of benefits – remains

Fair use or unjust enrichment?

Can patients that provide tissue samples expect that the research results remain in the public domain to promote prevention and treatment of the disease? This was at issue when sufferers of Canavan disease offered samples to a research hospital, which led to a patent on the gene causing the disease. In a lawsuit the patient group tried to assert legal rights against the commercialization of the research results (Greenberg et al. v. Miami Children's Hospital Research Institute). The case was settled between the parties: the patient group agreed not to further challenge the patent and the hospital to allow royalty-free research by institutions, donors, and scientists.

Humanitarian Licensing

The Public Intellectual Property Resource for Agriculture (PIPRA) initiative has developed licensing language for a humanitarian use reservation of rights, which includes the following: 'University hereby reserves an irrevocable, non-exclusive right in the Invention/Germplasm for Humanitarian Purposes. Such Humanitarian Purposes shall expressly exclude the right for the not-for-profit organization and/or the Developing Country, or any individual or organization therein, to export or sell the Germplasm, seed, propagation materials or crops from the Developing Country into a market outside of the Developing Country where a commercial licensee has introduced or will introduce a product embodying the Invention/Germplasm.' (Source: www.pipra.org)

controversial. It is another area where formal legal requirements may overlap or be influenced by ethical ideas about what is fair or equitable. This may go beyond the idea of simply apportioning shares of the financial returns – it may also be expressed in terms of providing favourable access to the technology. For instance, some research universities are developing 'humanitarian licensing' measures which provide guarantees of access to life sciences technologies to serve the needs of developing countries; while not legally bound to do so, some follow this policy for ethical reasons.

Pluralism: conciliating different value systems

A community's sense of morality and the values of that community may guide ethical judgments. Naturally, these values differ between societies, and the moral basis of ethical judgments will also differ. A technology that is considered immoral in one country may be considered morally acceptable, indeed positively desirable, in another. Some aspects of stem cell research fall into this category. This raises the question of how the IP system should deal with these different value systems, for instance in the interpretation and application of exceptions in patent law for technology that is contrary to morality.

Patenting higher lifeforms: ethical diversity?

There has been much ethical debate about the patenting of mammals – such as mice bred to be highly susceptible to cancer, for use in medical research. Some argue that patenting genetically modified mammals – however inventive they may be – is inherently immoral. Others take the view that a utilitarian balancing of welfare effects is required. Still others view the question as ethically neutral.

Photo by Harvard Medical School, © Harvard College

III. FOUR KEY ASPECTS OF IP AND BIOETHICS

A wide range of ethical questions arises in the debate over biotech IP rights. At times these questions can relate more to the technical field than to the IP right in relation to a certain technology. Ethical judgments may concern choices by the State or by government authorities, or may apply to the behavior of individuals, firms or institutions. Such issues are not clinically isolated from one another. Nonetheless, given the complexity of issues, it can be helpful to observe some conceptual, legal and ethical distinctions.

Working through the ethical issues can therefore be facilitated by grouping them into four clusters:

- The ethical aspects of a technology as such (e.g. should research on embryonic stem cells be permitted?);
- The ethical aspects of national authorities granting exclusive IP rights over a technology (e.g. is it contrary to morality to patent a genetically modified mammal? What ethical considerations should be weighed?);
- The ethical aspects of an individual, a firm or an institution seeking exclusive IP rights over a technology (e.g. should a publicly funded agency patent its research results? When is it unethical to do so – for instance, in the absence of any necessary consent?);
- The ethical aspects of how an IP right holder should exercise exclusive rights over a technology (e.g. should the holder of a patent over a basic research tool license it in an open or restrictive way? Are public institutions ethically obliged to license medical technology from an explicitly humanitarian perspective?).

The following examples may help to illustrate and distinguish between these four aspects:

Ethical aspects of technology as such

This aspect concerns ethical judgements over such matters as forms of research, including research involving human subjects and genetic materials, and over technologies such as genetic engineering. Bioethical issues may arise over such technologies whether or not they are patented. Important bioethical issues, such as prior informed consent, apply to the very practice of research, long before there is any research

Stem Cells

The "Edinburgh" case concerned a patent granted by the European Patent Office on a method of selectively culturing stem cells. Are human or animal embryonic stem cells patentable? Should concerns about the ethics of the research influence decisions about whether to patent research outcomes?

outcome that may or may not be patented. Research on stem cells, particularly embryonic stem cells, has raised considerable ethical debate. The question of whether to permit stem-cell research at all is distinct, and may have distinct ethical aspects, from the question of whether the outcomes of such research should be eligible for patent protection. As another example, some have argued that genetic use restriction technologies (GURTs), which prevent farmers from using harvested seeds for future crops, may be unethical, or alternatively should be legally prohibited; others argue that it is a legitimate technology with a valuable commercial role. But such ethical questions are strictly distinct from whether a patent should be granted over such technologies; a patent on a GURT does not entitle its owner actually to practice the technology, and cancelling a patent on the technology equally doesn't prevent its use.

Certain practices may be considered unethical and contrary to morality and consequently directly prohibited. However, such prohibition alone does not automatically prevent the grant of patents related to this knowledge. Not all countries have the same ethical or legal restrictions. Many patent laws exclude explicitly the grant of patents where the exploitation of inventions is considered to be contrary to *ordre public* or morality (such laws are therefore relevant to the following aspect).

On the other hand, biotechnological research in most cases is not merely allowed, but actively encouraged by society, such as the development of new pharmaceuticals. Many technologies have a positive ethical aspect; and some technologies may have ethical and unethical uses. Even pharmaceutical research that is initially promising, but ultimately unsuccessful, may be encouraged and welcomed by society as having a positive ethical character. Nonetheless, it is generally illegal to market a new pharmaceutical without the necessary regulatory approval that follows the successful conclusion of extensive clinical trials.

Life sciences technology: some ethical issues

- What life science technologies does society wish to promote and encourage, and what technologies are disapproved for ethical reasons? How to reconcile ethical differences over the moral implications of controversial technologies?
- What ethical expectations and obligations surround research practices and procedures in the life sciences?

Ethical aspects of granting exclusive IP rights over a technology

It is a separate ethical or moral question to consider the kinds of inventions over which national authorities should grant patent rights. As we have noted, some technologies are considered morally desirable (say, new surgical methods), but are still excluded from patent protection in some countries. In other cases, patent protection may be denied in some countries exactly because it would be contrary to morality to commercially exploit the technology (say, methods of cloning human beings). In practice, national patent laws typically preclude some forms or categories of technology as being ineligible for patent protection – as being 'unpatentable subject matter.' This question has a long history in patent law, and international negotiators, national legislators, patent authorities, and courts have all been involved in establishing and applying rules in this area.

US Library of Congress

*In 1912, the U.S. judge, **Learned Hand**, had to decide whether the Japanese medical researcher Takamine had created a patentable invention when he isolated and purified the naturally occurring hormone adrenalin. Allowing the patent, he said that the isolated hormone "became for every practical purpose a new thing commercially and therapeutically" when it was isolated for clinical use, as opposed to when it was naturally present in the human body.*

For example, a recurring issue in the application of patent law to biotechnology – dating back a century or more – is how to distinguish a patentable invention from a mere discovery. For instance, when should a patent be granted for a chemical structure when newly isolated from the human body?

What the international rules say

The WTO TRIPS Agreement permits, but does not require, national laws to exclude certain forms of inventions as patentable subject matter. Some of these possible exclusions have bioethical aspects. Members of the WTO "may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law" as well as "diagnostic, therapeutic and surgical methods for the treatment of humans or animals" and "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes." Plant varieties must be protected "by patents or by an effective sui generis system or by any combination thereof".

Some national legislatures choose to exclude from patent protection classes of inventions that would otherwise be eligible. Such choices can be influenced by ethical concerns, within a broader mix of public policy considerations. For instance, guided by various public policy reasons, including ethical considerations, some countries have chosen to exclude from patentability methods of medical treatment, even when they would otherwise be considered new, inventive and useful. This exclusion is based, of course, on a public policy choice not to cover such methods under the patent system, not because of any negative ethical judgment about novel medical treatments which may be of great social benefit. By contrast, other countries choose to allow patents for methods of medical treatment, presumably judging the grant of patents on such methods to have a predominantly positive ethical and policy character.

In parallel with the debate about the ethics of genetically modified organisms, there has been extensive debate about the ethics of patenting life forms, particularly higher life forms such as genetically modified mammals. National policymakers have chosen to resolve these issues in different ways; these differences correspond in part to different ethical perspectives and other social values.

Controversy continues to swirl around the patenting of genes or DNA sequences, especially without disclosing any specific known utility. Is it morally sound for society to grant exclusive property rights over nucleotide sequences that are derived from the human genome, when no specific use has been found and disclosed for the patented sequence? Are human genes ethically distinct from any other nucleotide sequences – in general, and especially when patents are concerned? Some have argued, on various policy, legal and ethical grounds, that the bare information provided in human gene sequences should not be patented. Others point to the positive benefits for society of securing clear property rights over useful genes, isolated from their natural setting, to promote the investment of resources in the creation of new forms of diagnosis and therapy. But this debate does not take issue with the ethical aspects of the sequencing of the human genome as such, which has been widely welcomed.

Another choice policymakers and, in individual cases, the patent authorities have to make is to define and apply the concepts of morality and *ordre public* guiding the application of specific exceptions to patentability based on these criteria. For example, the European Biotechnology Directive (98/44/EC) articulates the principle that inventions should be

considered unpatentable where their commercial exploitation would be contrary to the *ordre public* or morality. As an example of technology that is unpatentable on the basis of that it is morally unacceptable, it cites "processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes".

Patenting life sciences technology: some ethical issues

- What are the ethical questions that need to be weighed when considering whether or not to patent a controversial life sciences technology?
- When should a patent be denied on moral grounds for a life science technology that would otherwise be considered patentable? How should divergent ethical perspectives be reconciled?
- Should the grant of a patent over a certain technology be considered ethically neutral, distinct from regulation of that technology as such, or should it be considered a kind of badge of society's ethical approval of the technology?

Ethical aspects of seeking exclusive IP rights over a technology

We have just reviewed the ethical dimension of the decisions within national legislation to determine that some inventions should be unpatentable. But the actions and decisions of individuals also have an ethical dimension. Thus there may be ethical considerations in the choices of an individual actor – a firm, a research institution, or a university – over whether or not to pursue a patent for a particular invention, even if the invention as such would be legally eligible for a patent under national patent law. Again, there is an uncertain overlap between the legal and ethical aspects.

Thus, some argue that there should be constraints on seeking a patent for an invention which is based on genetic resources or traditional knowledge obtained without prior informed consent and without equitable benefit-sharing. This argument can arise even when the claimed invention would otherwise be eligible for patent protection. But are these constraints moral, legal, or both – or should moral constraints harden into legal ones? In fact, legal measures to address these concerns have been introduced in some national laws, and have been proposed for international law. This issue has therefore been dealt with as a legal matter, in terms of both international

and national law, but it may also have a continuing ethical aspect. For instance, what if the traditional knowledge that led to an invention was obtained strictly legally – in the sense that no law was broken – but nonetheless the actions of the patent applicant in obtaining and using that knowledge are considered unethical? Some laws have constraints on obtaining or exercising patent rights when they have been secured through inequitable behavior. While this is technically a legal question it may also be considered to have an ethical dimension – what forms of inequitable or improper behaviour should graduate from being considered simply unethical to being illegal, and prevented or punished by legal measures?

Seeking patents on life sciences technology: some ethical issues

- What are the strictly ethical considerations – apart from legal requirements – that should influence the choice whether or not to seek a patent on a new life sciences technology?
- Does the source of funding or the nature of other inputs to the invention – say human tissue samples – affect the ethical dimension of applying for a patent?

Ethical aspects of exercising exclusive rights over a technology

Some ethical questions do not directly concern the ethics of a technology as such, nor whether that technology should be patented, but rather arise over the ethics of how a patent holder chooses to exercise the rights granted by a patent. In some cases, there may be ethical questions about how a patent holder should exercise his or her patent. Certain ethical constraints could be argued to apply still when a patent holder operates within his or her legal entitlements, while still attracting ethical scrutiny.

How a patent right is licensed becomes important when there is strong public interest in the patented technology. The licensing of patented diagnostic tools has been debated recently. In particular, if a patent holder has exclusive rights over a diagnostic tool, and chooses to license those rights in a restrictive way, could it be argued that there are ethical obligations on that patent holder to grant wider access, even if the licensing approach is strictly legal? Yet we often rely on private capital to carry forward valuable technologies to reach the public: how do differences in the public/private mix of inputs into research and development affect our ethical expectations, as against legal obligations on patent holders?

Electron micrograph of a breast cancer cell

BRCA-1 and BRCA-2 are two genes linked to susceptibility for breast and ovarian cancer. The risk of falling ill increases if these genes show certain mutations. Identifying the mutations is therefore important for diagnosis and for monitoring higher-risk women. Myriad Genetics Inc., in collaboration with the University of Utah, sequenced the BRCA-1 gene, and applied for patent protection in 1994. The ensuing multifaceted debate over this patent partly concerned the ethical dimension of how a patent on a valuable diagnostic test should be licensed.

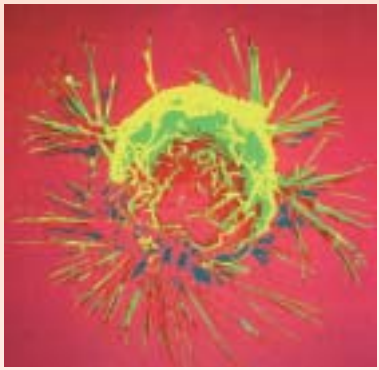
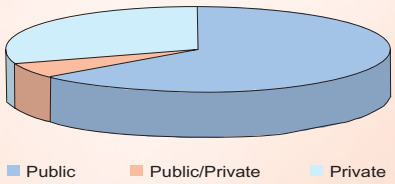


Photo: U.S. National Cancer Institute

Public interest safeguards apply to licensing and exploitation of IP rights. Legal restrictions delimitate how IP rights can be exercised in the marketplace. This includes the application of general competition principles, rules against abusive licensing practices and the application of specific remedies under patent law (such as compulsory licensing). But how one chooses to exercise IP rights can also be influenced by the ethical, 'best practice' and policy guidelines on licensing of key technologies. Examples include a growing practice among university technology offices to include model humanitarian provisions in their technology licensing agreements, and a set of OECD Guidelines for the licensing of genetic inventions which suggest a relatively open approach to licensing, particularly for genetic tests.

Who is applying for patents on undifferentiated human cells or tissues? PCT publications 1995-2007 by applicant



Informal breakdown of the status of applicants using the PCT system for patents in IPC class C12N-5/08 (Source: Patentscope)

Access to the benefits of scientific research may also be developed through other licensing structures. For instance the BiOS initiative characterizes open source licensing in the life sciences as follows:

"Usually, licenses for patented technology impose strict conditions on the user, commonly involving fees or royalties for use of the

materials or methods or both. Material Transfer Agreements (MTAs) typically impose the condition that the technology may only be used for certain purposes, often not allowing the development of products. Instead of royalties or other conditions that disfavor creation of products, under a BiOS-compliant agreement, in order to obtain the right to use the technology, the user must agree to conditions that encourage cooperation and development of the technology.

These conditions are that licensees cannot appropriate the fundamental "kernel" of the technology and improvements exclusively for themselves. The base technology remains the property of whatever entity developed it, but improvements can be shared with others that support the development of a protected commons around the technology, and all those who agree to the same terms of sharing obtain access to improvements, and other information, such as regulatory and biosafety data, shared by others who have agreed.

In other words, to maintain legal access to the technology, you must agree not to prevent others who have agreed to the same terms from using the technology and any improvements in the development of different products." (Source: *www.bios.net*)

Exercising exclusive rights over life sciences technology: some ethical issues

- What are the strictly ethical factors – apart from legal regulation – that should be weighed in determining how best to exercise the rights under a patent on a new life sciences technology?
- How does the ethical dimension of exercising a patent change according to factors, such as the degree of public sector funding, or the contribution of human genetic samples, to research activities? Is it different for public and private sector players? How?
- Does the humanitarian value of a patented technology affect the ethical dimension of how the patent should be exercised or licensed?

IV. CONCLUSION

This paper does not cover every aspect of the interaction of IP and bioethics, and offers no answers to the questions raised. Rather, it is intended only to stimulate further debate and research, as well as to contribute to a structured approach to the questions raised. Some general questions that emerge include the following:

- How to distinguish the ethical and legal aspects of issues concerned with life sciences patenting – and how do those complementary aspects interact? How far, for instance, should legal rules be determined by ethical judgments?
- Is a patent a badge of ethical approval for a life science technology? When should ethical questions be dealt with distinctly from the patent process?
- What approaches can be taken to reconciling divergent moral views over patenting life sciences?
- Apart from direct legal regulation of patent holders, what are the distinct ethical obligations or expectations that should guide how patent rights are exercised and licensed? And what is special about life science technologies as against the general run of technology?
- How to articulate the linkages between IP law and policy on the one hand, and bioethics and humans rights law on the other: especially, how can the IP system be applied positively to respond to bioethics concerns and to support recognition of human rights?

For more information contact the
World Intellectual Property Organization:

Address:
34, chemin des Colombettes
P.O. Box 18
CH-1211 Geneva 20
Switzerland

Telephone:
+41 22 338 91 11

Fax:
+41 22 733 54 28

e-mail:
wipo.mail@wipo.int

or its New York Coordination Office at:

Address:
2, United Nations Plaza
Suite 2525
New York, N.Y. 10017
United States of America

Telephone:
+1 212 963 6813

Fax:
+1 212 963 4801

e-mail:
wipo@un.org

Visit the WIPO website at:
http://www.wipo.int

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http://www.wipo.int/ebookshop

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