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مكتبة الإسكندرية

BioVisionAlexandria
www.bibalex.org/bioalex2004conf

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Intellectual Property & the Gene Patent Debate

In the midst of today's globalization and life science revolution, intellectual property rights have taken on a crucial role. Trade, patents and the questions surrounding them have brought forth many arguments. With these controversies come the debates dealing with the patenting of biological material, and especially genes. Should a gene be monopolized, if even for a limited period of time, or should it be kept in the public domain?

Intellectual property rights are the rights given to people over the creation of their minds. They are divided into two main categories. One is related to copyright, such as rights of authors, performers and producers. The other is related to industrial property, such as trademarks, industrial designs, trade secrets and patents.

A patent is an intellectual property right involving inventions, advances made in a technical field. An invention or discovery must be new, be practically useful and involve an inventive step in order to be "patentable". The requirement for an inventive step ensures that the invention or discovery is different from what has been previously known. Patents give the inventor the right to stop others from making, using, importing, or selling the invention without permission for a certain period of time.

Governments grant patents after deciding whether an invention qualifies for one or not. They can also refuse to grant them for reasons related to public welfare. However, patents are territorial, meaning that those granted by the Egyptian government are only valid in Egypt. This also means that the protection rights do not extend to any other country. If the inventor wants protection outside his country, he will have to get a patent from the specific foreign government.

But what is behind all this? The whole aim is to create a balance between public benefit and private gain. Inventions, without a doubt, are important to the human race and should be encouraged. However, costs of research and development are sometimes very high, and could discourage many people. Therefore, the protection of intellectual property aims to encourage inventors and

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INSIDE

Join us from **3-6 April 2004** at the Bibliotheca Alexandrina, where talks will target Ethics, Patents and the Poor.

creators because they can expect to earn some future benefits from their creativity by being the only ones who can produce or use their invention for a period of about 20 years. In return, the details of the invention are made available for others to study, even during the time of protection. When the protection period ends, the invention becomes available for others to use.

However, we have a dilemma when it comes to biotechnological inventions. Patents for DNA sequences have been issued for over twenty years, and most major industrialized countries, now, routinely grant patents for living organisms such as yeasts, bacteria, viruses, mammalian cell lines, and plants. Other patentable biotechnological inventions include vaccines, antigens, antibodies, and chemical processes using enzymes or living organisms. Yet, we must ask ourselves whether patents actually provide a positive force in science, for there are many claims to the contrary.

It all began with the Diamond *versus* Chakrabarty case in 1980, when the Supreme Court decided that a bacterium genetically engineered to consume oil spills was patentable. This marked a turning point in the patentability of bio-engineered organisms in the US, and with it, the medical and agricultural biotech industry was born. At the same time, it started a rush to claim patent rights on genes, and genetically modified animals and plants. But the enforcement of patent regulations, both by private companies and public researchers and institutions, is relatively new, and is raising concerns among clinicians and researchers who depend on this genetic information.

The biological and medical importance of gene sequences lies more in the wealth of information they contain than in the simple description of their structure. The depth, complexity, and physiological implications of that information are not obvious from the simple explanation of the sequence, but can only be determined by future experimentation. Such experimentation would be affected by the patent system, since during the years of validity of a gene patent, academic scientists may discontinue research for fear that their institution could suffer a costly lawsuit from a patent holder – usually a private corporation.

Successful patents can therefore have a dramatic impact on medical research as scientists wanting to use a patented gene to develop a drug or a diagnostic test will have to pay a license fee to the patent holder. That could prevent many researchers who cannot afford it, as well as discourage drug companies from investing in gene therapies if large portions of their profits will be used to pay license fees. As these tests are performed in fewer and fewer labs, opportunities for medical training become limited. License fees can also result in increased drug prices, consequently limiting the use of drugs by the poor.

Many believe that it is acceptable for companies to patent treatments that target specific genes, but not to patent the genes themselves. The principle can be expressed by analogy where protection of inventions such as the breathing apparatus is allowed, but not of the oxygen it uses. When one company has the right of exploitation, they in turn possess a monopoly and here rests the problem.

Sites on Patents

www.dnapatent.com
www.gene-watch.org
www.uspto.gov
www.patent.gov.uk
www.jpo.go.jp
www.egypo.gov.eg
www.wipo.int

A patent application contains a full technical description of the invention that the applicant wishes to protect

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Others question whether patenting genes and modified plants might restrict the ability of developing countries to use current biotechnology tools for enhancing their own crops and development. Some argue that patent protection claimed by multinational seed companies is unfair because varieties to be patented are bred using genes maintained by farmers of the developing world. Furthermore, the use of these genes is often not paid for.

On the other hand, it is claimed that patent protection provides an incentive for discovering genes, and is thus actually necessary for further research. If companies are not allowed to patent the products of their research, then other companies can exploit their findings to profit themselves. With no safeguards against this, companies will stop funding their Research and Development (R&D) departments, and the exploration of this potentially revolutionary area will end. Costs of drug discovery and development can reach hundreds of millions of dollars, and the risk is high. Banning patents would therefore take away the profitable incentive to invest in this area, and medical research would be hindered.

Gene patents have been in the spotlight since March 2000, when British Prime Minister Tony Blair and US President Bill Clinton stated that raw gene sequences should be kept in the public arena. And with this began a debate, which persists till now. It is this dilemma between private profit and public good and the need to balance between them that brings many speakers to **BioVisionAlexandria 2004**.

Join us from **3-6 April 2004** at the Bibliotheca Alexandrina, where talks will target Ethics, Patents and the Poor. The debate over whether patents offer a propelling force in science will be tackled during the parallel sessions. It goes without saying that biotechnological advancements hold great benefit and treasure, but it is our duty as humans to make sure that there be no self-interested barrier to genome research and the welfare of mankind.■

Register Now at
www.bibalex.org/bioalex2004conf

Speakers at BioVisionAlexandria 2004 on Biotechnology & Patents

Federico Mayor, former Director-General of UNESCO, is currently the President of the Foundation for a Culture of Peace in Madrid, Spain and Professor at the Center for Molecular Biology at the Autonomous University of Madrid.

"In all times and in all cultures the advancement of scientific knowledge and technological skill has been accompanied by ethical doubts, whose terms, intensity and exponents may vary."

Federico Mayor

Uma Lele is Senior Advisor at the Operations Evaluation Department of the World Bank. She was the first woman to obtain a Ph.D. in Agricultural Economics at Cornell University, and the first fellow of the American Agricultural Economic Association from a developing country, India.

"We have to address the consequences of plenty for the poor of the world. Agriculture needs to become central to development again."

Uma Lele

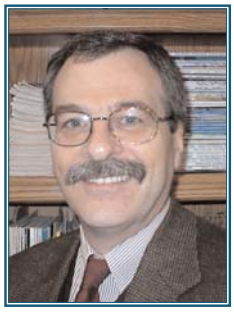
Francisco Reifschneider is the Director of the Consultative Group on International Agricultural Research (CGIAR), and before joining the CGIAR, he was Head of International Cooperation of the Brazilian Agricultural Research Corporation (EMBRAPA).

"As we have seen in the biotechnology revolution, speed of change has been increasing, therefore the need to adapt to these changes and the need to be responsive are indeed critical."

Francisco Reifschneider

Philip Pardey is Professor of Science and Technology Policy in the Department of Applied Economics, University of Minnesota. Prior to that he was a senior researcher at the International Food Policy Research Institute, IPFRI, Washington DC, (one of the 16 international research centers that form the Consultative Group on Agricultural Research, CGIAR) where he led the institute's Science and Technology Policy Program.

"While biotechnology has been passionately debated in affluent nations - especially in Europe and the United States - it is important to remember that poorer nations have a stake in this debate as well."■

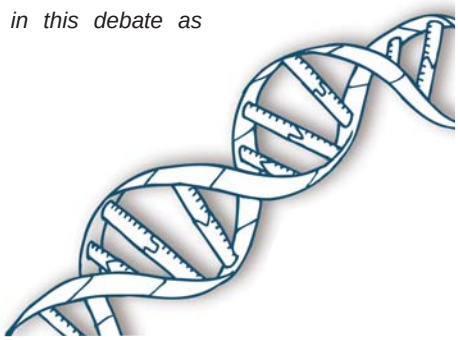


Philip Pardey

Suman Suhai is a geneticist and Head of Gene Campaign, a non-profit group based in New Delhi, dedicated to protecting the genetic resources of the countries of the South, and the rights of farming and tribal communities.

"The design of patents for biological material will ultimately lead to tremendous legal chaos. The only people who will benefit are lawyers and rich countries."

Suman Suhai



NEWSBULLETIN!

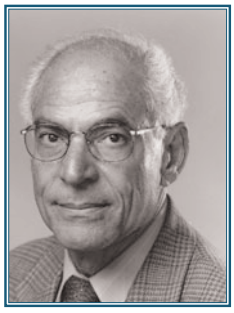
Nine Nobel laureates are coming to **BioVisionAlexandria 2004!** Meet them on Nobel Day, 3 April 2004:

- Werner Arber
- Sir James Black
- Jean Dausset
- Jean-Marie Lehn
- Ryoji Noyori
- Sherwood Rowland
- Wole Soyinka
- Harold Varmus
- Ahmed Zewail

Ahmed Zewail

International Egyptian figures of science attending BioVisionAlexandria 2004:

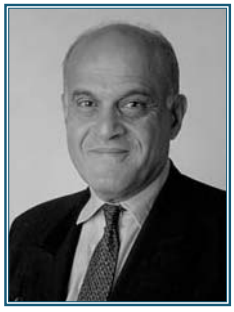
- Dr. Farouk El Baz is Research Professor and Director of the Center for Remote Sensing and is President of the Arab Society of Desert Research.
- Sir Magdi Yakoub is one of the world's most famous heart surgeons, having saved countless lives throughout his career!
- Dr. Ahmed Zewail is the 1999 Nobel laureate in Chemistry and is presently the Linus Pauling Chair Professor of Chemistry & Professor of Physics, and the Director of the NSF center, the Laboratory for Molecular Sciences (LMS), at Caltech.



Farouk El Baz

Interview of Dr. Ismail Serageldin, Director of Bibliotheca Alexandrina and Conference Chairman, was in the November 2003 issue of BioVision newsletter. In it, he commented on why he views Ethics and Patents as the central issues of Life Sciences in the developing countries.

Congratulations to our Head of Graphics Department, Dr. Medhat Nasr on winning the 2003 Egyptian Triennale Graphics Prize for his designs.



Magdi Yakoub

***Science* magazine may be BioVisionAlexandria's partner**, similar to *Nature*'s role in The World Life Sciences Forum BioVision 2003.

Pre-conference seminars about biotechnology will be held at the Bibliotheca Alexandrina. If interested, please contact Ms. Dina El-Sammak (dina.elsammak@bibalex.org) to know the schedule.

BioVisionAlexandria 2004 conference now appears on Google and Yahoo search engines.▪

Ismail Serageldin

Questions & Answers

Does 'intellectual property' always mean 'patent'?

The term 'intellectual property' does not always mean the term 'patent', because according to the World Intellectual Property Organization (WIPO), intellectual property includes copyrights, trademarks, industrial designs and geographic indications of source, in addition to patents.

Is a patent similar to a permit to put a product on the market?

No, because a patent only gives the inventor the right to prevent others from using or producing the patented invention. Patented pharmaceuticals still have to be tested and approved before they can be marketed.

What information can be found in a patent application?

A patent application contains a full technical description of the invention that the applicant wishes to protect. It also provides bibliographic data about the inventor and applicant, and includes a description of the invention.

How can patent information be useful?

Patent information helps to avoid redeveloping existing products, and thus helps to avoid "re-inventing the wheel". This is to evade wasting resources. It can also be used to find out which companies are active in a specific field and what they are doing.

What is the approximate status of filing on human genes and gene sequences?

To date, claims have been filed on more than 127,000 human genes or partial human gene sequences.

What are "expressed sequence tags" (ESTs)?

ESTs are fragments of genes that have been isolated by automated processes, often randomly. Sequencing of the human genome depends mainly on isolating ESTs, seeing where they overlap, and then patching them together to form entire genes. Both the process and the ESTs it finds can be patented.

What is 'biopiracy'?

Biopiracy refers to the unauthorized and uncompensated taking of biological and genetic resources by individuals or institutions that seek exclusive monopoly control (patents or intellectual property) over these resources.■

Did You Know ?

- The first patented transgenic animal was the Harvard mouse, a mouse that contained genes from another species. These genes were oncogenes, meaning they trigger cancer growth. This has facilitated studying the effects of anti-cancer drugs and suspected carcinogens, without human testing. Harvard's patent was particularly broad, covering any nonhuman mammal that had an oncogene inserted.

- Protease inhibitors aren't a cure for HIV infection, but they have greatly helped reduce the number of deaths from AIDS by making the disease manageable. However, through patenting, prices are set very high and many of the people who need this drug cannot afford it. This has raised a major criticism of patenting life-saving drugs.

- Growing new tissue to replace a failed spinal cord may be possible in a decade or so. The Vacanti brothers received a patent for a technique that has shown promise in treating spinal cord injuries in rats. It involved the use of a special hydrogel containing adult stem cells that grew into nerve cells for the spine.

- Hepatitis B death rates have fallen greatly, mainly because of an effective vaccine that has become a childhood inoculation in the past decade and a half. This high-tech vaccine is the first produced using genetic engineering, which facilitates the creation of antigens in great quantities.

- The race to patent genes and GMOs began in 1980, when the U.S. Supreme Court ruled in the Diamond *versus* Chakrabarty case that a genetically modified organism could be patented. The Court decided Chakrabarty's oil-eating bacteria was a novel invention and granted the patent. Because of this ruling, the U.S. Patent and Trademark Office has permitted the patenting of genes and gene fragments.

- The generics industry is expected to expand due to approximately $82 billion's worth of successful brands coming off patent protection by 2007. This provides unprecedented opportunities for generic manufacturers.■

Bibliotheca Alexandrina is offering research grants for young Egyptian postdoctoral researchers

Candidates must have the following eligibility requirements:

1. **A PhD degree obtained during the past five years (after 1998) in one of these fields:**

   - Agricultural Sciences
   - Biology
   - Biochemistry and Biophysics
   - Chemistry
   - Physics and Astronomy
   - Earth Sciences
   - Information Technology
   - Mathematics
   - Medical Sciences
   - Engineering Sciences and Technologies

2. **Currently working at a University or a Research Center/Institute in Egypt (public or private).**

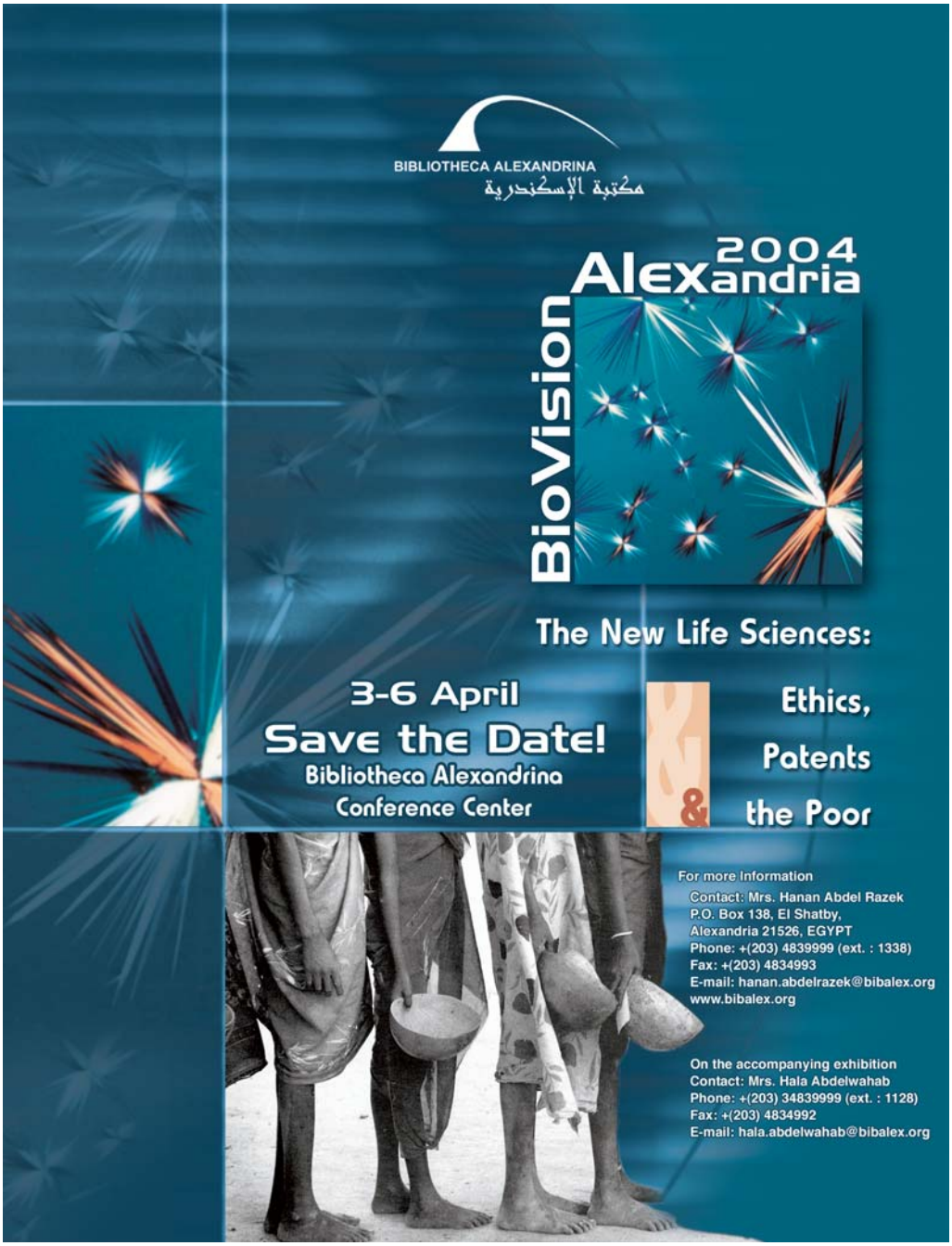
3. **Currently engaged or can arrange to work in a joint research project with foreign counterpart(s) at a University or a Research Center abroad.**

If you meet all the above requirements and are looking for research funds, then you are eligible to apply for Bibliotheca Alexandrina research grants. You will be required to submit the application form, which is available at: **www.bibalex.org/cssp/add.htm**

Please apply before 15 February 2004.

The Center for Special Studies and Programs

The Center for Special Studies and Programs (CSSP) is affiliated to the Bibliotheca Alexandrina, and aims to play a significant role in the progress of science and technology in Egypt. Today, development is highly dependent on the capacities of science and technology, and the need for research excellence is vital. To this effect, the CSSP will help researchers and scientists get the best support needed to advance their work through international collaborations.



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Visit the BioVisionAlexandria 2004 Book Fair during the conference !