



Geneva, 15 December 2008

**Policy Guidelines on Intellectual Property of
the INTERNATIONAL CENTRE
for GENETIC ENGINEERING and
BIOTECHNOLOGY (ICGEB)**

International Centre for Genetic Engineering and Biotechnology

A centre of excellence for research and training in genetic engineering and biotechnology with regard to the needs of developing world



International Centre for Genetic Engineering and Biotechnology (ICGEB)

- **ICGEB** is an international, intergovernmental organisation conceived as a centre of excellence for advanced research and training in genetic engineering and biotechnology with special regard to the needs of the developing world
- It holds out the prospect of **advancing knowledge** in the fields of:
 - ❖ Biomedicine
 - ❖ Crop improvement
 - ❖ Environmental protection/remediation
 - ❖ Biopharmaceuticals production
 - ❖ Biopesticides production
- It **strengthens** the **research capacity** of its members through training and funding programmes and advisory services, representing a comprehensive approach to promoting biotechnology internationally



Originally...

ICGEB

TRIESTE COMPONENT
& HEADQUARTERS



NEW DELHI
COMPONENT



Today...

ICGEB

TRIESTE COMPONENT
& HEADQUARTERS



NEW DELHI
COMPONENT



CAPE TOWN
COMPONENT



And...



...a network of 38 affiliated centers worldwide



.. SLOVENIA ... UNITED ARAB EMIRATES ... IRAN ... Some of the 38 ICGEB Affiliated Centres world-wide ... SERBIA ... POLAND...

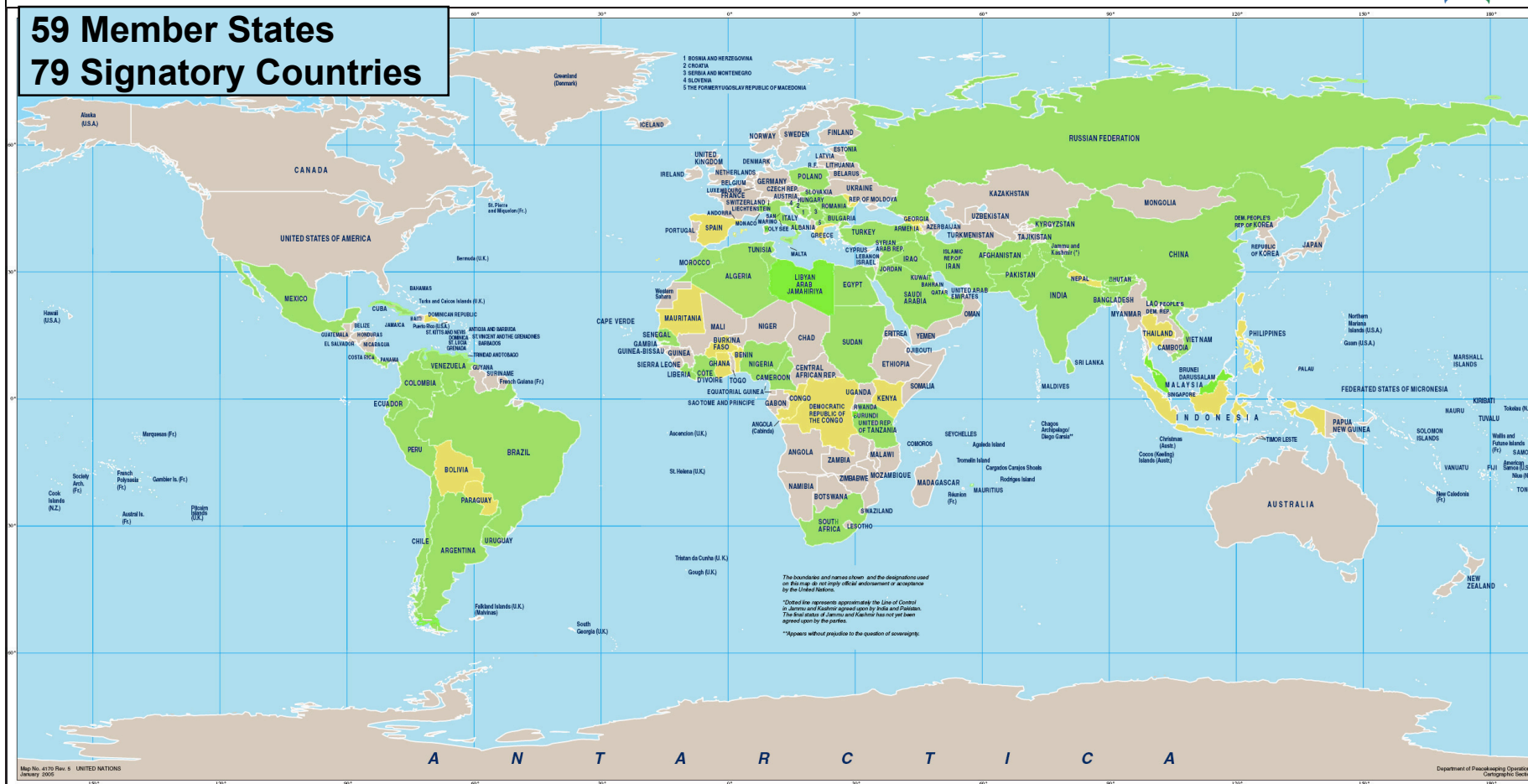


وزارت علوم، تحقیقات و فناوری
پژوهشگاه ملی مهندسی ژنتیک و زیست فناوری
National Institute of Genetic Engineering & Biotechnology



THE ICGEB CONSTITUENCY

59 Member States
79 Signatory Countries



One Centre: three Components, two Outstations and a Network of Affiliated Centres



Developing **knowledge**

- **Research projects**
- **Long term training**
- **Short term training**
- **Collaborative research programme**
- **Cooperation with industrial sector**
- **Scientific services**
- **Institutional services**



...facts & figures

- International peer reviewed publications ⇒ **>1.700**
- Long term fellowships ⇒ **600 awarded**
- Short term training ⇒ **9.500 trainees**
- Research grants ⇒ **338 awarded (Euro 13.5 million)**
- Patents ⇒ **55 filed**
- Technology transfer agreements ⇒ **80 signed**

ICGEB in a nutshell...



INTERNATIONAL INSTITUTION owned by Member Countries

CUTTING-EDGE RESEARCH BY SCIENTISTS FROM OVER 50 COUNTRIES - Equal cooperation North-South

SCIENTIFIC EXCELLENCE as a major goal - Research activities supervised by an International Scientific Council including several Nobel laureates

Hands-on **CAPACITY BUILDING** for sharing development - Specific courses held all over the world and long-term training (PhD course + post-doctoral) in the 3 Components

Research focus on **TOPICS OF OUTMOST RELEVANCE FOR DEVELOPING COUNTRIES** (HIV, malaria, tuberculosis, vanguard plant biotechnology and biosafety) - No market-driven research

Scientific services in the field of **BIOSAFETY** promoting safe and sustainable use of biotechnology in agriculture, i.e. environmental release of GMOs

INTELLECTUAL PROPERTY RIGHTS OWNED AND SHARED - Research and technology transfer made available to all Member Countries

Developing knowledge



IPRs: copyright, trade marks and patents



Today's focus: ICGEB & patents

PATENT as:

- Mechanism to encourage innovation
- Social contract: patent in exchange of disclosure
- Balance of interests between society (taxpayers) and patentee
- Monopoly to the inventor

...what is the situation in developing countries?



“Most research institutes in developing countries lack even minimal capacity in IP management. Increasingly however, public research institutes will have to develop their own IP policies and management capacity with a combination of legal, business and technical knowledge consistent with market size and costs.”

D. Byerlee and K. Fischer, *Accessing Modern Science: Policy and Institutional Options for Agricultural biotechnology in Developing Countries*, AKIS Discussion Paper, 2000

In this context ICGEB membership is an asset...

...as the ICGEB serves the interests of Member States:

“...access to intellectual property rights concerning the results emanating from the research work of the Centre shall be granted to members and to developing countries that are not members of the Centre in accordance with applicable international conventions.” *[Policy guidelines on Patents, Licensing, Copyrights and other Rights to Intellectual Property of the ICGEB]*

...with the following objectives:

- 1. Promote the development, production and wide application of biotechnology in the interest of developing countries**
- 2. Promote the transfer of technology and know-how to member countries**
- 3. Overcome difficulties encountered by developing countries in fostering innovation, ownership and in-house application**



...in line with ICGEB statutory mandate...

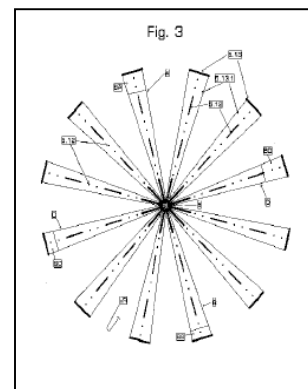
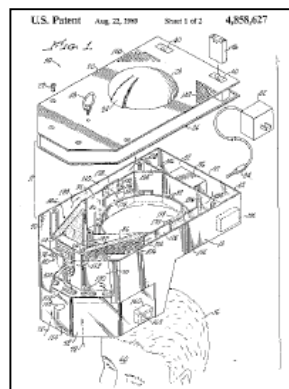
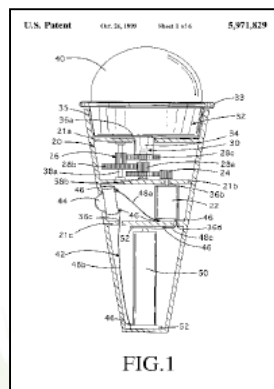
“...to assist developing countries in strengthening their scientific and technological capabilities in the field of genetic engineering and biotechnology” [Statutes, art.2(a),(d),(c)]

“...to support in particular research development and application for the benefit of developing countries and maintain close contacts with industry” [Idem, art. 3(a),(h),(j)]



FILING A PATENT APPLICATION - 1. Preliminary step

1. Group Leaders shall notify the Director-General of any invention or conception of invention developed by staff members of the Centre or visiting fellows
2. Group Leaders shall ascertain that any scientific manuscript, poster, slide or transparency does not constitute a disclosure of the technology to be patented
3. Evaluation of the potential general commercial value of the invention by the ICGEB management



FILING A PATENT APPLICATION - 2. Procedure

- 1. Evaluation with the patent attorney:** to ascertain the existence of the protection requirements (novelty, inventiveness, industrial applicability), enough experimental evidence and fulfilment of the requirements related to the patenting of biotechnology
- 2. Filing of the application at a national level (priority date)** and awaiting or requesting a **search report** (some national patent offices conduct search reports automatically as in the case of Italy receiving a report from EPO)
- 3. Within 12 months from priority date, entering the international phase:** extension of the application internationally through the Paris Convention Treaty (PCT)
- 4. Within 30 months: entering the national phases of the PCT extension (if applicable)**

FILING OF A PATENT APPLICATION -

3. Notification of Application to ICGEB Member States

- 1. Following the filing of a Patent application, ICGEB shall inform its Member States**
- 2. Within 4 months (and not later than 8 months from the Priority date) Member States can indicate their specific interest in the invention: ICGEB will extend the Patent in the Member States that so require**
- 3. Filing and maintenance costs in that specific Member State will be borne by the relevant government**
- 4. The centre may file subsequent Patent applications in other Member States informing the respective MS accordingly**



LIFE OF A PATENT APPLICATION - IP Ownership

- 1. ICGEB staff members and visiting fellows vest in the Centre all rights, including title, Copyright and Patent rights, in any work performed as part of their official duties**
- 2. Results emanating from the research implemented in the framework of the Collaborative Research Programme (CRP) belong to the Affiliated Centre and to the scientists which have carried out the research**
- 3. In case of inventions protected at the expenses of a Member State, the Patent will be co-owned by the ICGEB and by the respective Member State**



LIFE OF A PATENT APPLICATION - Commercial development

- 1. In case of an invention with potential commercial value the Director-General will negotiate non-exclusive or exclusive license agreements with interested industrial partners**
- 2. Such license agreement will contain a down payment, payable in instalments (e.g. 40%-40%-20%) and royalties as a percentage (e.G. 2-4%) of the net sales of products sold**
- 3. If no suitable industrial partner is identified within 30 months from the priority date, the Patent is abandoned**



BENEFITS FROM AN ICGEB PATENT - Royalty distribution

- **1/3 to the inventor, with a ceiling of us \$200,000 per year and 5% of any sum in excess to that ceiling**
- **1/3 to the research budget of the group in which the inventor operates, with a ceiling of us \$200,000 per year and 5% of any sum in excess to that ceiling**
- **1/3 to the ICGEB general fund, plus 90% of the sums in excess of the ceilings of us \$200,000 described above**

BENEFITS FROM AN ICGEB PATENT - Case study

Baralle F.E., Scodeller E., Tisminetzky S., Molecular presenting system

Priority date: 8 August 1994, Austrian Patent Granted no: 402898

(Use of an insect virus as a carrier for the presentation of multiple epitopes showing high antigenic properties)

08/08/94 First filing in Austria (priority date)

04/08/95 International extension via PCT

01/03/96 International Preliminary Examination (ipe)

08/02/97 Entering the regional (Europe) and national (USA) phases

28/08/98 Licensing of the product to a US pharmaceutical company

Down payment: 40% - upon execution of the contract

60% - 24 months after the signature

Royalties: 1% of the net sales of products sold, on quarterly basis

BENEFITS FROM AN ICGEB PATENT - Case study

Main contractual conditions

EXCLUSIVITY CLAUSE

- Exclusive rights in all OECD nations, except Italy
- Non exclusive rights in all ICGEB Member States (full members at the time of signature)
- Loss of non exclusive rights should a company in an ICGEB Member State request the licensing of the Patent.

INTELLECTUAL PROPERTY RIGHTS:

- The industrial partner is responsible for all the costs for the maintenance of the Patent in those countries for which it has exclusive and/or non-exclusive rights.



A New Paradigm?

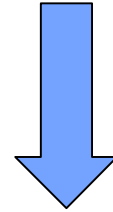
**Some Developing Countries are now
generating Technological Innovation**

BUT

**They often lack a specific culture on
Intellectual Property Rights**



A New Paradigm?



**Need for Tailor-Made Programmes
Involving ALL the concerned Players**

I.E.

**Scientists
Entrepreneurs
Lawyers
Policy-Makers
Judges**

WORLD
INTELLECTUAL
PROPERTY
ORGANIZATION





Thank you

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