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and Biotechnology**

ICGEB Trieste, Italy



**Structural and functional
genomics and related
biotechnologies are keys
for the development of
healthcare and agricultural
innovations over
the coming decades.**



Biopharmaceuticals

A biopharmaceutical is a naturally occurring or modified polypeptide, DNA or RNA molecule, produced by recombinant DNA technology.

The biological systems for production can be bacteria, eukaryotic cell lines, transgenic animals or plants.

They can be used for therapy, prophylaxis or diagnostics.

1970s

Birth of recombinant DNA technology

1980s

First biotechnology company in the capital markets (Genentech)

1982

First biopharmaceutical in the market: recombinant human insulin

2007

Global biopharmaceutical market of 60 billion US\$



Therapeutic proteins

The therapeutic proteins market grew by 11% in 2005, faster than the pharmaceutical industry as whole, and is forecast to achieve sales of over \$70 B by 2010 (Datmonitor 7-02).

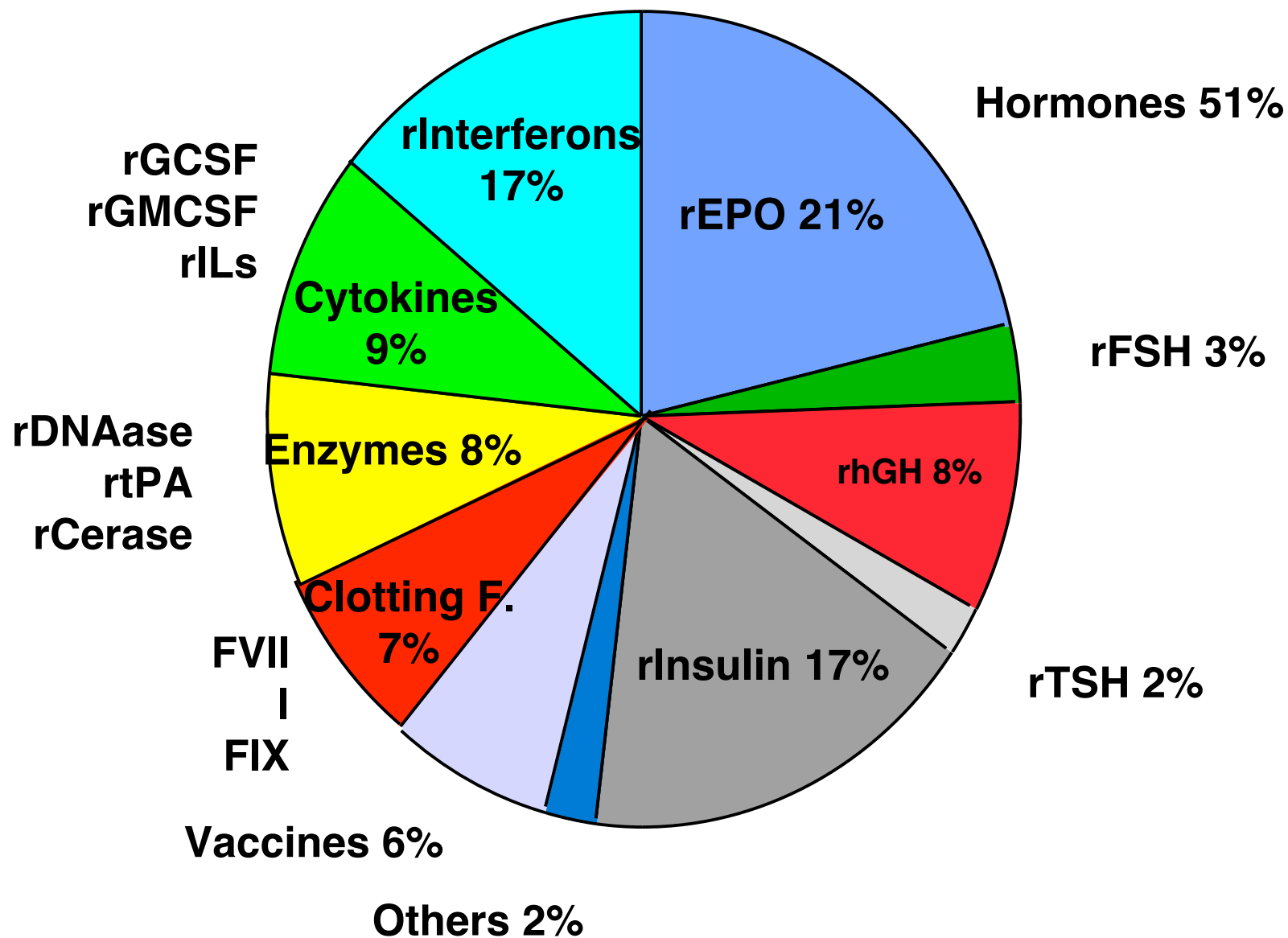
Growth to date has been dominated by sales of EPOs and insulins.

Over \$13.5 B of the \$27 B therapeutic proteins market in 2001 is currently exposed to generic competition.

Erythropoietins	24%
Insulins	16%
Interferons	14%
Blood factors	10%
Colony Stimulating Factors	10%
Growth hormones	8%
Mab	6%
Enzymes	4%
Plasminogen activators	3%
Calcitonins	2%
Others	2%
Interleukins	1%



2007 Total: \$ 60 Billion



Biogenerics

The first recombinant biopharmaceuticals patents are now over 20 years old and a 13.5 billion generics market is now being opened.

The biopharmaceutical industries in countries such as Argentina, Brazil, China, Cuba, India, Korea, etc. are in a position to take a considerable share of this market.



The top ten biotechnologies with scores based on rankings of the expert panel

BIOTECHNOLOGY FINAL RANKING & SCORE

0. Basic science development and training

- | | |
|--|-------|
| 1. Modified molecular technologies for affordable, simple diagnosis of infectious diseases | [288] |
| 2. Recombinant technologies to develop vaccines against infectious diseases | [262] |
| 3. Technologies for more efficient drug and vaccine delivery systems | [245] |
| 4. Technologies for environmental improvement (sanitation, clean water, bioremediation) | [193] |
| 5. Sequencing pathogen genomes to understand their biology and to identify new antimicrobials | [180] |
| 6. Female-controlled protection against sexually transmitted disease, both with and without contraceptive effect | [171] |
| 7. Bioinformatics to identify drug target and to examine pathogen-host interactions | [168] |
| 8. Genetically modified crops with increase nutrients to counter specific deficiencies | [159] |
| 9. Recombinant technology to make therapeutic products (I.e. insulin, interferons) more affordable | [155] |
| 10. Combinatorial chemistry for drug discovery | [129] |

The essential raw material needed are the scientist with adequate knowledge of the scientific method, skilled in biotechnological techniques and with as wide as possible scientific culture.

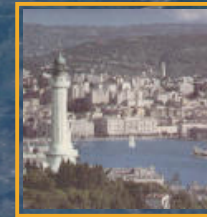
There is a need to simplify technology and adapt it to developing world needs and possibilities. The meaning of this statement is not to lower the quality of the scientific questions but to avoid unnecessary sophistication.

There is the need to avoid prestige only projects, based on automated repetitive procedures. These type of projects have very little added value in terms of capacity building and skills gained.

From the point of view of the wide political guidelines on project selection, there is no need to restrict this action to the so-called third world diseases. More people die in the developing world from Cardiovascular Diseases than from Parasitosis.

Basic research should be actively encouraged because its social value goes beyond the hypothetical economic return of a given project. The fundamental value of basic research is the creation of a collective scientific competence that promotes the acquisition and diffusion of innovation in the social fabric.

to
Austria

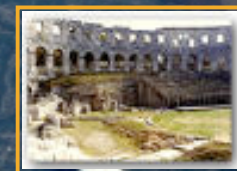


Trieste



to Venice

Piran
(Slo)



to Pula
(Croatia)



Developing knowledge

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



- 55 Member States
- 74 Signatory Countries
- 38 Affiliated Centres



One CENTRE made of
three Components, two Outstations and a Network of Affiliated Centres



Funding opportunities

**Long and short-term fellowships
to train scientists from Member States through:**

International PhD Programme

Postdoctoral fellowships

Flexible fellowships

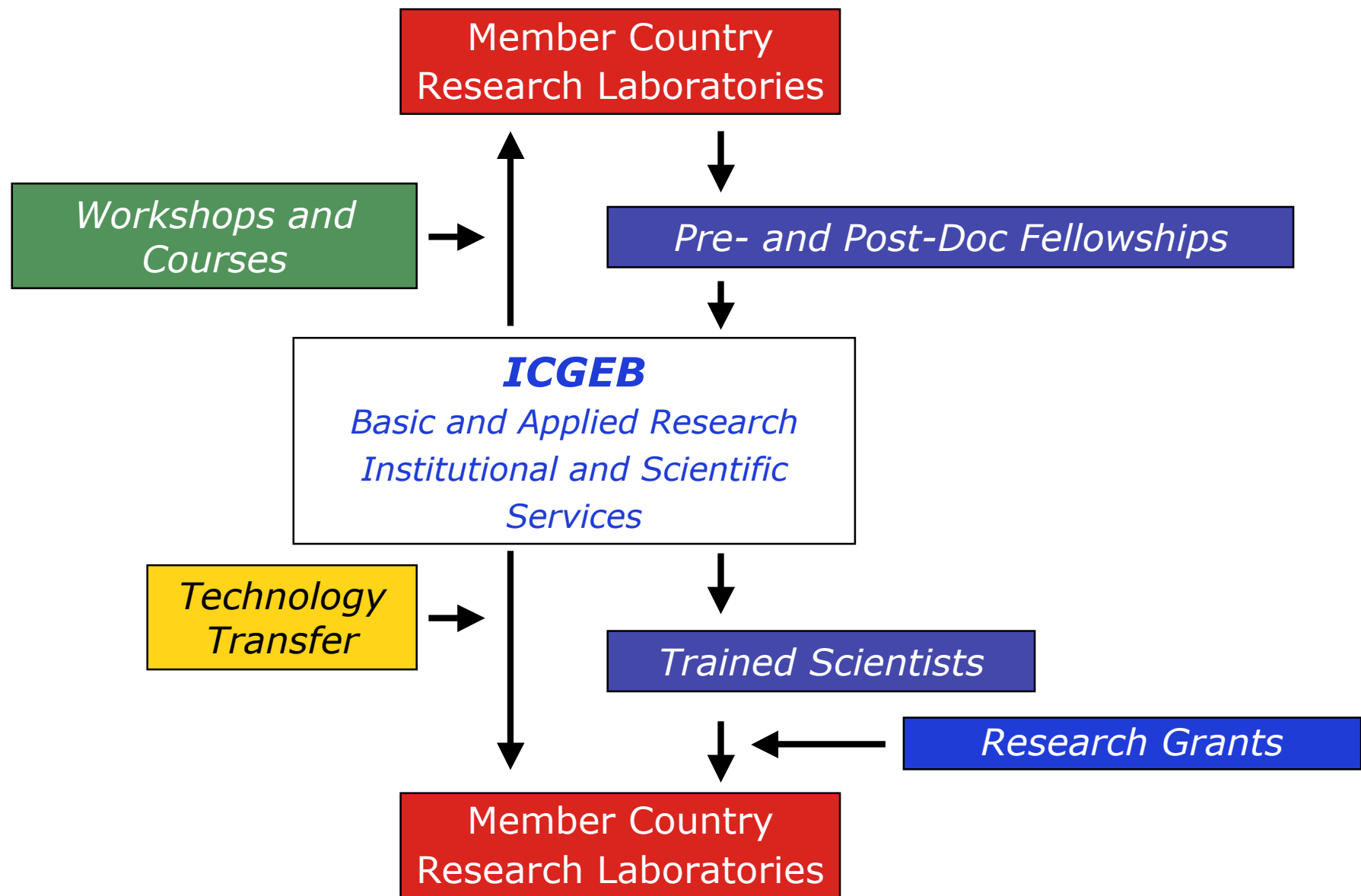
Training courses, meetings and workshops

Research grants through:

Collaborative Research Programme

Mobility funding

Training grants





Research and Development Focus

Human Health

Basic and applied research in infectious diseases and the genetic component of tumors and cardiovascular pathologies

Crop improvement

Biotic and abiotic stress, plant transformation, insect resistance, biopesticides

Biosafety risk assessment

Technology development and transfer

Cooperation with other UN bodies



New Delhi Component

Human Health

Basic and applied research in infectious diseases and structural biology, vaccine and diagnostic development in malaria, dengue and tuberculosis

Agriculture

Biotic and abiotic stress, plant transformation, insect resistance, biopesticides, etc

Technology development and transfer



Trieste Component

Inherited genetic disorders

Gene and cell therapy of cardiovascular disorders

Basic molecular biology

*Regulation of mRNA processing
Mammalian DNA replication,
Chromosomal stability in yeast
Mechanisms of DSB repair*

Genetics of antibodies

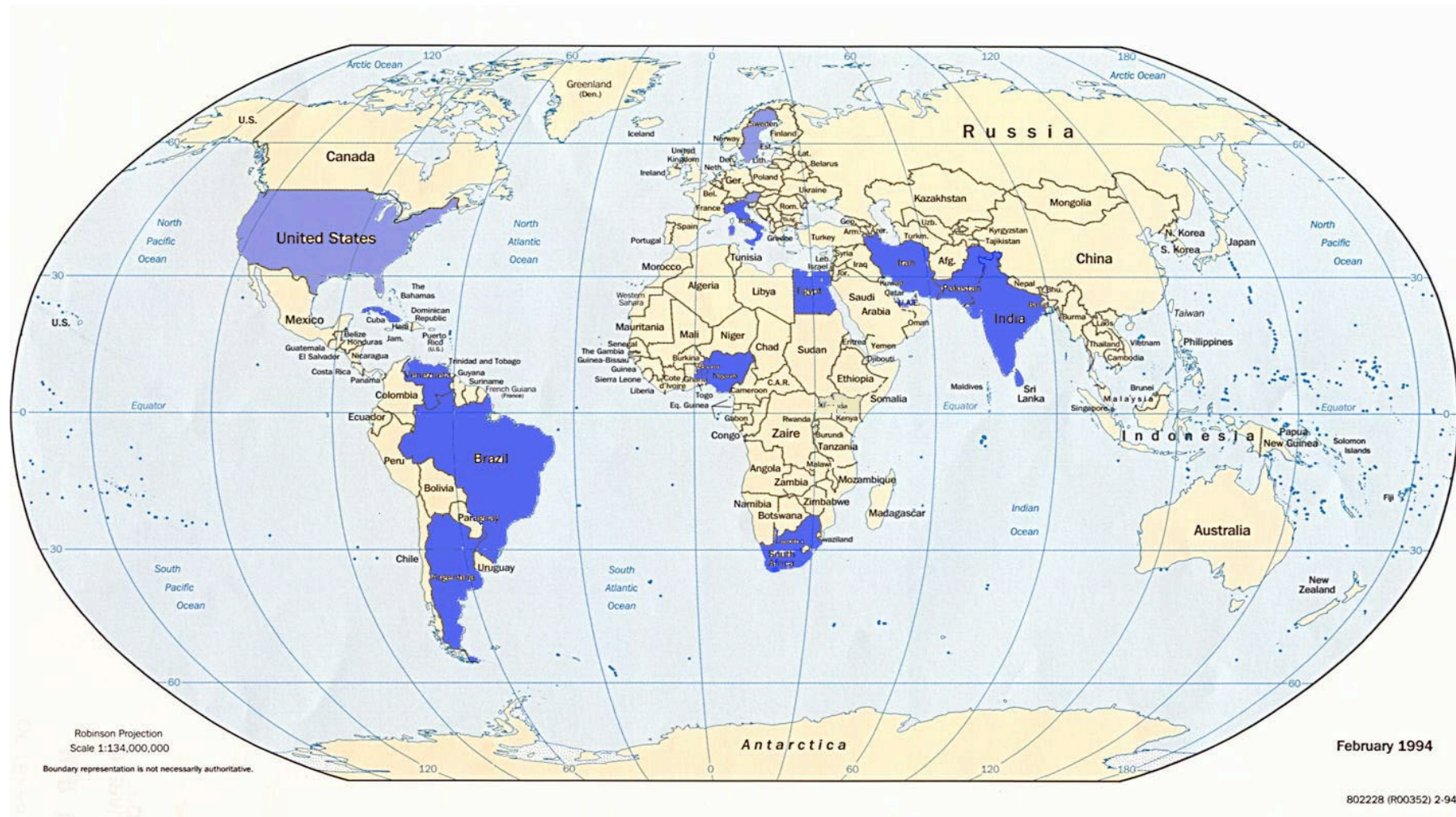
Molecular biology of viral infections

Protein structure and bioinformatics

Quorum sensing in bacteria

Production of recombinant proteins for human therapy

72 TECHNOLOGY TRANSFER AGREEMENTS IN 16 COUNTRIES



Biotechnology Transfer Unit

Biopharmaceuticals

- Development of bacterial and eukaryotic cellular strains for their production
- Development of new purification processes
- Quality control (QC) analysis
- Training of scientists from the ICGEB Member States in biotechnological processes and biopharmaceutical QC
- Transfer of the developed technologies to the Pharmaceutical Industries of the Member States



Transfer of Technology related to present and future biogenerics suchs as Erythropoietin, Alfa Interferon, Granulocyte Colony Stimulating Factor and Insulin has been carried out by the Biotechnology Development Group.

Institutions and companies of the following countries were involved: Argentina, Cuba, Egypt, India, Iran, Italy, Jordan, Sri Lanka, United Arab Emirates and Venezuela

Patents have been licensed also to companies based in non member countries such as USA and Canada but exclusivity was restricted to defined areas leaving the option open for licensing in ICGEB member countries



Technology transfer standard procedure

GENERAL

Two scientists from the Company receiving the transfer will be trained for 4 to 8 weeks at ICGEB

PHASE 1

Production process and quality control will be carried out under the supervision of ICGEB Staff

PHASE 2

Reproduction at Company's headquarters of the process seen at ICGEB

Technologies Available

Erythropoietin

Interferons

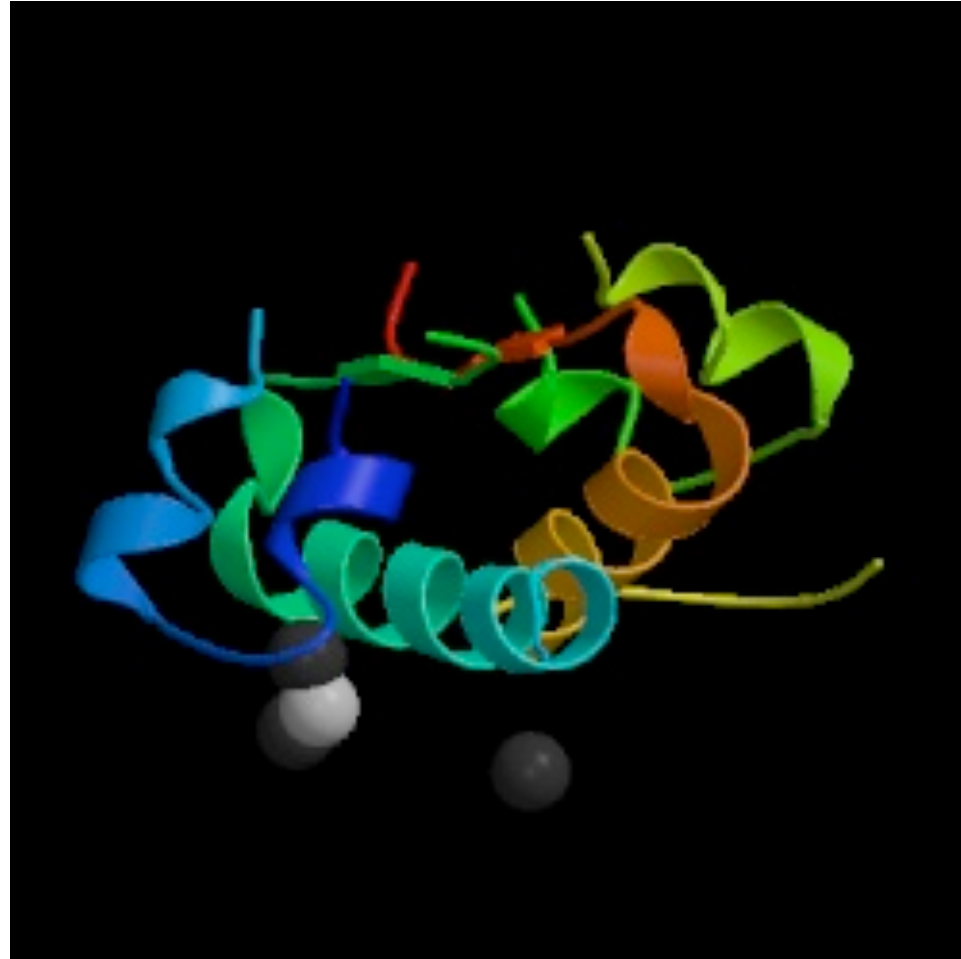
Granulocyte Colony Stimulating Factor

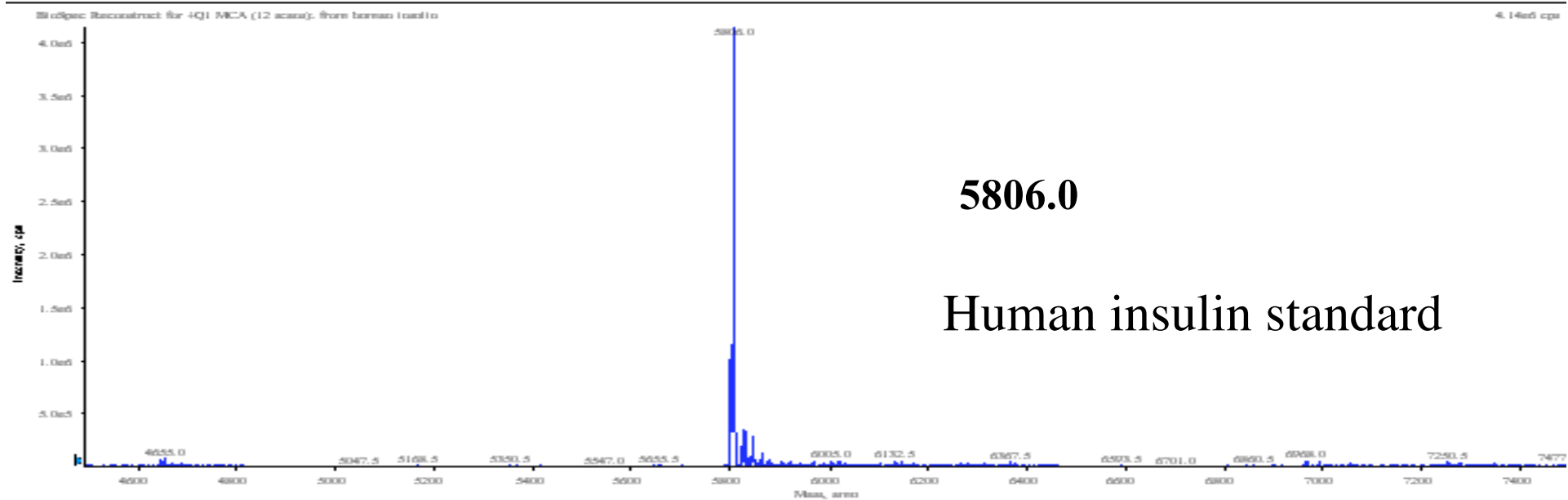
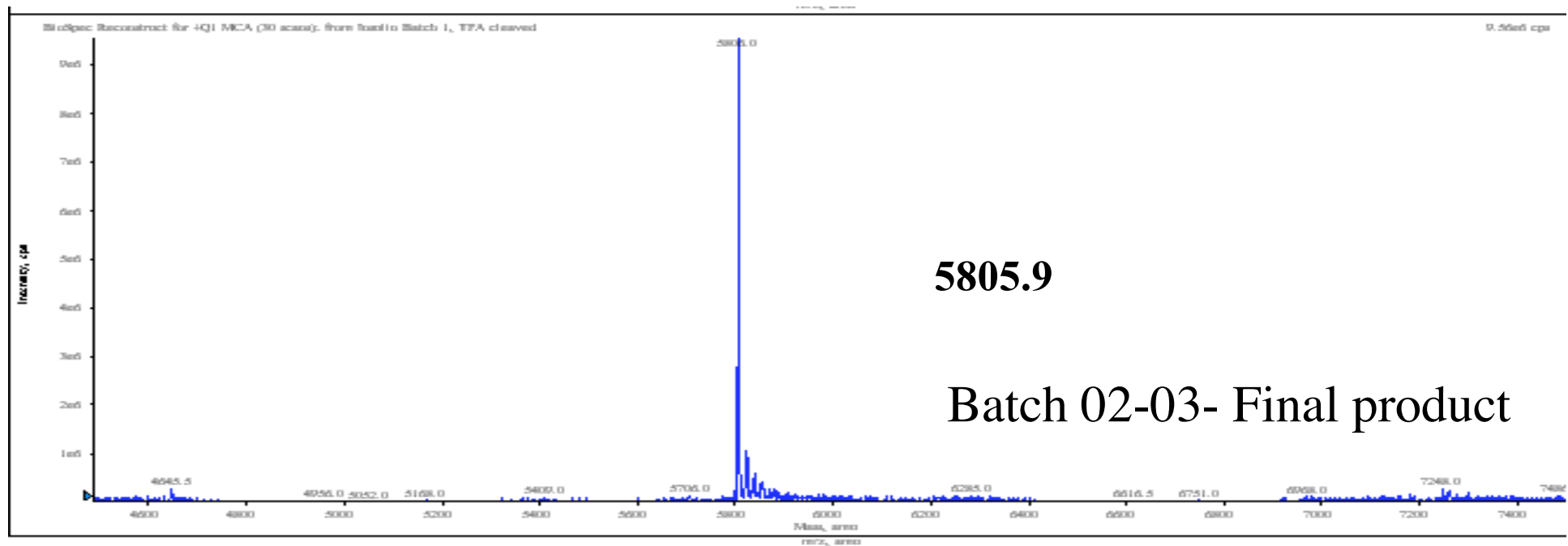
Insulin

Slow Release Preparations

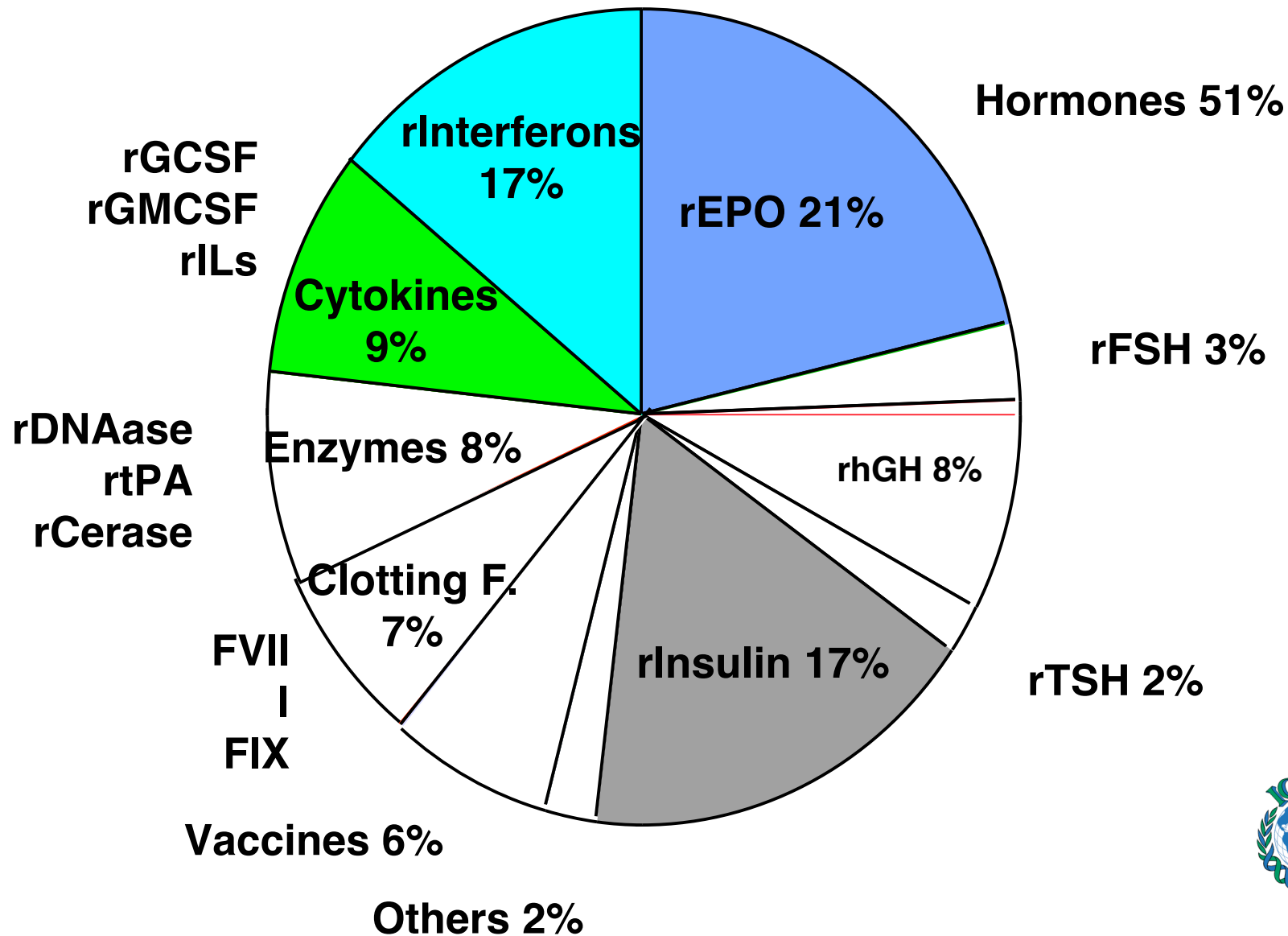
Hepatitis B Vaccine

Human Insulin Hormone





2007 Total: \$ 60 Billion





Institutional Activities

- Technology transfer
- Co-operation agreement with the united nations (UNIDO, UNESCO, WHO, etc.)
- Johannesburg summit on sustainable development
- Observer status with the Economic and Social Council (ECOSOC)
- Article x of the biological weapons convention
- Biosafety and risk assessment of GMOs
- UN-BIOTECH (GA resolution a/58/200)
- Intellectual property rights





BENEFITS FROM AN ICGEB PATENT: A CASE STUDY

THE PRODUCT: USING AN INSECT VIRUS AS A CARRIER FOR THE PRESENTATION OF MULTIPLE EPITOPES SHOWING HIGH ANTIGENIC PROPERTIES (MOLECULAR PRESENTING SYSTEM).

PROCEDURAL ITER

- 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**



A NEW PARADIGM:

SOME DEVELOPING COUNTRIES ARE NOW
GENERATING TECHNOLOGICAL INNOVATION

BUT

THEY OFTEN LACK A SPECIFIC CULTURE
ON INTELLECTUAL PROPERTY RIGHTS



THERE IS A NEED FOR TAILOR-MADE PROGRAMMES
INVOLVING ALL THE CONCERNED PLAYERS

SCIENTISTS
ENTREPRENEURS
LAWYERS
POLICY-MAKERS
JUDGES



THE INTERNATIONAL CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY

An international organisation
dedicated to advanced research and training in molecular biology and
biotechnology,
with special regard to the needs of the developing world



This Centre promotes the safe use of biotechnology

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