Meeting of “Commission on Intellectual Property Rights, Innovation and Public Health” – OMS

FIOCRUZ – Brasil - Rio de Janeiro

02/02/2005
SUMMARY

✓ Background
✓ Main Activities

  Intellectual Property
  Transfer of Technology
  Public Policies

✓ Main Results
✓ Main Barriers
✓ Re-structuring Project of GESTEC
✓ GESTEC’s Team
**GESTEC: HISTORICAL**

<table>
<thead>
<tr>
<th>Year</th>
<th>Institutionalization Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>1987</td>
<td>Creation of the Center for Special Studies of Presidency (NEP) (Act from Fiocruz’s President No. 125/86 of 14 July 1986). Signature of a Cooperation Agreement with the National Institute of Industrial Property (INPI).</td>
</tr>
<tr>
<td>1990-1991</td>
<td>Establishment of NEP as a new department entitled Division for Technology Management (GESTEC) covering activities related to Intellectual Property and Technology Transfer, taking part in the Office of Strategic Planning of FIOCRUZ</td>
</tr>
<tr>
<td>1996</td>
<td>Creation of the Policy of Intellectual Property and Technology Transfer through GESTEC (Act from Fiocruz’s President No. 294/96).</td>
</tr>
<tr>
<td>1998</td>
<td>GESTEC is directly linked to FIOCRUZ’s Presidency (Act from Fiocruz’s President No. 114/98). Standardization of the official use of the elements related to the Visual Indentity of FIOCRUZ (Act from Fiocruz’s President No. 693/98).</td>
</tr>
<tr>
<td>1999</td>
<td>Creation of a Committee aiming the improvement of the decision process related to the protection and preservation of the technical and intellectual property of FIOCRUZ (Act from Fiocruz’s President No. 135/99).</td>
</tr>
<tr>
<td>2002</td>
<td>Creation of a Committee to act together with GESTEC in IP matters as well as in the Transfer of Technology of FIOCRUZ (Act from Fiocruz’s President No. 240/2002).</td>
</tr>
<tr>
<td>2003</td>
<td>Internal Regulation of FIOCRUZ: formalize GESTEC’s attachment to Presidency.</td>
</tr>
<tr>
<td>2004</td>
<td>Improving the institutional policy in Technological Management: review and proposition of re-organization/re-structuring (Fiocruz’s Plan 2001-2005).</td>
</tr>
</tbody>
</table>
GESTEC - Main Activities

✓ Intellectual Property:

- Patents

Interaction with technical scientists to review patent feasibility; search for the state of the art; development of patentability strategies, determination of the scope of protection (claims); carrying out the procedures for patent applications (involving technical and legal aspects); patent prosecution follow up; monitoring of possible infringements, including interference practice.

- Trademarks

- Authorship rights

✓ Transfer of Technology:

Cooperation, commercialization and negotiation of technology including drafting and following up of agreements and contracts, which involves Fiocruz either as technology demander, or technology supplier;

✓ Public Policies:

Participation in discussions, elaboration and implementation of public policies on intellectual property, biosafety, bioethics, and protection of genetic resources (Ghente Project - www.ghente.org), etc.;
Intellectual Property Committee of FIOCRUZ

- The Committee was created through Presidencial Act No. 240 of FIOCRUZ in 2002.

- **Main Points:**
  - Patent protection of Inventions resultants from activities developed in Fiocruz;
  - Partnership establishment for the Inventions Development and Commercialization;

- **Committee Constitution:**
  - A President (Gestec’s Coordinator) and 14 members (from Gestec, Research and Development Units).

  OBS.: When necessary, the Committee can include members Ad Hoc.

- **Committee Responsability:**
  - To analyze and evaluate the pertinence of the legal protection to the research results, considering the technical-scientific merit, based on a Gestec’s technical report about the legal conditions of patentability.
  - To monitor and promote the researches, having patent granted or patent applications already filed, looking for the continuous development until obtainment of the resultant products and the interaction with industry;
  - To formalize co-operations looking for the technological development, which is still going on in Fiocruz Units, proposing procedures to systematize future co-operations;
  - To discuss and propose institutional policies to intellectual property and technology transfer.
PATENTABILITY CRITERIA AT FIOCRUZ

1. Patenteability requirements

2. Project stage and results

3. Strategic potential and the relevance of the research results in view of National Policy and Public Health

Evaluation of the relation between cost and benefits

Emerick, M.C.
PATENTABILITY PROCEDURES:

1. A Disclosure of Invention Form (DIF) is submitted (by the researcher) to GESTEC.
2. The GESTEC reviews the DIF, discusses the invention with the disclosers and initiates a search for the state of the art.
3. The patentable invention is submitted to the Intellectual Property Committee to decide about the filing.
4. Filing the patent application (GESTEC is responsible by the prosecution of the case during its life).
Technology Transfer: Licensing and Partnerships

- Types of Agreements

- Fiocruz as technology licensor

- Fiocruz as technology licensee

- Fiocruz and technological partnerships
Fiocruz as Technology Licensor

- Patent protection in strategic markets
- Good Laboratory Practices (GLP)
- Mid-Stage R&D Project
- Good Manufacturing Practices (GMP)
- Academic Tradition and Market Rules

Science: Information of Free Use to mankind

X

Technological Innovation and Proprietary Information
Fiocruz as Technology Licensee

✓ Governmental Purchases and Technology Transfer
  • Ministry of Health Demand as a Guideline
  • Technology Transfer as a basic premise

✓ Technology Selection
  • Public Bid (Terms and Conditions)
  • Proprietary Information Identification

Fiocruz is in position to operate in the International Technological Market
Public Law and Private Law

Intellectual Property Legislation as a Private Law Statute and the Rules of the Brazilian Public Law

✓ Possible constraints to the Operation of Public Entities

Substantive Aspects vs. Formal Aspects

Innovation Law: Regulates incentives to innovation and scientific and technology research in the productive environment.

Main Purpose: the Effective Achievement of the Public Interest
Fiocruz and Technological Partnerships

✓ Collaboration Promotion in Science and Technology with Public and Private Institutions

- Neglected Diseases
- Animal Health Products/ Human Health Products
- Optimization outputs from cumulative knowledges
- Specific Productive Arrangements to take advantage of particular market and the Public Interest.
Public Policies

- GESTEC takes part in the elaboration and implementation processes of public policies formally since 1995 (Objectives and Goals Plan).

- Attends to emergent demands in the field of technological innovations through partnership with research institutions, state governmental authorities (executive and legislative representatives) and representatives of society, in the field of:
  - Intellectual Property,
  - Biosafety,
  - Bioethics,
  - Ethics in the research with humans
  - Access, utilization and delivery of human genetic material
  - Access and utilization of biodiversity.

GHENTE Project – “Social, Ethical and Legal Studies related to the Access and Utilization of Genome in Health, particularly the Human one” – www.ghente.org
### FIOCRUZ PATENTS AND PATENT APPLICATIONS – Activity Sector

1989 a January 2005

<table>
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<tr>
<th>Types of Products</th>
<th>Research Projects</th>
<th>Patents</th>
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<tr>
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<td>10</td>
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<tr>
<td>(fitoterapico, fitofarmac, etc)</td>
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<td>Vaccines/Production Process of Antigens and Vaccines</td>
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<td>07</td>
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<td>Bioinsecticide</td>
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<td>01</td>
<td>08</td>
<td>09</td>
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<td>Method or composition for identification/detection of unicellular and/or pluricellular</td>
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<td>(Insects devices, Education games, Culture means to verify sterilization, Effluent treatment)</td>
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<td><strong>63</strong></td>
<td><strong>111</strong></td>
<td><strong>14</strong></td>
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PATENT APPLICATIONS FILED BY FIOCRUZ IN BRAZIL AND ABROAD, DISTRIBUTION ACCORDING TO FIOCRUZ UNITIES (1989 to January 2005)

PATENTES SOLICITADAS PELA FIOCRUZ NO BRASIL
PERÍODO: 1989-2005

PATENTES SOLICITADAS PELA FIOCRUZ NO EXTERIOR
PERÍODO: 1989-2005
PATENT GRANTED BY FIOCRUZ IN BRAZIL AND ABROAD, DISTRIBUTION ACCORDING TO FIOCRUZ UNITIES (1989 to january 2005)

PATENTES CONCEIDAS À FIOCRUZ NO BRASIL
PERÍODO: 1989-2005

PATENTES CONCEIDAS À FIOCRUZ NO EXTERIOR
PERÍODO: 1989-2005
## Trademarks (Filed and Granted)

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<th>Unities</th>
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<td>IOC</td>
<td>ZIG-ZAIDS</td>
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<td>07.06.1995</td>
<td>818559586</td>
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<td>ENSP</td>
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## PORTFOLIO AGREEMENTS

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<tr>
<th>Types of Agreements</th>
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<tr>
<td>Secrecy Agreements</td>
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<td>Contract for Supply of technology</td>
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<td>Patent License Agreement</td>
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<td>Trademark License Agreement</td>
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<td>Biological Material Transfer Agreement</td>
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<td>Technological Cooperation Agreements</td>
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<td>Memorandum of Understanding</td>
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## Evolution of the Annual Meetings of Intellectual Property and Commercialization of Technology

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<tr>
<th>Kind of Institution</th>
<th>1998</th>
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<td>R&amp;D Center</td>
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<td>275</td>
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Políticas de Propriedade Intelectual, Negociação, Cooperação e Comercialização de Tecnologia em Universidades e Instituições de Pesquisa: Análise e Proposições.

III Encontro de Propriedade Intelectual e Comercialização de Tecnologia
24, 25 e 26 de julho de 2000
Hotel Rio Othon

Rio de Janeiro
Hotel Rio Othon Palace
22, 23 e 24 de Julho de 2001
FIOCRUZ/GESTEC - Main Results
1989 – January 2005

✓ Patents

- Applications: 111
  - Brazil: 48
  - Abroad: 63
- Granted: 52
  - Brazil: 14
  - Abroad: 38

✓ Trademarks

- Applications: 10
  - Granted: 01
  - Licensed: 01

✓ Technology Licensing

- executed agreements: 149

✓ Public Policies

Ghente Project – Social, ethical and legal studies concerning the access and use of Human Genoma: management of the internet site www.ghente.org

✓ Education Activity

REPICT- Intellectual Property and Commercialization of Technology Network

REPICT is coordinated by Fiocruz since 1998, and as the objective to disseminate the Intellectual Property before Education and Research Institutions in Brazil.
Barriers Points and Potential Conflicts:

- Co-ownership
- Conflict of interests
- Return on capital vs profit share
- Appropriate knowledge valorization vs financial support
- Publishing vs Patenting
- Confidential information in the academic environment.
Re-structuring Proposal of GESTEC

FIOCRUZ/GESTEC

- Sc, Tech, Innov Advice
- IP Committee
- Adm & Fin. Support

IP

- Prod Protection
  - Patents
- Commerce. Protection
  - Trademarks
  - Authorship Rights

Tech Info

- Search Report

Tech Transfer

- Contracting
  - Negotiations
  - Contract Manag
- EVTE
- Industry Interaction
  - Partnership Prospect
  - Marketing

Monitoring
Re-structuring of GESTEC for the Strengthening of its Business Strategy: from Technical Knowledge to Market Product

✓ Goals:

Improvement and/or implementation of means, tools and activities to assure the strengthening of GESTE’s actions addressed to the achievement of its business strategy.

Impelling technical knowledge profiting.

Strengthening of GESTEC as a strategic organizational tool.
Re-structuring of GESTEC for the Strengthening of its Business Strategy: from Technical Knowledge to Market Product

✓ Implementation:

1. Tactical actions survey (macro-processes, products and byproducts);
2. Identification and definition of evaluation parameters of activities and results for each one of GESTEC’s areas;
3. Improvement, and diffusion of Standard Operational Procedures – SOP through modern available techniques (Intranet, Internet, etc.);
4. Improvement of GESTEC Database through electronic means in order to conform it with other FIOCRUZ units;
5. Technical and economical feasibility studies, improvement of contract management process, improvement of technological information access, deepening of partnership prospecting and interaction with industry.
Challenges for the Management of Intellectual Property and Technology Transfer

✔ Organizational Culture
✔ Fast moving international scenario with many entangled issues
✔ Information technology
✔ IP system can bring benefit to developed and developing countries
✔ Highly skilled negotiators
✔ Strategic “office”
## GESTEC’S TEAM

### Coordinator
- Maria Celeste Emerick
  - Sociologist
  - M.Sc

### Patents
- Adriana Campos Moreira
  - Chemical Engineer
  - Doctor student
- Suzana de Souza B. Cruz
  - Chemical Engineer
- Leila Costa Duarte Longa
  - Biologist
  - Master student
- Fábio Dias Meneses
  - Biologist Student

### Technology Transfer
- Patrícia Seixas da Costa
  - Lawyer
  - M.Sc
- Maria Elza Possas
  - Psychologist
  - M.Sc
- Márcia de Andrade Amaral
  - Chemist

### Public Policies
- Mª Helena de M. Lino
  - Lawyer
  - Master student
- Micheli Meneguelli P. Pereira
  - Lawyer

### Administrative Support
- Aline C. de Morais Santos
  - Law Student
- Lúcia Rodrigues de Paiva
- Francisco de Assis C. Nogueira
- Jaqueline Teixeira Xavier

Note: GESTEC has the assistance of Bhering, Almeida & Associados Firm, Intellectual Property Consultants.
THANK YOU FOR ATTENTION

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