

**A BIODIVERSITY BASED PLATFORM TO INSERT BRAZIL  
IN THE GLOBAL PHARMACEUTICAL SCENARIO –  
SEPTEMBER 2010**

Luiz Antonio Barreto de Castro  
Research and Development Secretary  
Ministry of Science and Technology

# COMMENTARY

## A platform to insert Brazil in the global pharmaceutical industry scenario

Luiz Antonio Barreto de Castro and Virna Y Suda

Focus on public private partnerships, interactions between large and small pharmaceutical companies and the use of the available incentives are elements that can boost health biotech sector in Brazil.

**A recent survey carried out by the Brazilian Institute of Public Opinion and Statistics has suggested that health was chosen by 41% of the interviewees as the main concern of Brazilians.** This demonstrates that much effort should be done in this field. A couple of years ago, Nature Biotechnology published two Articles on limitations for the development of a Health Biotech industry in Brazil. The first (1) presents a comprehensive analysis of Health Biotech in Brazil emphasizing several parameters that hinder innovation in the area, such as the poor public private relations. Luiz A. B. Castro contributed to the second short Article (2), which cited legal aspects as additional factors influencing negatively the same context. Assessments made during the 2009 Biotechnology Industry Organization International Convention (BIO), held in Georgia, and 2010 BIO, held in Chicago, allowed the proposal of a platform to insert Brazil in the global pharmaceutical industry scenario. The platform proposes partnerships between domestic Brazilian pharmaceutical companies and large pharmaceutical corporations to correct an additional problem. Today these two company groups do not interact. The first group of companies is represented by the **National Association of Pharmaceutical Laboratories (ALANAC - [www.alanac.org.br](http://www.alanac.org.br))** and the second group is represented by **Brazilian Research-Based Pharmaceutical Manufacturers Association (INTERFARMA - [www.interfarma.org.br](http://www.interfarma.org.br))**.

Submitted to Nature Biotechnology

# A IMPORTANCIA DA BIODIVERSIDADE

Paterson I., Andersen E.A., *The Renaissance of Natural Products as Drug Candidates*. Science 310:451 (2005)

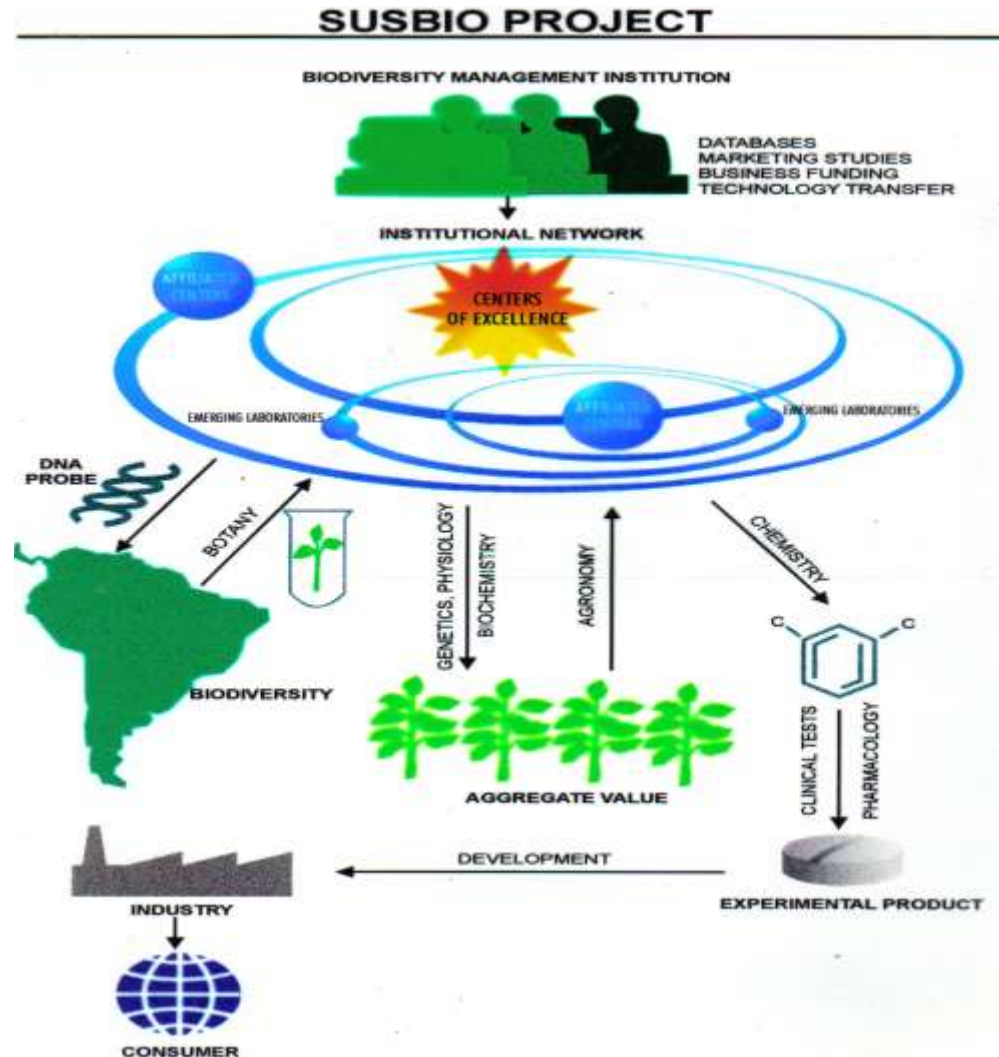
*Around half of the drugs currently in clinical use are of natural product origin.*

*Vimblastina, Vincristina - Anticancerígenos*

*Pilocarpina-Colírio Anti glaucoma*

*Artemisina - Antimalárico*

# AGREGATE VALUE TO THE PRODUCTS OF BIODIVERSITY – A STRATEGY TO REVERT THE TREND OF DEFORESTATION IN THE AMAZON



# BIOECONOMIA

## Industrial biotechnology sales soar

**The demand for plant-based chemicals is growing so fast that the industry could generate sales of as much as £12bn in the UK**

Tom Bawden

The demand for plant-based chemicals, which are used in everything from skin cream to car tyres, is growing so fast that the industry could generate sales of as much as £12 billion in the UK and £360 billion globally by 2025, according to research.

Industrial biotechnology — manipulating the cells of plants and other biological resources to create chemicals — is increasingly used to make ingredients that have traditionally been generated using oil and other fossil fuels.

Goodyear is working on a bio-based alternative to isoprene, a chemical compound derived from petrol that it uses in the production of synthetic rubber for its tyres.

Boots teamed up with the Centre for Novel Agricultural Products at the University of York last year and created a hand cream that incorporates fatty acids from hemp plant oil.

Times June 1st 2009

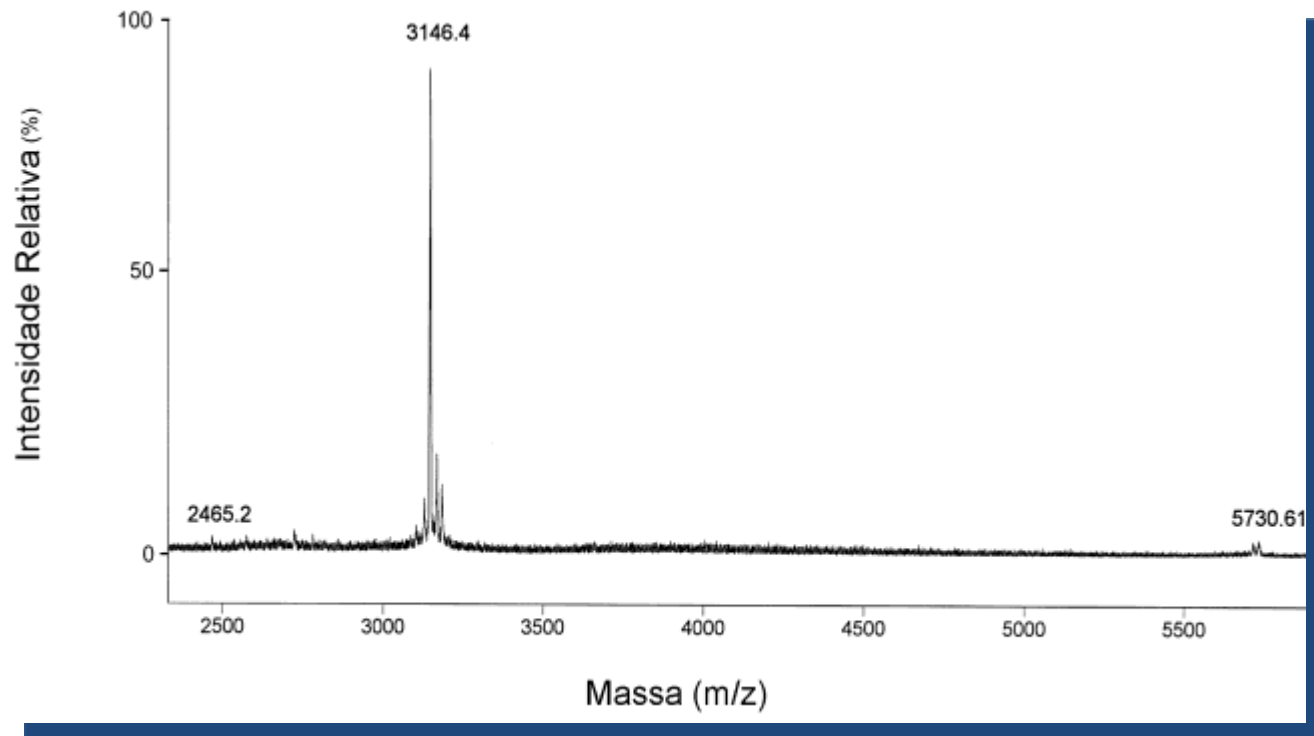
**DERMASEPTINS : ANTIFUNGIC PEPTIDES FROM FROGS FOUND IN PLANT GENOMES WERE THEY CAN BE ENGINEERED TO PERFORM THE SAME FUNCTIONS THE NEW CONCEPT IS CALLED INTRAGENICS**

Carlos Bloch – CENARGEN/EMBRAPA





# ANTI FUNGIC PEPTÍDE - MOLECULAR MASS DETERMINED BY MALDI-TOF/MS



# Acheflan



**achē**

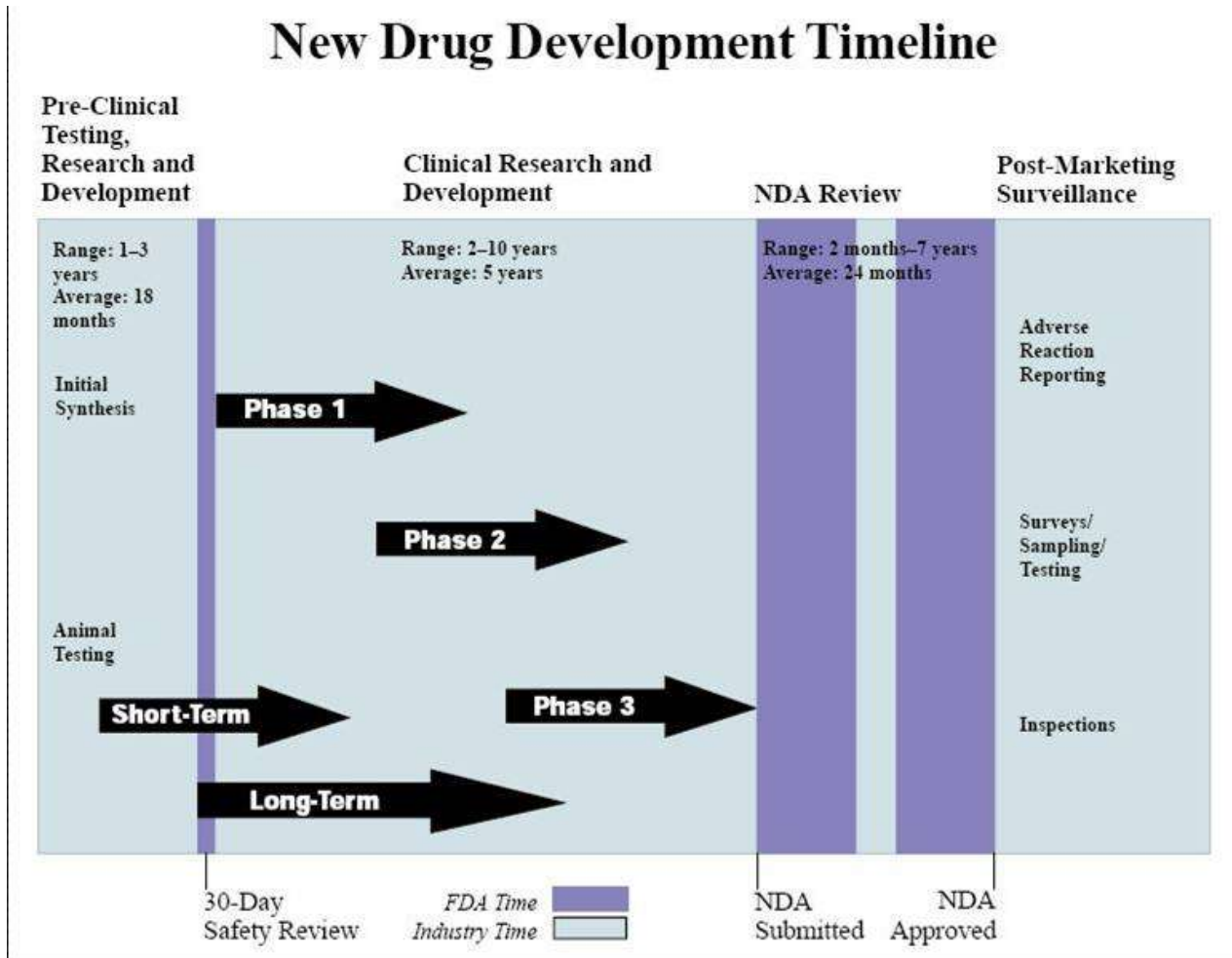
## Medicamento desenvolvido com a *Cordia verbenacea*, uma planta medicinal brasileira.

Atletas ou praticantes de esportes eventualmente necessitam fazer uso de anti-inflamatórios em caso de contusões. Esses medicamentos, entretanto, muitas vezes trazem consigo diversos efeitos colaterais. Há 20 anos, um dos fundadores do Aché machucou-se durante uma partida de futebol em seu sítio e foi tratado pelo caseiro com compressas de erva-baleeira, planta nativa da Mata Atlântica. Impressionado com os resultados, incentivou o início de pesquisa para a elaboração de um anti-inflamatório à base de planta. Lançado em 2005, o Acheflan alcançou, em apenas um ano, a liderança do mercado brasileiro de anti-inflamatórios de uso tópico com prescrição médica e conquistou vários prêmios de inovação tecnológica. Em 2007, com o surgimento da nova apresentação em aerosol, foram vendidas cerca de 700 mil unidades do produto. Em 2008 chegou ao mercado americano e canadense, sendo usado por atletas da NBA e da NFL, ligas americanas de basquete e futebol, respectivamente.

# Biopharmaceutical Blockbusters (2009)

Product	Sales value (\$ billions)	Company
<b>Enbrel</b> (etanercept; anti-TNF)	6.58	Amgen, Wyeth, Takeda pharmaceuticals
<b>Remicade</b> (infliximab; anti-TNF)	5.93	Centocor (J&J), Schering plough, Mitsubishi Tanabe pharma
<b>Avastin</b> (bevacizumab; anti-VEGF)	5.77	Genentech, Roche, Chugai
<b>Rituxan/MabThera</b> (rituximab; anti CD20)	5.65	Genentech, Biogen-IDEC, Roche
<b>Humira</b> (adalimumab; anti-TNF)	5.48	Abbott, Eisai
<b>Epogen/Procrit/Eporex/ESPO</b> (epoetin alfa)	5.03	Amgen, Ortho, Janssen-Cilag, Kyowa Hakko Kirin
<b>Herceptin</b> (trastuzumab; anti-HER2)	4.89	Genentech, Chugai, Roche
<b>Lantus</b> (insulin glargine)	4.18	Sanofi-Avenits
<b>Neulasta</b> (pegfilgrastim)	3.35	Amgen
<b>Aranesp/Nespo</b> (darbepoetin alfa)	2.65	Amgen, Kyowa Hakko Kirin

# Da Idéia ao Produto → 10 a 12 anos



**MINISTÉRIO DA CIÊNCIA E TECNOLOGIA**  
**Secretaria de Políticas e Programas de Pesquisa e Desenvolvimento**

**PROJETOS - Edital: RENORBIO/2010**

<b>ÁREAS DE PROJETOS</b>	<b>QUANTIDADE</b>	<b>%</b>
<b>Recursos Naturais(*)</b>	39	47,0%
Saúde Humana	17	20,5%
Agropecuária	14	16,9%
Marcadores Genética Molecular	6	7,2%
Microbiologia/Biorremediação	4	4,8%
Controle Biológico	2	2,4%
Propriedade Intelectual	1	1,2%
<b>TOTAL DE PROJETOS</b>	<b>83</b>	<b>100,0%</b>

(\*)Instituições: Fiocruz, UECE, UEMA, UESC, UFAL, LIFAL, UFBA, UFC, UFES,UFMA, UFPB, UFPE, UFRN, UFRPE, UFS, UNICAP, UNIFOR

**A AREA FARMACEUTICA : O  
CONTEXTO MUNDIAL E O  
CONTEXTO BRASILEIRO**

# As empresas de maior valor de mercado

Leaders in Market Capitalization	Value (Yahoo Finances May 2010)
Amgen Inc. [AMGN] (Thousand Oaks, CA) – 17,000 cols	<b>\$50.3 B</b>
Gilead Sciences, Inc. [GILD] (Foster City, CA) – 3,800 cols	<b>\$32.2 B</b>
Celgene Corporation [CELG] (Summit, NJ) – 2,800 cols	<b>\$24.6 B</b>
Genzyme Corporation [GENZ] (Cambridge, MA) – 12,000 cols	<b>\$13.7 B</b>
Biogen Idec Inc [BIIB] (Cambridge, MA) – 4,700 cols	<b>\$12.9 B</b>
Life Technologies Corporation [LIFE] (Carlsbad, CA – Individualized Medicine) – 9,000 cols	<b>\$8.9 B</b>
Dendreon Corporation [DNDN] (Seattle, WA - active cellular immunotherapy ) 484 cols	<b>\$5.8 B</b>
Illumina, Inc. [ILMN] (San Diego, CA – integrated systems for the analysis of genetic variation and biological function) – 1,700 cols	<b>\$4.8 B</b>
Qiagen N.V. [QGEN] (Netherlands - provides its products to molecular diagnostics laboratories, academic researchers, pharmaceutical and biotechnology companies) – 3,500 cols	<b>\$4.7 B</b>
Human Genome Sciences, Inc. [HGS] (Rockville, MD - pipeline includes novel drugs to treat hepatitis C, lupus, inhalation anthrax, and cancer) – 850 cols	<b>\$4.5 B</b>

# PANORAMA BRASILEIRO

## Vendas 06/2005

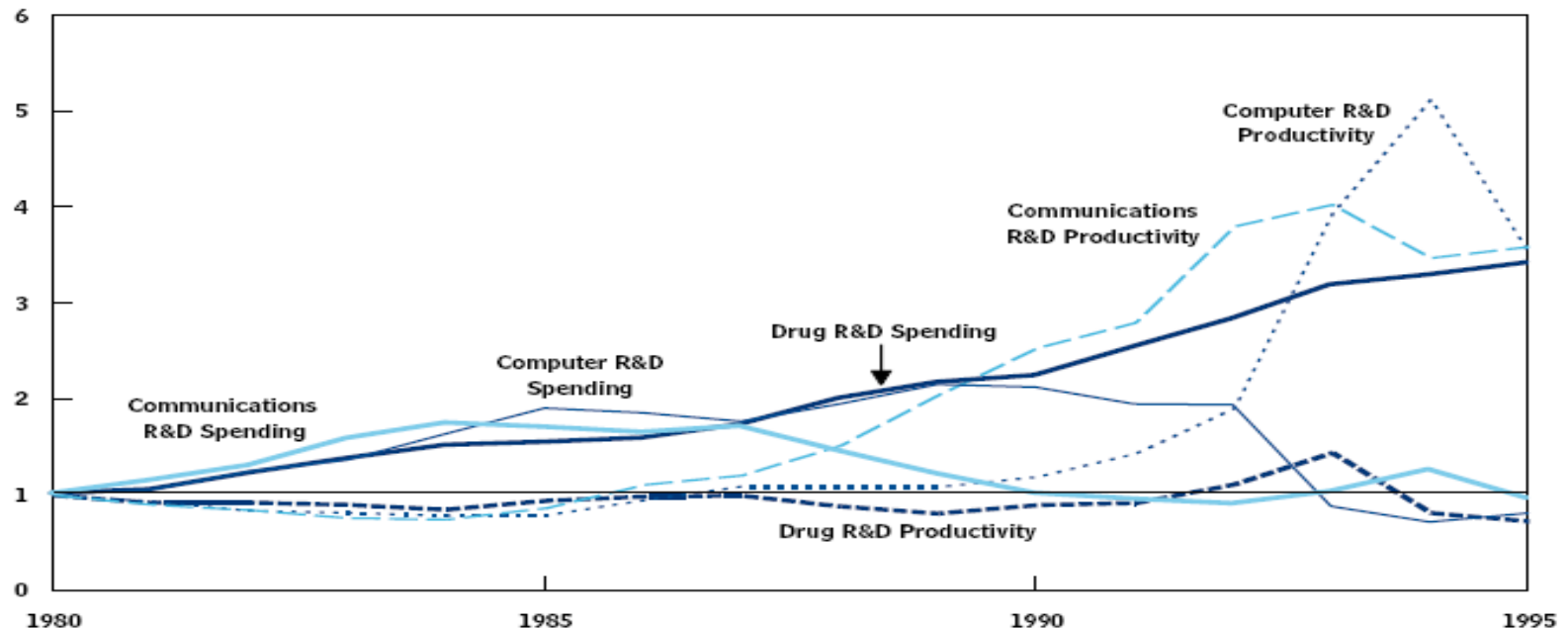
Posto	Indústria	Venda R\$	Participação %
3	Aché	875.823.161	5,45
5	EMS	799.542.478	4,98
<u>6</u>	<u>COINFAR</u>	<u>786.024.440</u>	<u>4,89</u>
6	Medley	607.404.299	3,78
8	Schering Plough	477.030.236	2,97
11	Eurofarma	442.620.159	2,75

# A INDUSTRIA FARMACEUTICA MUNDIAL : A CRISE NO MODELO

**Figure 5-2.**

## Research and Development Spending and Productivity for Various U.S. Industries

(Index, 1980 = 1.0)



Source: Congressional Budget Office based on National Science Foundation table "Company and Other (Except Federal) Funds for Industrial R&D Performance, by Industry and by Size of Company: 1953-98," available at [www.nsf.gov/statistics/iris/search\\_hist.cfm?indx=10](http://www.nsf.gov/statistics/iris/search_hist.cfm?indx=10); and Bronwyn H. Hall, Adam B. Jaffe, and Manuel Tratjenberg, *The NBER Patent Citation Data File: Lessons, Insights, and Methodological Tools*, Working Paper No. 8498 (Cambridge, Mass.: National Bureau of Economic Research, October 2001).

Notes: This figure measures productivity as the number of patents granted in an industry per dollar of research and development spending. R&D spending in one year is compared with successful patents two years later, reflecting the lag with which such spending leads to patent applications.

*CBO. R&D in the Pharma Industry (2006) [www.cbo.gov](http://www.cbo.gov)*

# Conclusões

- **Indústria farmacêutica mundial atravessa intensa remodelação**
- **Indústria de biotecnologia ganha maior destaque na cadeia de desenvolvimento**
- **Aumenta a importância das universidades na etapa de descoberta com conhecimento de fronteira para reduzir tempo e custo para levar inovação ao desenvolvimento**
- **Motor do desenvolvimento farmacêutico: cadeia tecnológica de biotecnologia e prestadores de serviço (spin offs de universidades)**
- **Universidades geram valor na etapa de descoberta (PI)**
- **Cadeia tecnológica gera valor na etapa de desenvolvimento (regulatório)**

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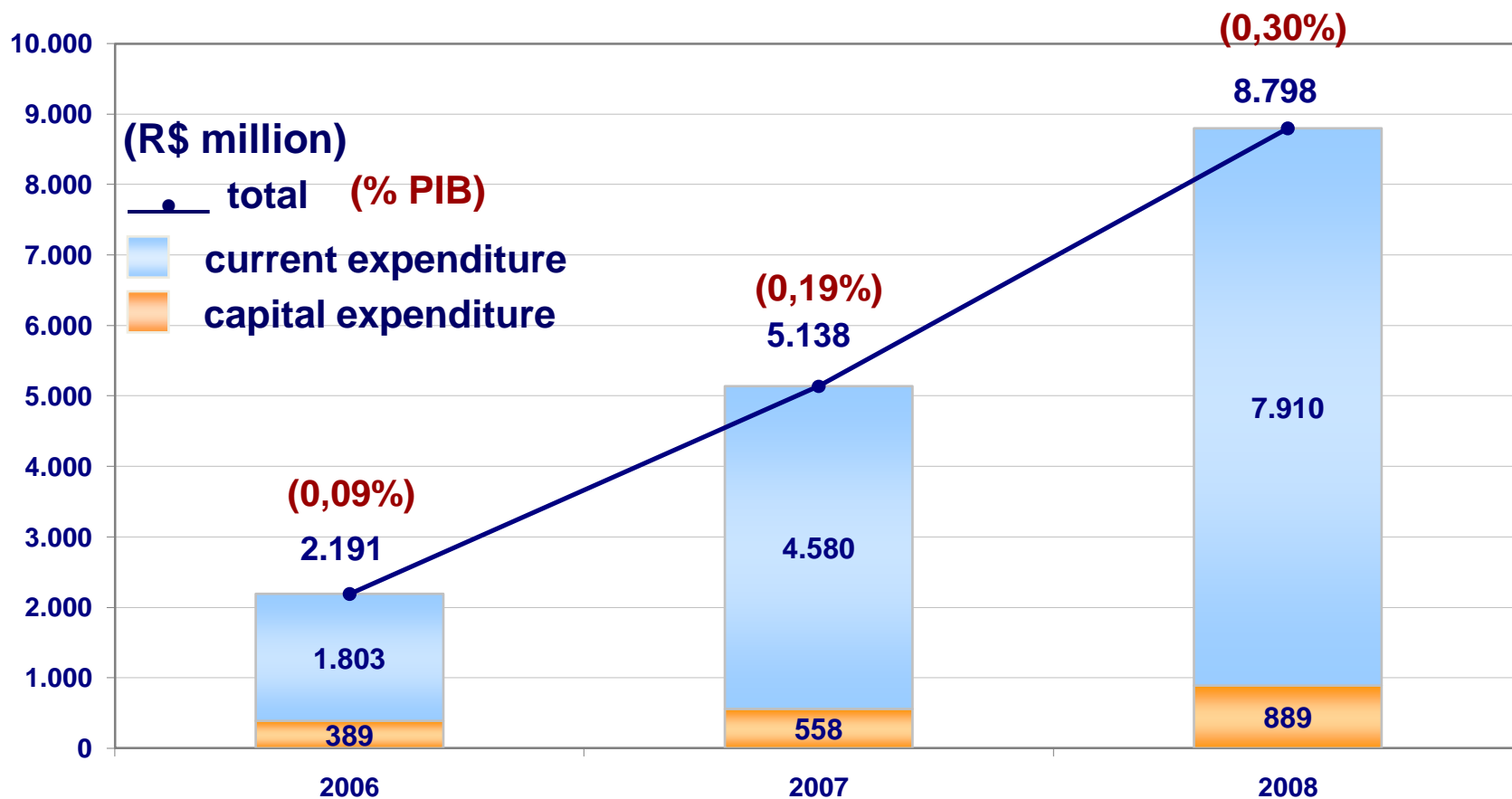
# Avanços importantes

- **Lei de inovação**
- **Política Industrial, Tecnológica e de Comércio Exterior**
- **BNDES – Profarma**
- **FINEP – Editais mais dirigidos à pesquisa aplicada e desenvolvimento**
- **Fundos setoriais**

# III Brazilian Seminar on Biotechnology

**“Good Law”: incentives for innovation**

**R&D investments made by companies (R\$ million)**

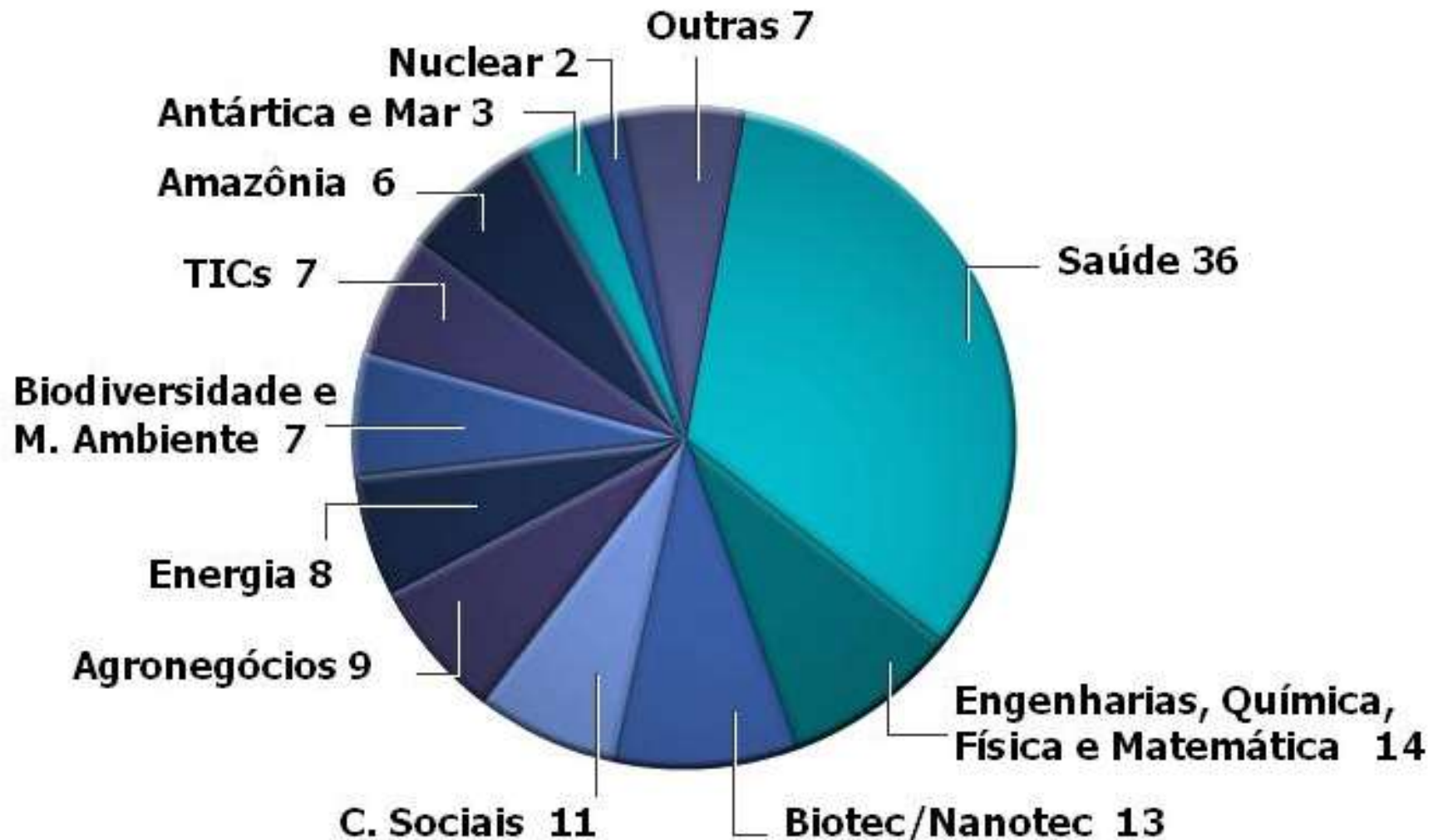


# WHAT CAN BE PATENTED?

- Types of product claims in Pharmaceutical Inventions
- Markush formulae
- Polymorphs
- Salts, hydrates, other "modified products"
- Biopharmaceuticals
- Plant extracts
- Galenic formulations
- Combinations
- Kit-of-parts

**NATIONAL INSTITUTES FOR SCIENCE AND TECHNOLOGY FUNDED IN 2008 BY THE MINISTRY OF SCIENCE AND TECHNOLOGY  
US\$ 200 MILLION – 36 in the area of health**

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## MATRIZ SÃO ROQUE

O Instituto Royal possui um moderno centro de tecnologia em São Roque-SP, onde funciona sua matriz. A Infra-estrutura disponível nesta unidade foi concebida para a garantia e efetividade de todos os serviços oferecidos pelos seus diversos laboratórios que incluem:

Biotérios de criação especialmente projetados para produção de animais de qualidade dentro das mais rígidas normas sanitárias.

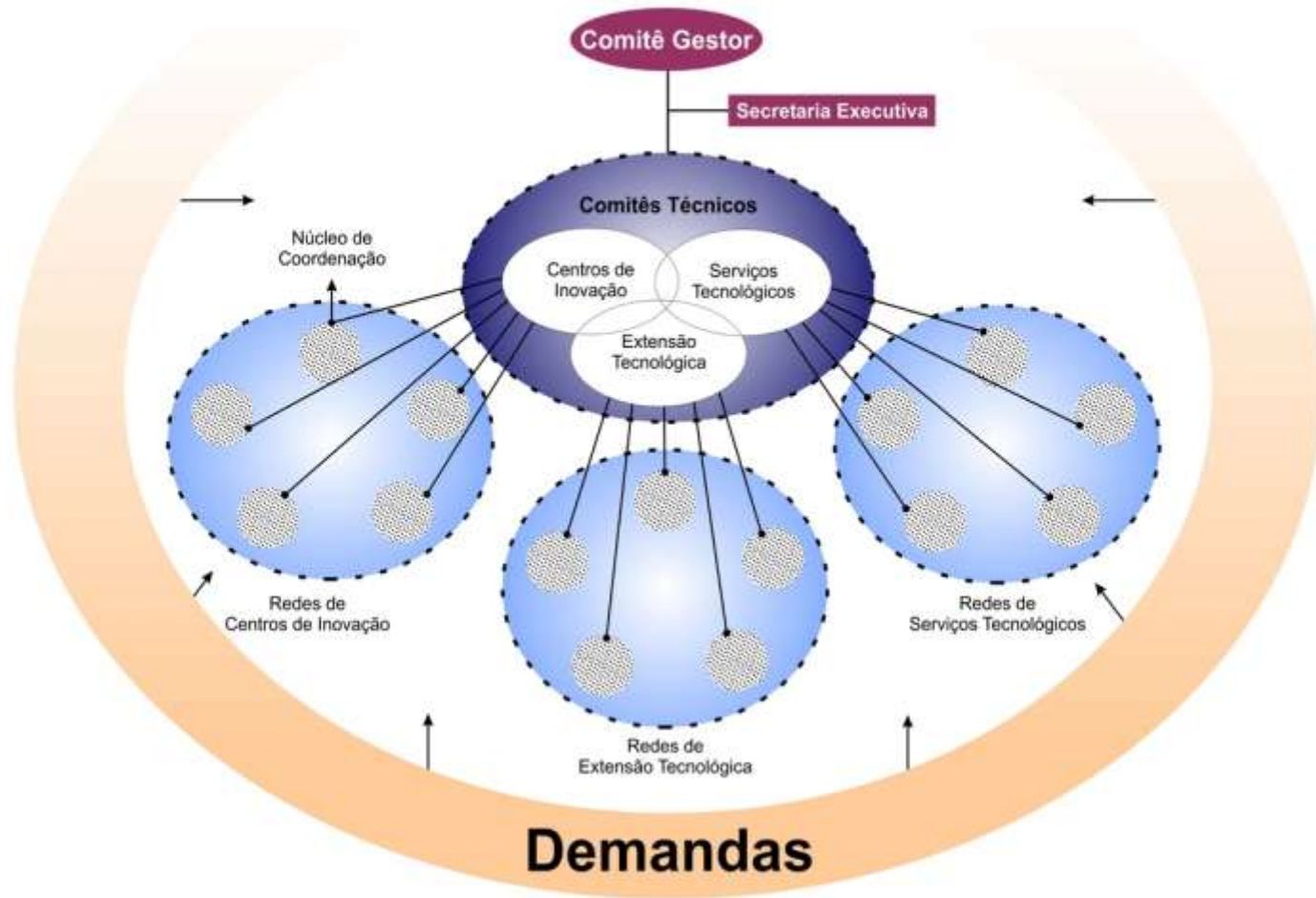
- ratos
- camundongos
- coelhos
- cães da raça Beagle

### Laboratórios

- Ensaio Toxicológicos
  - Ratos
  - Camundongos
  - Cães
- Genotoxicidade
  - Laboratório de Microorganismos
  - Sala de Experimentação Animal
  - Laboratórios de Cultura de Células
  - Laboratórios de Biologia Molecular
  - Laboratórios de Microscopia
- Laboratórios Analíticos
  - Laboratório de Análises Clínicas
    - . Hematologia
    - . Bioquímica
    - . Uranálise
  - Laboratório de Patologia
    - . Necropsia
    - . Histopatologia
- Áreas de Suporte

# Sistema Brasileiro de Tecnologia – SIBRATEC

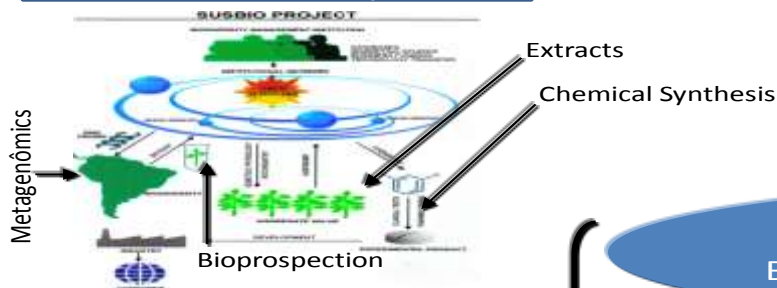
## Governança



**Secretaria Executiva do SIBRATEC**  
**sibratec@mct.gov.br**

# A platform to insert Brazil in the global pharmaceutical industry scenario

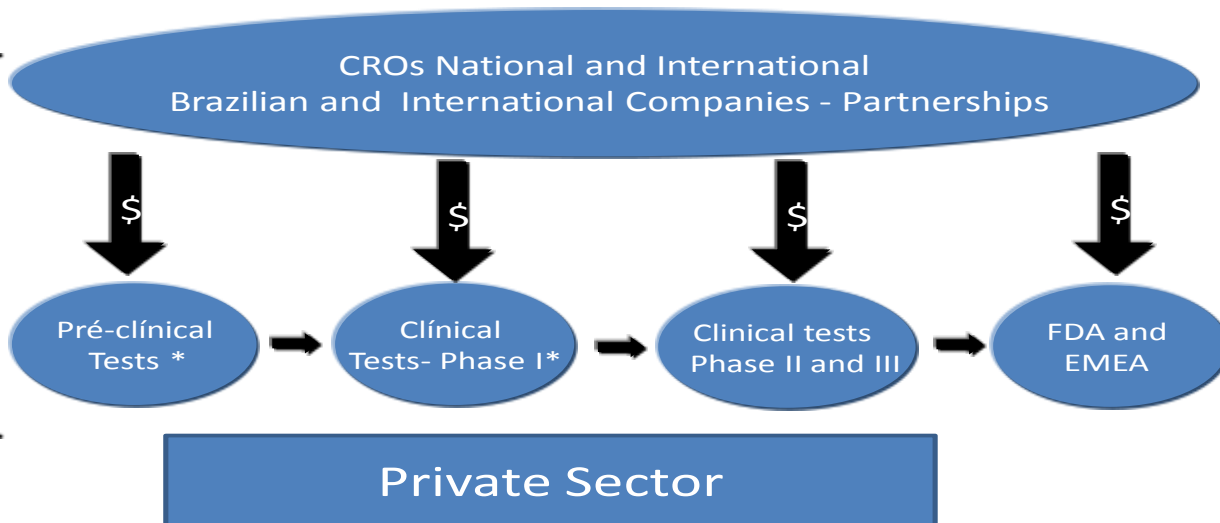
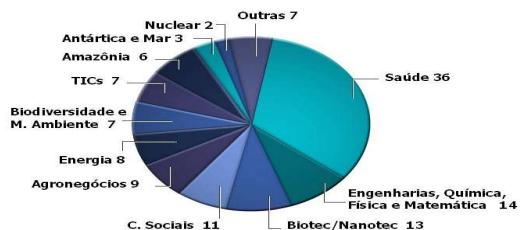
## Biodiversity



**Públic and Private Funds \***

## Academia

**INCT - 123**



**\* Law 11.487 – 06/15/2007 ,”Subvenção”, SIBRATEC**

## VALOR DE MERCADO\*

TESTES	Pré-clínico	Fase I	Fase II	Fase III	Registro/ Mercado
Valor de Mercado	0,1%	10 - 20%	30 - 50%	60 - 80%	100%

\* Valor de mercado de produtos em função de oportunidades reais dos produtos de chegarem ao mercado. Este valor reflete o retorno possível de quem investe. Está implícito que o produto é protegido por patente e foi escolha eficiente do mercado diante de competidores.

# **China spurs pharma innovation**

Chinese government's efforts to boost innovation have resulted in drug discovery research collaborations between Chinese academic institutions and multinational pharmaceutical companies: Astra , Zeneca, Glaxo Smith and Kline , Johnson & Johnson, Novartis, Pfizer , Roche and Sanofi Aventis