

Pharmaceutical companies and University relationship on drug design



Instituto Nacional de Ciência e Tecnologia

de Fármacos e Medicamentos

INCT-INOFAR

www.inct-inofar.ccs.ufrj.br



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Professor of Medicinal Chemistry – UFRJ



2nd International symposium on drug discovery – Faculdade de Ciências Farmacêuticas, UNESP, Araraquara, S.P., Brazil – 27-29 August, 2011

A Brazilian network for pharmaceutical innovation

Summary

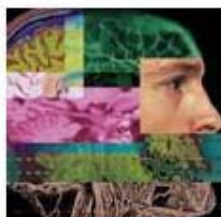
● Prologue

- ▶ **Introduction: general considerations;**
- ▶ **Contemporary scientific research;**
- ▶ **Interdisciplinarity of drug discovery process;**
- ▶ **Pharmaceutical industry & therapeutic innovation;**



● The INCT-INOFAR initiative

- ▶ **Radical innovation in drug discovery & design: NCE's;**
- ▶ **Incremental innovation: new opportunities in generic drugs & strategic synthetic intermediates;**
- ▶ **Final remarks;**



the **Pharmaceutical Century**

TEN DECADES OF DRUG DISCOVERY

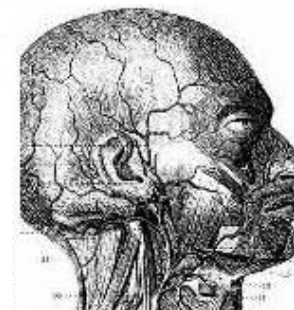
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Introduction

We live today in a world of drugs. Drugs for pain, drugs for disease, drugs for allergies, drugs for pleasure, and drugs for mental health. Drugs that have been rationally designed; drugs that have been synthesized in the factory or purified from nature. Drugs fermented and drugs engineered. Drugs that have been clinically tested. Effective. Safe.



zoom

*"We live today in a world of **drugs**.* Drugs for **pain**, drugs for **disease**, drugs for **allergies**, drugs for **pleasure**, and drugs for **mental health**. Drugs that have been **rationally designed**; drugs that **have been synthesized** or **purified from nature**. Drugs **fermented** and drugs **engineered**. Drugs that have been clinically tested. Effective. Safe."

The drug discovery process...



- *Science* **2000**, 287, 1951 (J.Uppenbrink, J.Mervis)

Science **2004**, 303, 1713 (Donald Kennedy Ed)

- Rethinking Drug Discovery
- Surviving the Blockbuster Syndrome
- Orphan Drugs of the Future?
- Protein Kinase Inhibitors: Insights into Drug Design from Structure
- Polyketide and Nonribosomal Peptide Antibiotics: Modularity and Versatility
- Organic Chemistry in Drug Discovery
- The Many Roles of Computation in Drug Discovery
- Drug Delivery Systems: Entering the Mainstream

is scientific research based.

“Science is made of facts, just as houses are made of stones; but a mere collection of facts is no more science than a pile of stones a house”



Henri Poincaré, 1902

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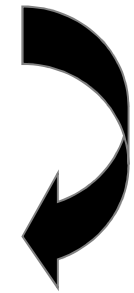
● The INCT-INOFAR initiative

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- ▶ **Final remarks;**

The scientific research through the ages...



Galileo, Newton, Darwin, & Einstein



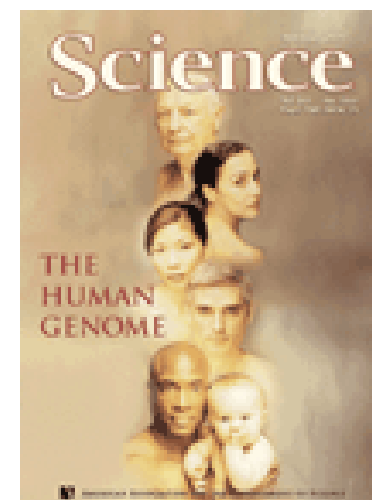
The physical Crick & the biologist Watson



The human genome team

The Sequence of the Human Genome

J. Craig Venter, Mark D. Adams, Eugene W. Myers, Peter W. Li, Richard J. Mural, Granger G. Sutton, Hamilton O. Smith, Mark Yandell, Cheryl A. Evans, Robert A. Holt, Jeannine D. Gocayne, Peter Amanatides, Richard M. Ballew, Daniel H. Huson, Jennifer Russo Wortman, Qing Zhang, Chinnappa D. Kodira, Xiangqun H. Zheng, Lin Chen, Marian Skupski, Gangadharan Subramanian, Paul D. Thomas, Jinghui Zhang, George L. Gabor Miklos, Catherine Nelson, Samuel Broder, Andrew G. Clark, Joe Nadeau, Victor A. McKusick, Norton Zinder, Arnold J. Levine, Richard J. Roberts, Mel Simon, Carolyn Slayman, Michael Hunkapiller, Randall Bolanos, Arthur Delcher, Ian Dew, Daniel Fasulo, Michael Flanigan, Liliana Florea, Aaron Halpern, Sridhar Hannenhalli, Saul Kravitz, Samuel Levy, Clark Mobarry, Knut Reinert, Karin Remington, Jane Abu-Threideh, Ellen Beasley, Kendra Biddick, Vivien Bonazzi, Rhonda Brandon, Michele Cargill, Ishwar Chandramouliswaran, Rosane Charlab, Kabir Chaturvedi, Zuoming Deng, Valentina Di Francesco, Patrick Dunn, Karen Eilbeck, Carlos Evangelista, Andrei E. Gabrielian, Weiniu Gan, Wangmao Ge, Fangcheng Gong, Zhiping Gu, Ping Guan, Thomas J. Heiman, Maureen E. Higgins, Rui-Ru Ji, Zhaoxi Ke, Karen A. Ketchum, Zhongwu Lai, Yiding Lei, Zhenya Li, Jiayin Li, Yong Liang, Xiaoying Lin, Fu Lu, Gennady V. Merkulov, Natalia Milshina, Helen M. Moore, Ashwinikumar K Naik, Vaibhav A. Narayan, Beena Neelam, Deborah Nusskern, Douglas B. Rusch, Steven Salzberg, Wei Shao, Bixiong Shue, Jingtao Sun, Zhen Yuan Wang, Aihui Wang, Xin Wang, Jian Wang, Ming-Hui Wei, Ron Wides, Chunlin Xiao, Chunhua Yan, Alison Yao, Jane Ye, Ming Zhan, Weiqing Zhang, Hongyu Zhang, Qi Zhao, Liansheng Zheng, Fei Zhong, Wenyan Zhong, Shiaoping C. Zhu, Shaying Zhao, Dennis Gilbert, Suzanna Baumhueter, Gene Spier, Christine Carter, Anibal Cravchik, Trevor Woodage, Feroze Ali, Huijin An, Aderonke Awe, Danita Baldwin, Holly Baden, Mary Barnstead, Ian Barrow, Karen Beeson, Dana Busam, Amy Carver, Angela Center, Ming Lai Cheng, Liz Curry, Steve Danaher, Lionel Davenport, Raymond Desilets, Susanne Dietz, Kristina Dodson, Lisa Doup, Steven Ferriera, Neha Garg, Andres Gluecksmann, Brit Hart, Jason Haynes, Charles Haynes, Cheryl Heiner, Suzanne Hladun, Damon Hostin, Jarrett Houck, Timothy Howland, Chinyere Ibegwam, Jeffery Johnson, Francis Kalush, Lesley Kline, Shashi Koduru, Amy Love, Felecia Mann, David May, Steven McCawley, Tina McIntosh, Ivy McMullen, Mee Moy, Linda Moy, Brian Murphy, Keith Nelson, Cynthia Pfannkoch, Eric Pratts, Vinita Puri, Hina Qureshi, Matthew Reardon, Robert Rodriguez, Yu-Hui Rogers, Deanna Romblad, Bob Ruhfel, Richard Scott, Cynthia Sitter, Michelle Smallwood, Erin Stewart, Renee Strong, Ellen Suh, Reginald Thomas, Ni Ni Tint, Sukyee Tse, Claire Vech, Gary Wang, Jeremy Wetter, Sherita Williams, Monica Williams, Sandra Windsor, Emily Winn-Deen, Keriellen Wolfe, Jayshree Zaveri, Karena Zaveri, Josep F. Abril, Roderic Guigó, Michael J. Campbell, Kimmen V. Sjolander, Brian Karlak, Anish Kejariwal, Huaiyu Mi, Betty Lazareva, Thomas Hatton, Apurva Narechania, Karen Diemer, Anushya Muruganujan, Nan Guo, Shinji Sato, Vineet Bafna, Sorin Istrail, Ross Lippert, Russell Schwartz, Brian Walenz, Shibu Yooseph, David Allen, Anand Basu, James Baxendale, Louis Blick, Marcelo Caminha, John Carnes-Stine, Parris Caulk, Yen-Hui Chiang, My Coyne, Carl Dahlke, Anne Deslattes Mays, Maria Dombroski, Michael Donnelly, Dale Ely, Shiva Esparham, Carl Fosler, Harold Gire, Stephen Glanowski, Kenneth Glasser, Anna Glodek, Mark Gorokhov, Ken Graham, Barry Gropman, Michael Harris, Jeremy Heil, Scott Henderson, Jeffrey Hoover, Donald Jennings, Catherine Jordan, James Jordan, John Kasha, Leonid Kagan, Cheryl Kraft, Alexander Levitsky, Mark Lewis, Xiangjun Liu, John Lopez, Daniel Ma, William Majoros, Joe McDaniel, Sean Murphy, Matthew Newman, Trung Nguyen, Ngoc Nguyen, Marc Nodell, Sue Pan, Jim Peck, Marshall Peterson, William Rowe, Robert Sanders, John Scott, Michael Simpson, Thomas Smith, Arlan Sprague, Timothy Stockwell, Russell Turner, Eli Venter, Mei Wang, Meiyuan Wen, David Wu, Mitchell Wu, Ashley Xia, Ali Zandieh, and Xiaohong Zhu



Science **2001** 291, 1304-1351 [DOI: 10.1126/science.1058040]

Summary

● Prologue

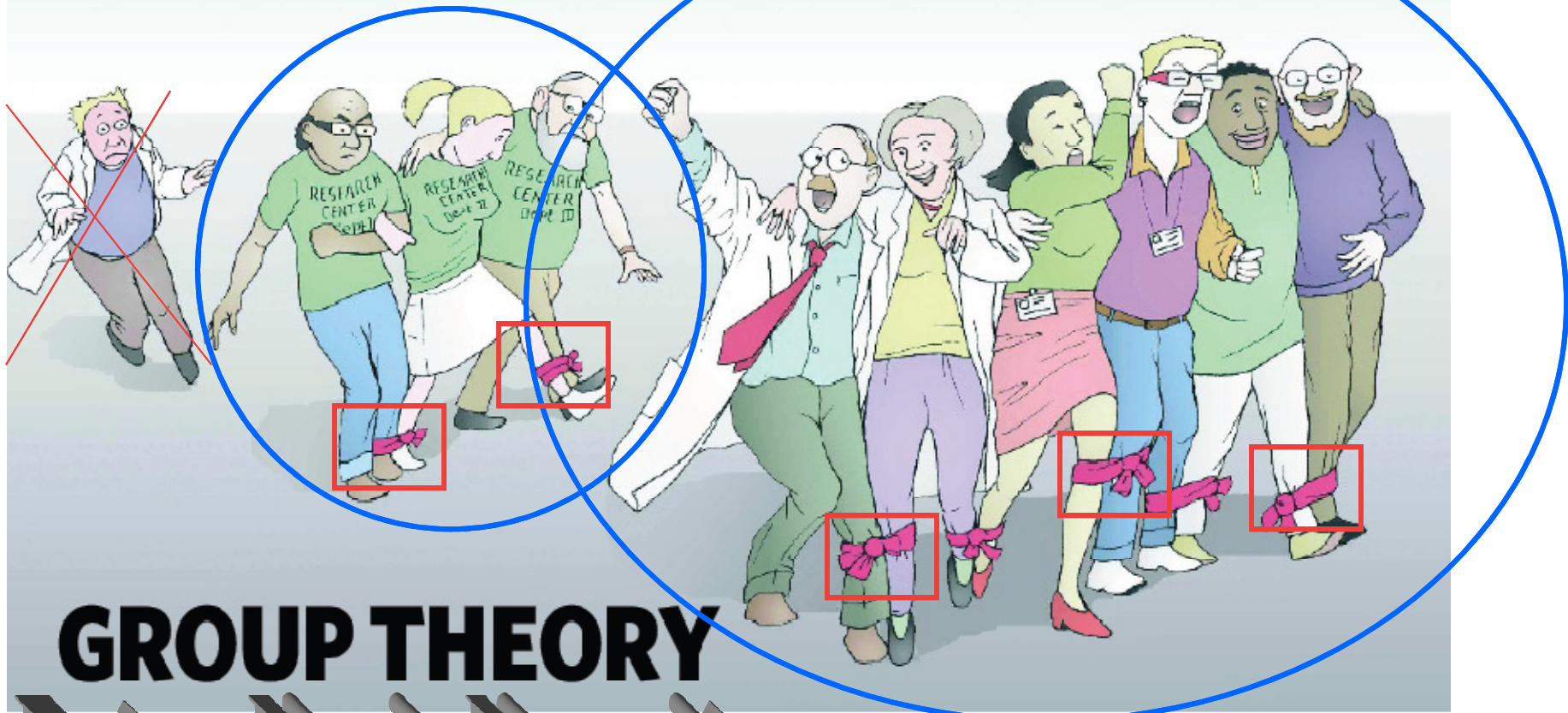
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What makes a successful research team?



GROUP THEORY

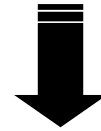
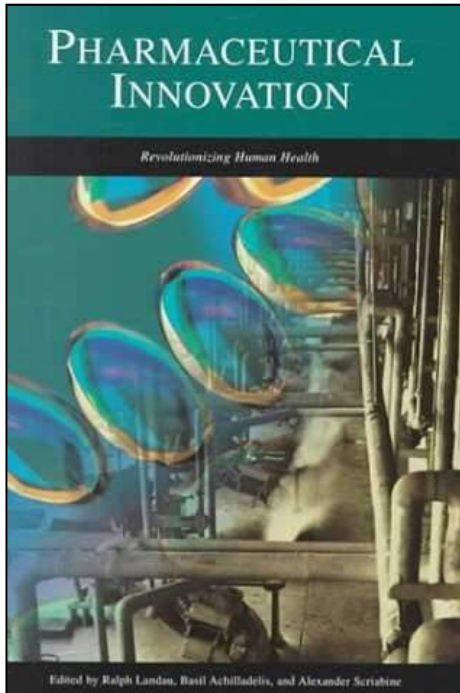
Interdisciplinarity

J. Whitfield, *Nature* 2008, 455, 720

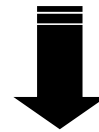
“A good scientist is someone who succeeds in getting the various scientific disciplines to work together harmoniously just as the fingers of a hand can function properly only if they work in concert.” P. Janssen

The Pharmaceutical Innovation

Technological innovation is a dynamic process perhaps the most dynamic of all industrial activities;



The dynamism of technological innovation also dependent of the interaction of Science & Technology;

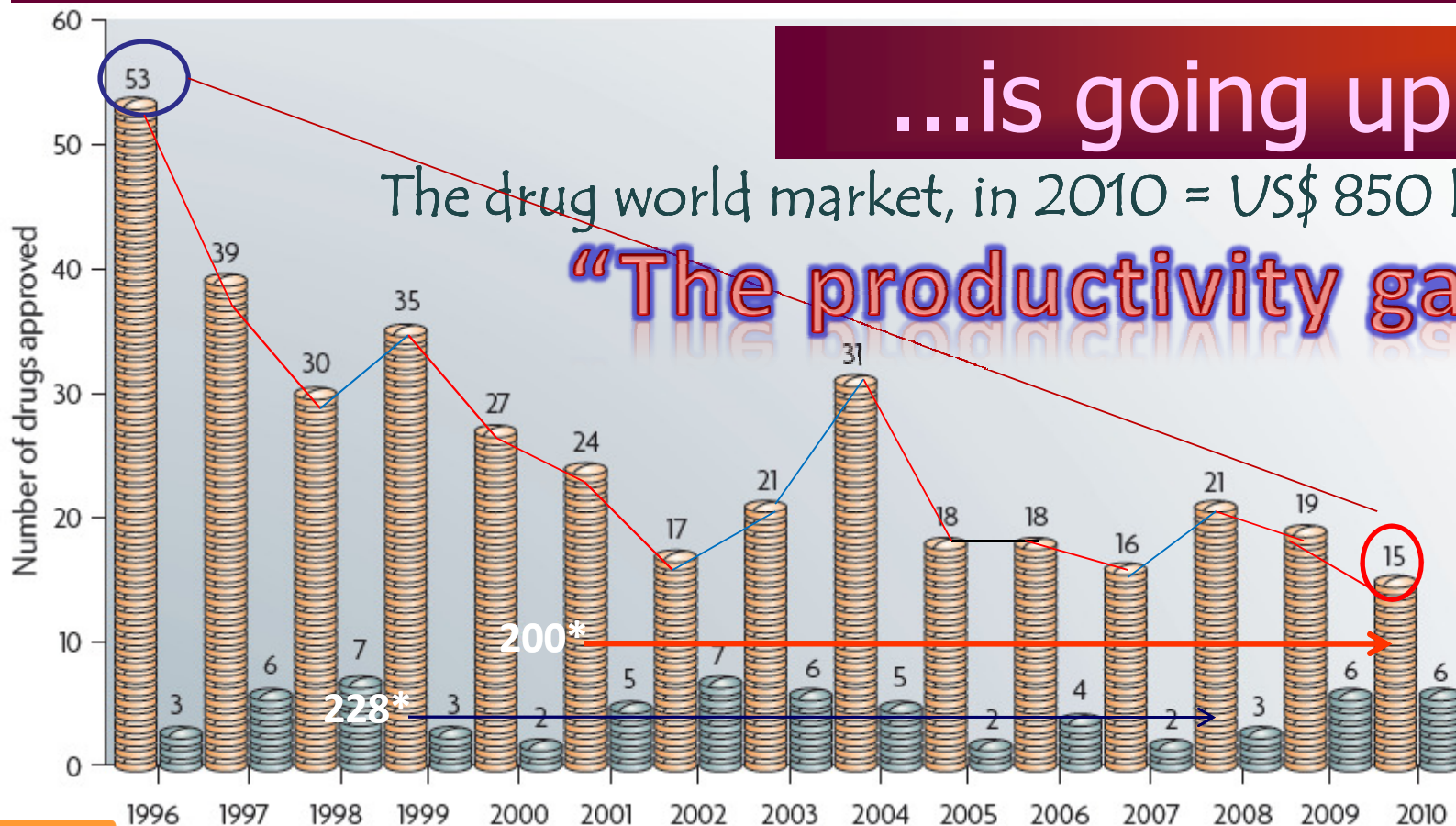


The technological innovation is the principal driving-force of pharmaceutical industry;



The Big Pharma innovation crisis...

...is going up !



The drug world market, in 2010 = US\$ 850 bi

“The productivity gap”



* A. Mullard, 2010 FDA drug approvals, *Nature Rev. Drug Discov.* **2011**, *10*, 82.

“In the 10-year period between 1999 and 2008, the FDA approved 183 small-molecule drugs...”

D Swinney & J Anthony, *Nature Rev. Drug Discov.* **2011**, *10*, 507.

The pharmaceutical industry invest *ca.* 10-15% year in R&D

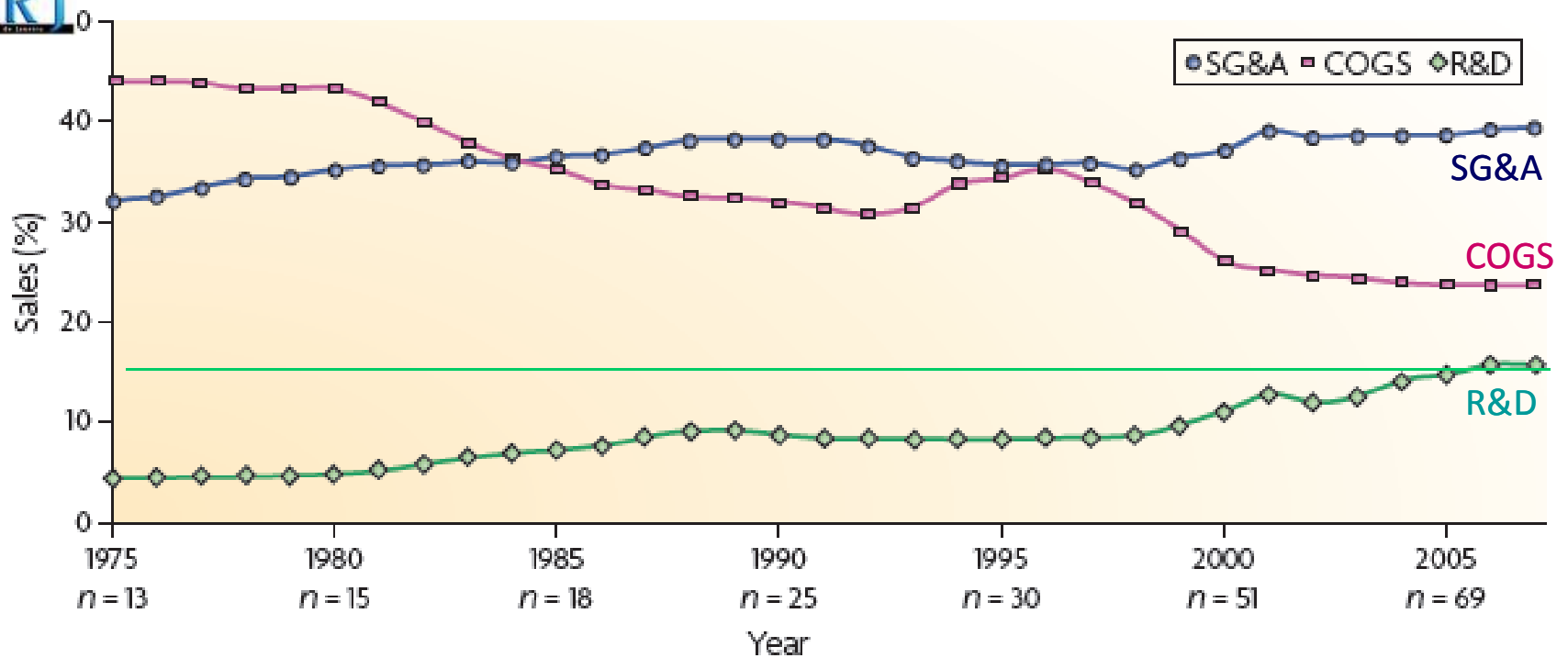


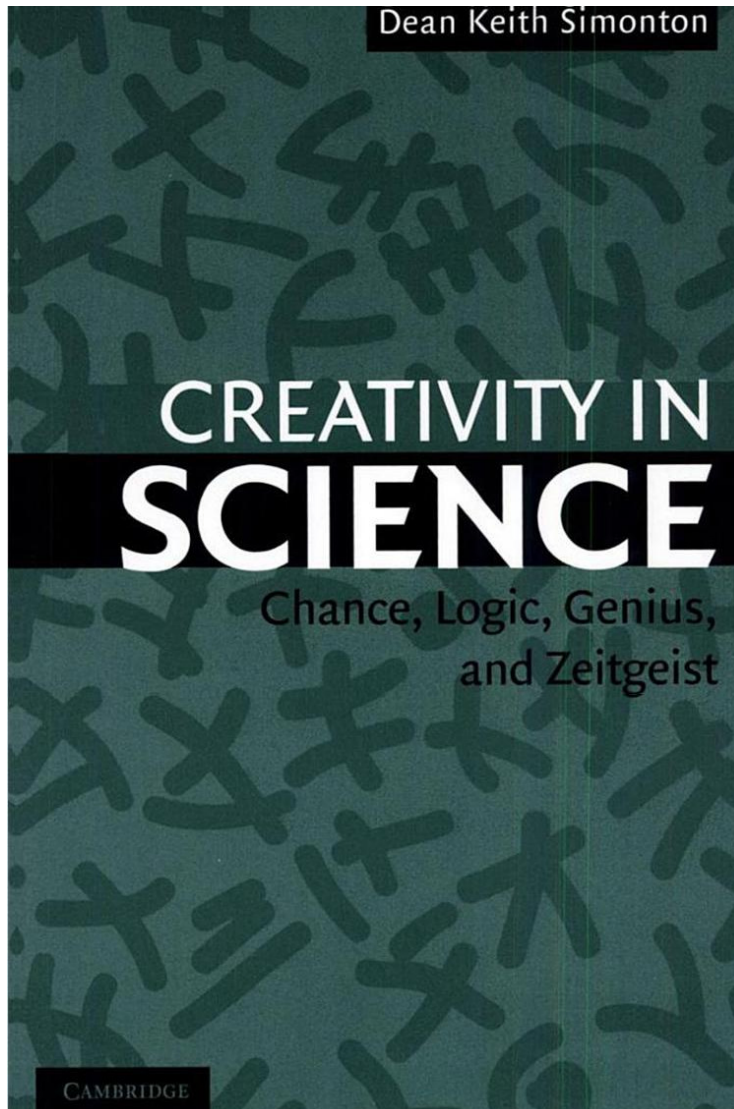
Figure 1 | Trends in resource allocation to SG&A, R&D and COGS in the pharmaceutical industry: 1975–2007. The figure plots median percentage of sales (smoothed). Investment in SG&A (sales, general and administrative costs) is shown in blue circles, COGS (costs of goods sold) is shown in pink squares and R&D (research and development) is shown in green diamonds.

- R&D. Research and development expenditures include raw materials and professional services used in R&D projects, salaries of R&D personnel, depreciation of infrastructure and cost of utilities committed for R&D purposes. R&D expenditures do not include costs of knowledge or formulas acquired from other companies.
- SG&A. Sales, general and administrative expenditures include costs of sales, promotions, customer support and training, marketing, advertising campaigns, public relations, distribution, sponsorships, general corporate activities and compensation of senior executives.
- COGS. Costs of goods sold include manufacturing costs such as raw materials, subcontractors, salaries of production labour, depreciation of machines, production lines and infrastructures, utilities, maintenance costs and other manufacturing costs.



D Weiss, P Naik, R Weiss, The 'big pharma' dilemma: develop new drugs or promote existing ones?, *Nature Rev. Drug Discov.* **2009**, *8*, 533.

Creativity & innovativeness



zeitgeist or "spirit of the times"

"discoveries and inventions become virtually inevitable (1) as prerequisite kinds of knowledge accumulate in man's cultural store; (2) as the attention of a sufficient number of investigators is focused on a problem – by emerging social needs, or by developments internal to the particular science, or by both"

Robert K. Merton (1961)

The role of genius in scientific advance. *New Scientist*, 12, 306-308

" without a dramatic improvement in R&D productivity, the pharmaceutical industry cannot sustain ... innovation ..."

D Swinney & J Anthony, How, were new medicines discovered?, *Nature Rev. Drug Discov.* 2011, 10, 507.

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Innovation in Drugs and Medicines



Project CNPq 573.564/2008-6

Home

INCT-INO FAR

Team

Scientific adviser board (SAB)

Research groups

Research people

Useful articles

Publications

Meetings

Videos



The Mission

- Organize the Brazilian scientific capacity in an effective drug discovery network;
- Support multi-institutional research projects in drug discovery & design;
- Contribute to Brazilian radical & incremental innovation in new & generic drugs;
- Studies in total synthesis of generic drugs & advanced synthetic intermediates and starting materials;
- Contribute to continuous high qualification of students in medicinal chemistry & pharmacology;

INCT-INO FAR



Innovation in Drugs and Medicines

Governance committee

Comitê de Governança & Acompanhamento (CGA)

Dra Vanderlan Bolzani (UNESP)
Dra Heloisa Beraldo (UFMG)
Dr Angelo C Pinto (UFRJ)
Dr Luiz Carlos Dias (UNICAMP)
Dr Marco Aurélio Martins (Fiocruz)



Coordenação
Dr Eliezer J Barreiro (UFRJ)
Vice-coordenação
Dr Fernando Q Cunha (USP-RP)

Superintendência Científica
Dra Lídia Moreira Lima (UFRJ)

Grupos de Pesquisa Associados
13 IES & 3 ICT

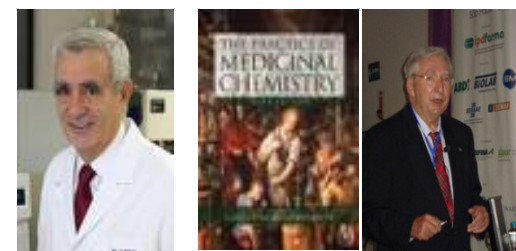


Consultoria Científica

Dr. Francisco S Guimarães (USP-SP)
Dr Vitor F Ferreira (UFF)

Dr Antonio Monge (Espanha)
Dr Camile G Wermuth (França)

Foreign scientific consultants



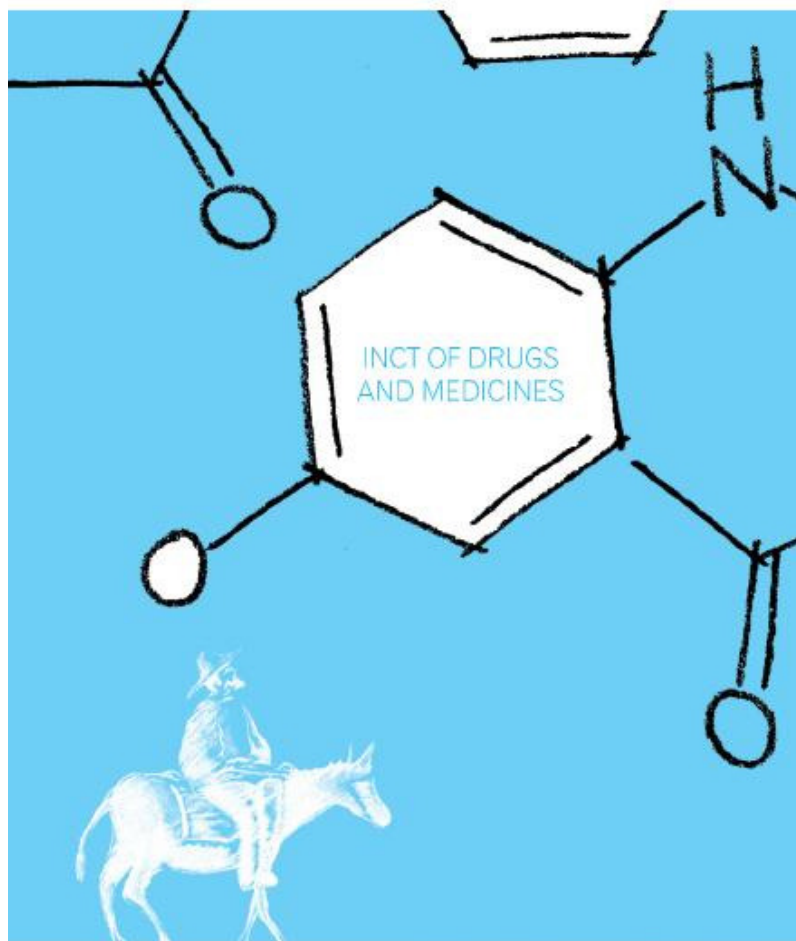
Antonio Monge, Universidad de Navarra, ES
Camille G. Wermuth, Prestwick Co., Ilkirch, FF

Research partners



INCT-INO FAR

Annual Activities Report



Interdisciplinary & multi-team research projects

- **Radical innovation**
pain, inflammation,
asthma, CNS,
neglected diseases,
cardiovascular system,
anticancer
- **Incremental innovation**
 SUS (BR healthcare)
 new generic drugs



2010

ANNUAL ACTIVITIES REPORT

www.inct-inofar.ccs.ufrj.br/download/aar/2010.pdf



INCT-INO FAR

Radical *In*novation

ADVANCED PROJECTS

1. *Development of new anti-asthmatic pharmaceutical prototypes (LASSBio-596).*
Prof. Patricia Rieken Macedo Rocco (UFRJ) -
Prof. Lidia Moreira Lima (UFRJ)
2. *Study of functionalized n-phenylpiperazine derivatives as prototypes for the development of new atypical antipsychotics.*
Prof. Stela Maris Kuze Rates (UFRGS)
3. *Study of the potential anti-inflammatory effect of the LASSBio 897 compound, on silicosis and asthma models.*
Prof. Patricia Machado Rodrigues e Silva (FIOCRUZ-RJ)
Prof. Marco Aurelio Martins (FIOCRUZ-RJ)

22%



INTERMEDIATE PROJECTS

1. *Benzaldehyde Semicarbazone(BS).*
Prof. Heloisa de Oliveira Beraldo (UFMG)
2. *Therapeutic potential of the new vasodilator compound (LASSBio 1289) in arterial and pulmonary hypertension.*
Prof. Gisele Zapata Sudo (UFRJ)
3. *Evaluation of antiparasitary activity of a series of semicarbazone and hydrazine-n-acylhydrazone derivatives.*
Prof. Magna Suzana Alexandre Moreira (UFAL) -
4. *Prospection of Opportunities in New Generic and Innovative New Generic Medications.*
Prof. Adelaide Maria de Souza Antunes (INPI)
5. *Planning, synthesis and pharmacological evaluation of vectorized and self-organized neuroactive prototypes.*
Prof. Ricardo Menegatti (UFG)
6. *Planning, synthesis, structural characterization and pharmacological evaluation of new anti-inflammatory, anti-infective, and neuroactive pharmaceutical candidates.*
Prof. Claudio Viegas Junior (UNIFAL-MG)

43%

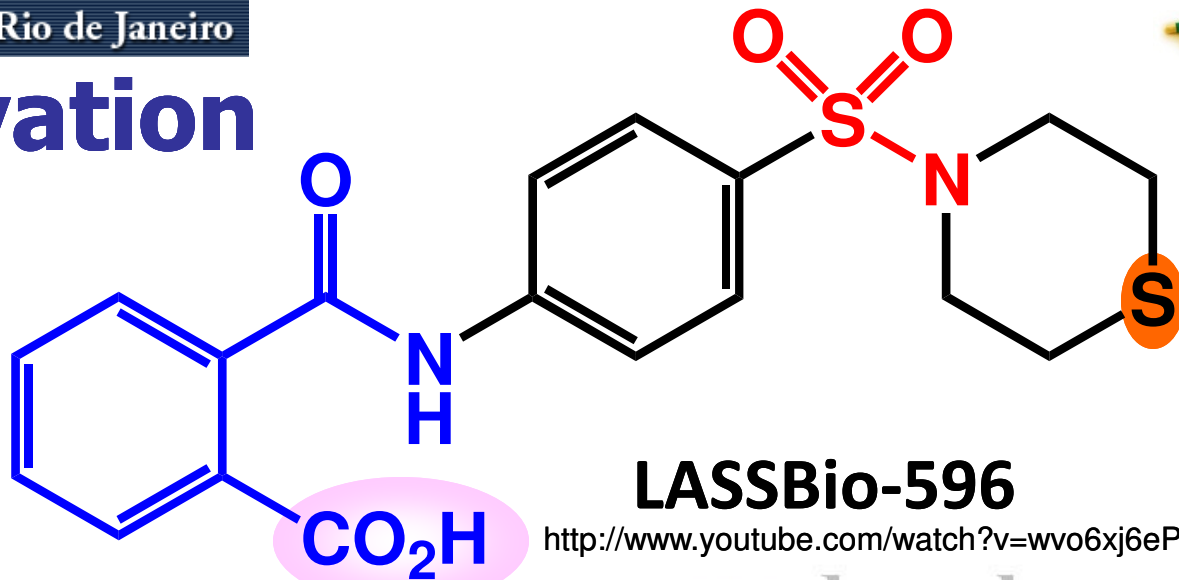
EARLY STAGE PROJECTS

1. *Theoretical Investigation of the Action Mechanism of Dialkylphosphorylhydrazones as Ribose 5-Phosphate Isomerase Enzyme Inhibitors of Trypanosoma cruzi and Plasmodium falciparum.*
Prof. Carlos Mauricio R. de Sant'Anna (UFRJ) -
2. *Evaluation of the antitumoral activity of new molecules planned structurally from the imatinib prototype.*
Prof. Patricia Dias Fernandes (UFRJ)
3. *Triage of new replication inhibitors for the acquired human immunodeficiency virus Type 1 (HIV-1) from the LASSBio Chemical Library.*
Prof. Luciana Jesus da Costa (UFRJ)
4. *Pharmacological evaluation of new neuroactive Zolpidem derivatives.*
Prof. Roberto Takashi Sudo (UFRJ)
5. *"In silico" prediction and "in vitro" production through bioconversion of human metabolites of pharmaceutical prototype candidates.*
Prof. Valeria de Oliveira (UFG)

35%

Radical *In*novation

Innovation in Drugs
and Medicines



LASSBio-596

<http://www.youtube.com/watch?v=wvo6xj6ePPs>

medicinal chemistry

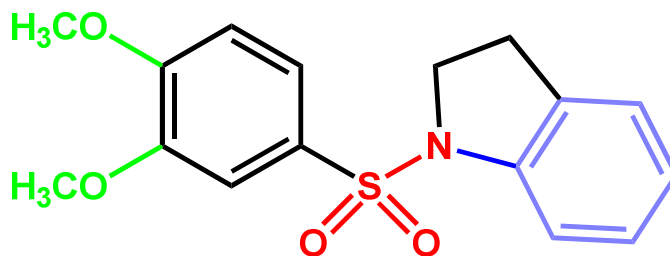
BR Patent Of.
PI0401660-2

NMA

Anti-asthma

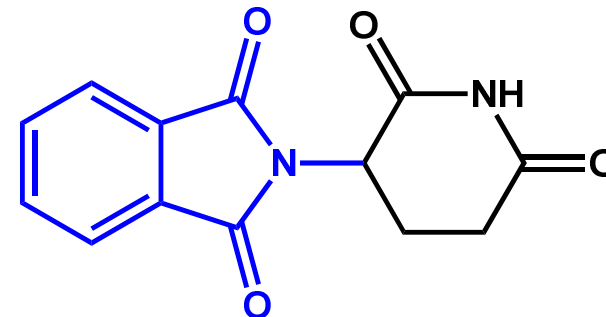


Molecular hybridization
Bioisosterism



Phosphodiesterase-4
Montana, 1998

Metabolic stability



TNF- α
Thalidomide, 1957

L. M. Lima *et al.*, *Bioorg. Med. Chem. Lett.*, **12**, 1533, 3067 (2002) ; P. R. M. Rocco *et al.*, *Eur. Respir. J.*, **22**, 20 (2003); L. M. Lima *et al.*, *Anti-inflammatory & Anti-allergy Agents in Medicinal Chemistry*, **3**, 9 (2004) ; J. V. Bevilaqua *et al.*, *Applied Biochem. Biotechnol.*, **121**, 117 (2005); M. S. Alexandre-Moreira *et al.*, *International Immunopharmacology*, **5**, 485 (2005); H. S. Campos *et al.*, *Braz. J. Med. Biol. Res.*, **39**, 283 (2006) ; L.M. Lima *et al.*, *Anti-inflammatory & Anti-alergy Agents in Medicinal Chemistry*, **5**, 79 (2006); C. Viegas-Junior *et al.*, *Current Medicinal Chemistry*, **14**, 1829 (2007); E J Barreiro, C A M Fraga, *Current Drug Therapy*, **3**, 1 (2008); G M C Carvalho *et al.*, *Toxicol.*, **56**, 604 (2010); P.R.M. Rocco *et al.*, *Rev. Virtual Quim.*, **2**, 14 (2010); N.V. Casquilho *et al.*, *Toxicol.*, **58**, 195 (2011);



Atorvastatin

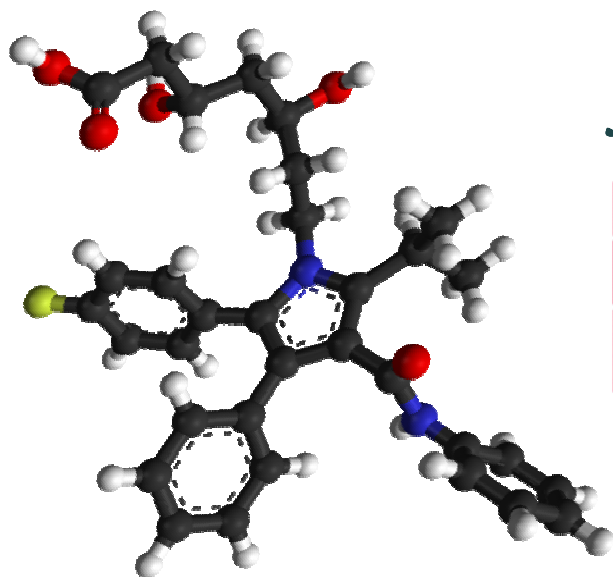
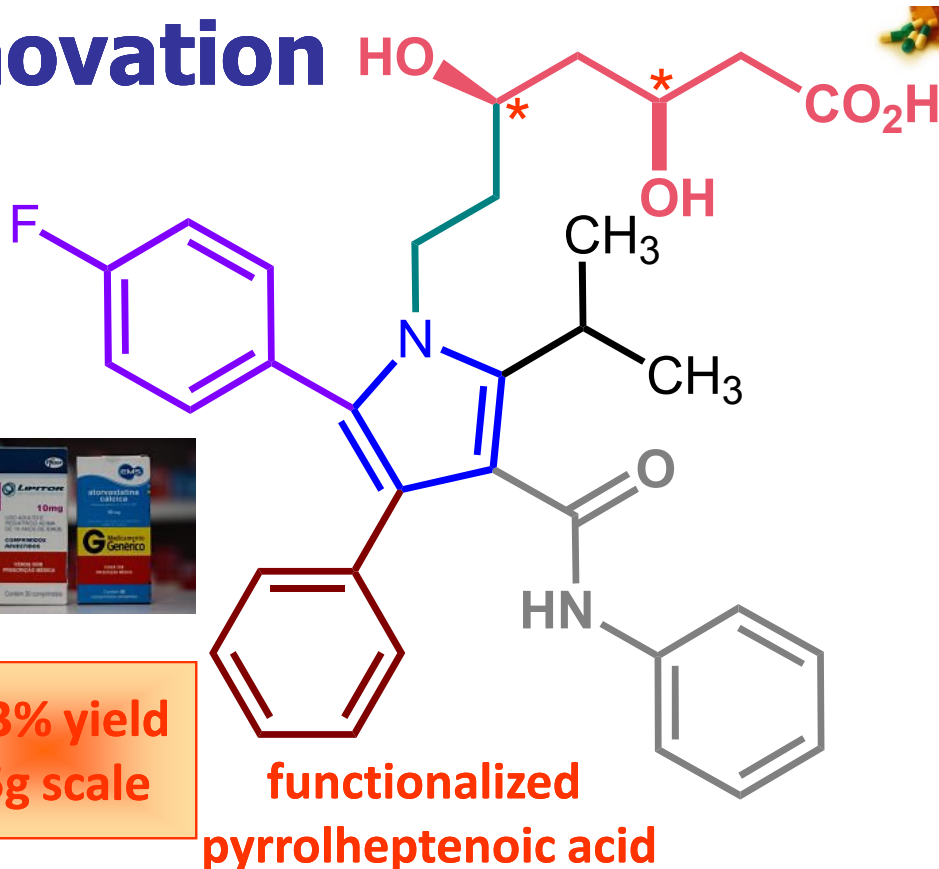
1991



- Synthesized, in 1985, by Bruce D. Roth
- Patent US 5273995 Pfizer (1991)
- New stereoselective synthesis by Professor **Luiz Carlos Dias** & Dr **Adriano S. Vieira**, UNICAMP, BR (2010) – INPI Patent, 2011



19.3% yield
2.5g scale



super blockbuster-drug



- B. D. Roth, BD (2002). "The discovery and development of atorvastatin, a potent novel hypolipidemic agent", [*Prog Med Chem* 2002, 40, 1–22](#)
- K. Maggon, "Best-selling human medicines 2002–2004", [*Drug Discovery Today* 2005, 10, 739–42](#)



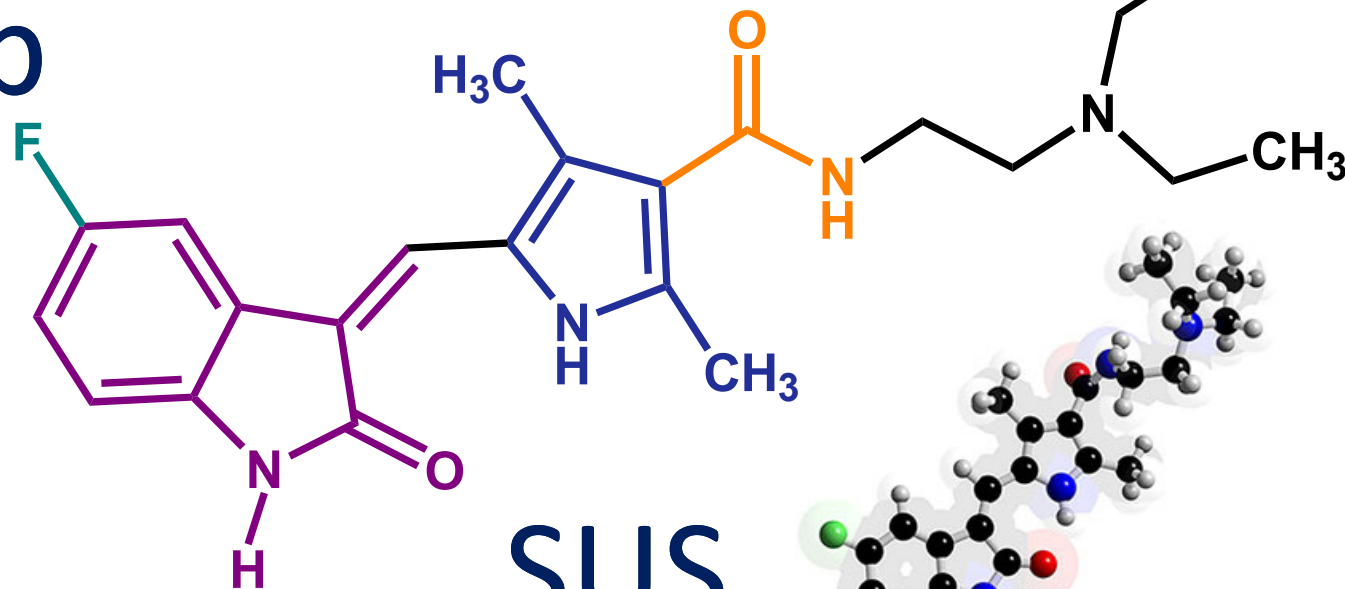
Incremental *In*novation

Sunitinib

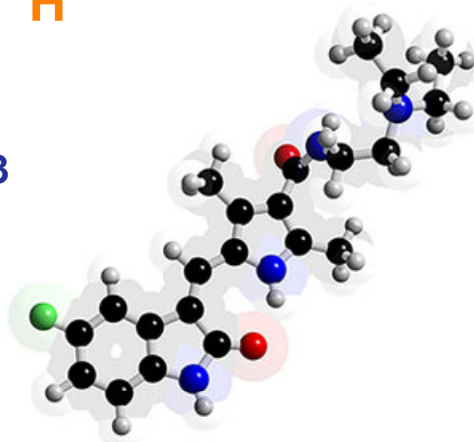


2006

Sutent[®]



SUS



- Synthesised in 1999, Pfizer
- US Patent 2001
- Inhibitor of BCR-ABL Tyr-kinase
- Launched for CA-stomach / kidney in 2006
- Total synthesis Prof. **Angelo da Cunha Pinto** & Dra **Bárbara Vasconcellos da Silva** UFRJ (**2011**)

50 mg / 28 caps *ca.* R\$ 20.837,90

Total sales of tinibs in
 US market:
 US\$ 18,5 bi (2009)

Brazil imports
ca. US\$ 3 mi / y

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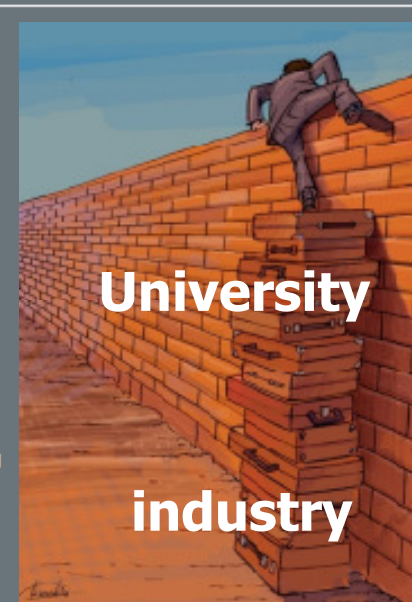
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Drug Discovery Today • Volume 14, Numbers 1/2 • January 2009

07 October 2009 vol 1, issue 1, 95-101

REVIEWS



Reviews • POST SCREEN

Drug discovery: new models for industry–academic partnerships

Cathy J. Tralau-Stewart, Colin A. Wyatt, Dominique E. Kleyn and Alex Ayad

Drug Discovery Centre and Business Development, Imperial College London SW7 2AZ, UK

The re-focusing of pharmaceutical industry research away from early discovery activities is stimulating the development of novel models of drug discovery, notably involving academia as a ‘front end’. In this article the authors explore the drivers of change, the role of new entrants (universities with specialised core facilities) and novel partnership models.

PG Wyatt, The emerging academic drug-discovery sector. *Future Med. Chem.* **2009**, *1*, 1013; R Kneller, The importance of new companies for drug discovery: origins of a decade of new drugs. *Nature Rev. Drug Discov.* **2010**, *9*, 867; AJ Stevens *et al.*, The role of public-sector research in the discovery of drugs and vaccines. *N. Engl. J. Med.* **2011**, *364*, 535.

Pharmaceutical industry

- Is intensive in Sci-research activity (no in BR);
- The competition pattern depend on new products (not original in BR);
- High innovation activity, radical >> incremental (in BR is the opposite);
- *ca. 8-12% of chiffre d'affaires* in RD&I investments (no in BR);
- High active in IP (very poor in BR);
- High qualify (PhD's) mainpower (no in BR);
- High expenses in marketing (*ca. 14%*; more than this in BR).

Pôle de recherche interdisciplinaire pour le médicament



Parc d'Innovation d'illkirch
Communauté Urbaine de Strasbourg



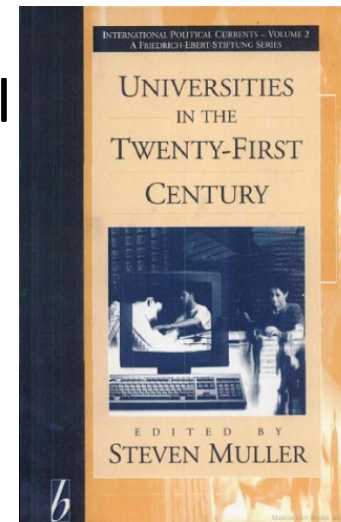
The effective and productive industry-university interaction in Brazilian pharmaceutical sector is poor, superficial and occasional.

University-Pharmaceutical industry partnerships in Brazil



• New drug discovery consortium (Rede de Conhecimento)

- A BR-based Consortium to discover & development novel drug candidates (lead-compounds), with BR Pharma industries, government financial agencies and selected DD research group from public universities;
- The virtual Consortium need to be manager by a multiple members committee (*e.g.* Uni / Ind / Gov);
- The Consortium needs experienced and dynamic Medicinal Chemistry research groups well articulate with Pharmacology research teams;
- The Consortium brings the core intellectual resource to:
 - (i) contribute to BR innovative cycle in DD as an effective international player;
 - (ii) develop high-tech DD start-up's in Brazil;
 - (iii) promote in partnership with industries the translation from a lead compound to a potential drug in clinical...



Final remarks

*“For all the **efforts to industrialize** and **automate discovery**, history suggests **drug discovery is art** as well as science **and relies heavily on the skill of experienced drug hunters...**”*

C&EN
CHEMICAL & ENGINEERING NEWS



Charles H. Reynolds

Johnson & Johnson Pharmaceutical Research and Development, Spring House, Pa
em Pharma's Road Ahead , C&EN Special Issue, Volume 84, number 25, June 19, 2006

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Thank you for attention.