L'esperienza di un ricercatore nello sviluppo e nella *litigation*

Margherita Morpurgo
University of Padova

“My” places

Università di Padova (IT)
The University of Alabama in Huntsville (USA)
Weizmann Institute of Science (IL)
Integrated Technology Corp (IT)
Mount Sinai Medical School (USA)

Università di Padova (IT)
ANANAS Nanotech (IT)
- Start Cup (2006)
- PNI – Premio Nazionale Innovazione (2006)
- Nanochallenge (2008)
- Expo 2010 Shangai (2010)

Universitie and Biotech companies are where most of the innovative drugs come from

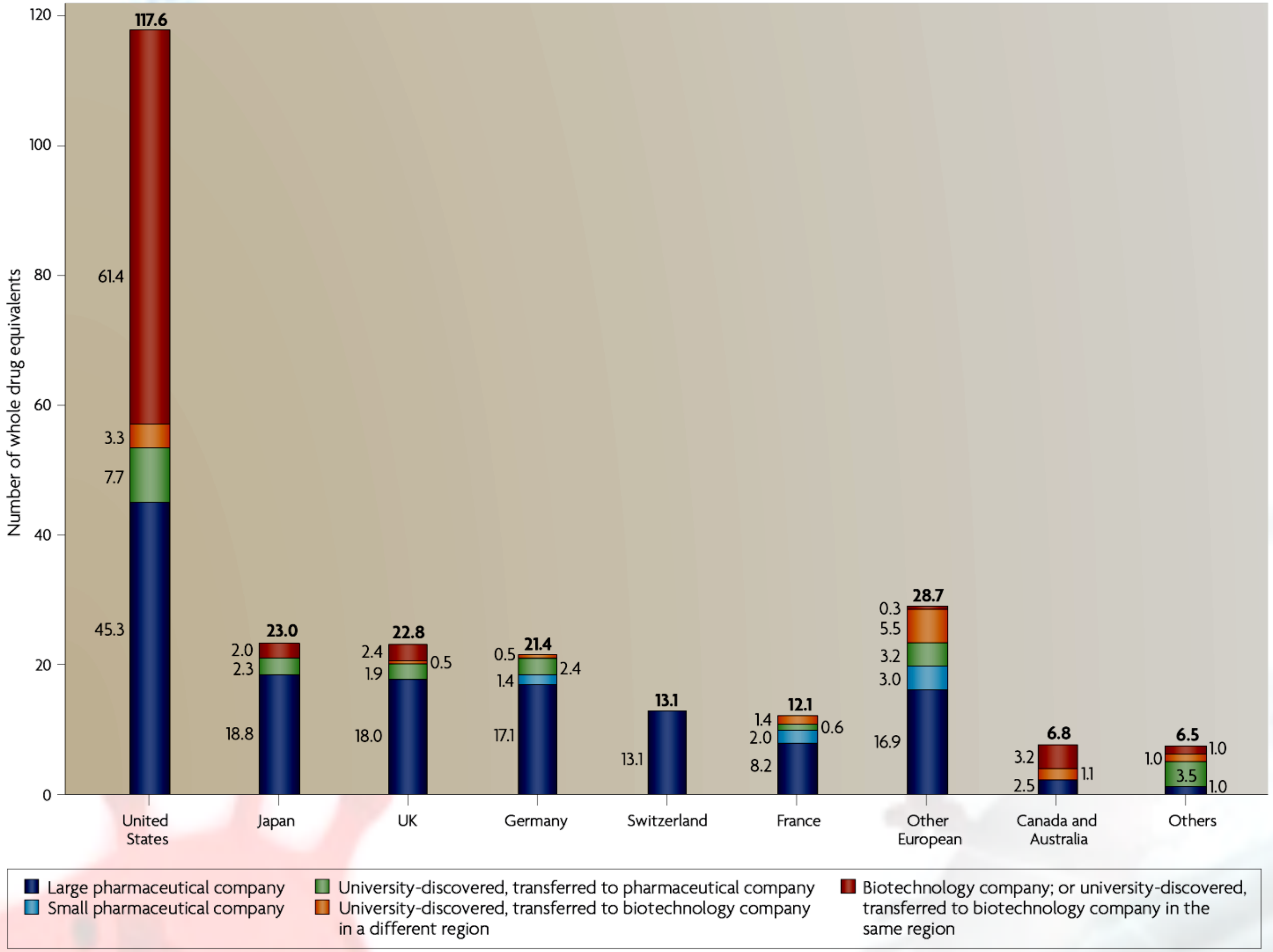


Figure 1 | **Allocation of the 252 new drugs approved by the US Food and Drug Administration between 1998 and 2007.** The distribution of the discovery of all 252 drugs according to the type of the discovering organization (see key) among the six leading drug-discovering countries (United States, Japan, UK, Germany, Switzerland and France), other countries in continental Europe (principally Italy, Denmark, Belgium, Sweden, the Czech Republic and Spain), Canada and Australia combined and other countries (principally Israel). The numbers represent whole drug equivalents; for details,

Kneller, R. The importance of new companies for drug discovery: origins of a decade of new drugs. Nat Drug Discov 2010. 9. 867-882

1.

Why Tech Transfer in Life Science *is different*

Why Tech Transfer in Life Science *is different*

«Science is certainty, **research is uncertainty**. Science is supposed to be cold, straight, and detached; research is warm, involving, and risky. Science puts an end to the vagaries of human disputes; **research creates controversies**»

Latour, B. (1998). From the world of science to the world of research? Science, 280(5361), 208-209.

Why Tech Transfer in Life Science *is different*

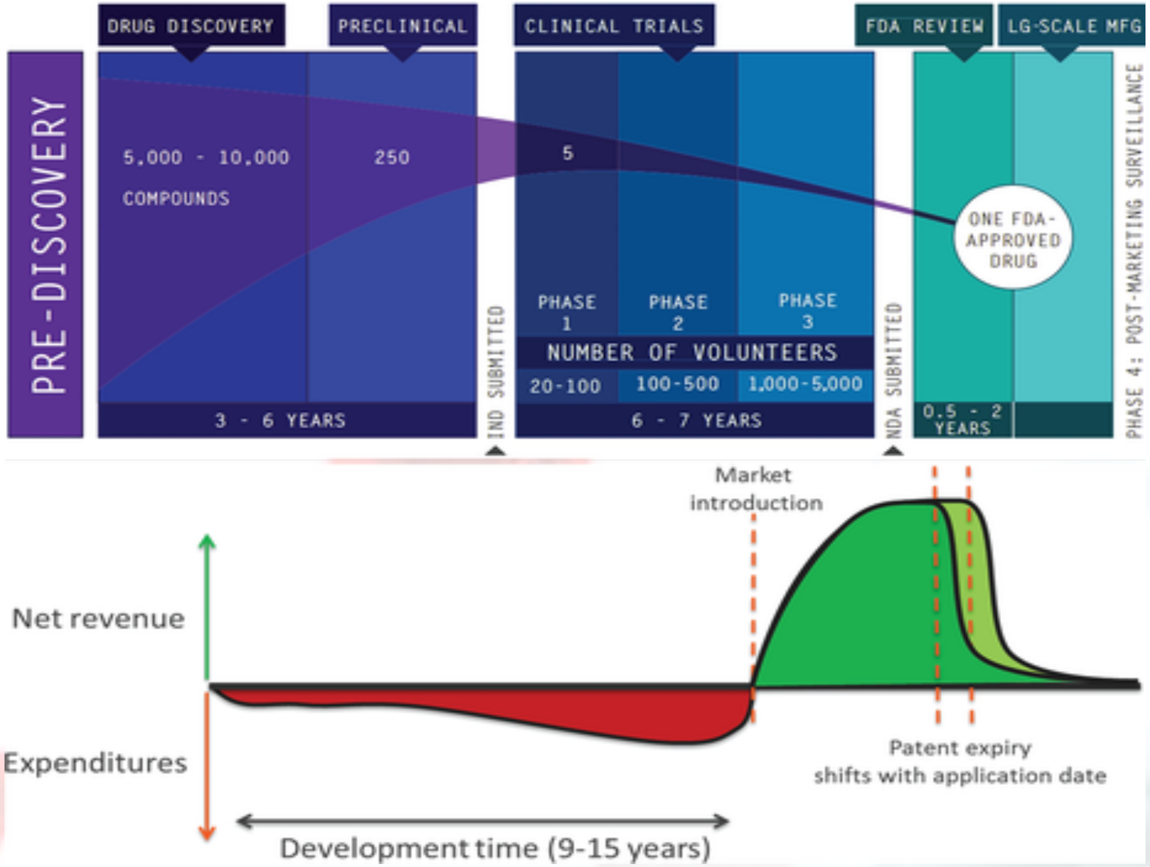
Low reproducibility rates within life science research undermine cumulative knowledge production

Freedman, L. P., Cockburn, I. M., & Simcoe, T. S. (2015). The economics of reproducibility in preclinical research. PLoS Biol, 13(6), e1002165

Why Tech Transfer in Life Science *is different*

Developing a new prescription medicine that gains marketing approval, a process often lasting *longer than a decade*, is estimated to cost ***$2,558 million***

(Tufts Center for the Study of Drug Development 2014)



A scientist normally gets scared by these numbers

Netval

Why Tech Transfer in Life Science *is different*

2014	2013	2012

Top sellers 2014

#	Product	2014 ($m)	2013 ($m)	Growth ($m)	Growth (%)
1	Humira	13021	11105	1916	17
2	Sovaldi/Harvoni	12410	139	12271	8828
3	Remicade	10151	9900	251	3
4	Enbrel	9120	8894	226	3
5	Lantus	8152	7343	809	11
6	MabThera/Rituxan	7356	7410	-54	-1
7	Avastin	6841	6667	174	3
8	Seretide/Advair	6700	8356	-1656	-20
9	Herceptin	6690	6481	209	3
10	Crestor	6617	6960	-343	-5
11	Abilify	6416	9502	-3086	-32
12	Lyrica	5435	4838	597	12
13	Revlimid	4980	4280	700	16
14	Gleevec/Glivec	4746	4693	53	1
15	Spiriva	4722	4564	158	3
16	Neulasta	4596	4392	204	5

A scientist normally doesnt know these numbers

1. So what?

- University/Research Institution laboratories make the difference!
- Research creates controversies, not certainties but a market product must give certainties
- Life Science results have Low reproducibility rates: risk
- Drug development is very costly but can be extremely rewarding

2.

Which Business Model in Life Science ?

“Life sciences” is not only DRUGS

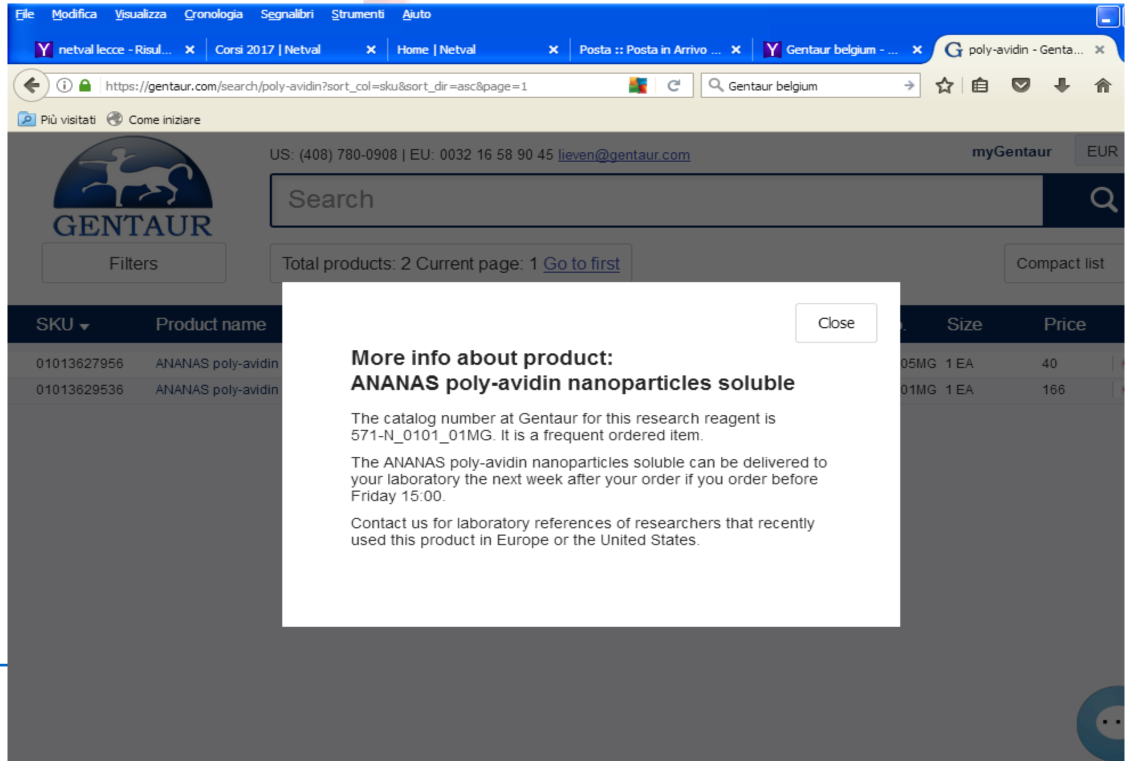
Experiences that changed my life

Dear Nektar Customer,

For more than a decade, we have been wo
Shearwater, and now as Nektar. In that time
breakthrough and blockbuster products, including:

- – Neulasta® (pegfilgrastim) by Amgen
- – Somavert® (pegvisomant) by Pfizer
- – PEGASYS® (peginterferon alfa-2a) by Roche
- – PEG-INTRON® (peginterferon alfa-2b) by Schering-Plough
- – Definity® (perflutren lipid microsphere) by Bristol-Myers Squibb
- – Macugen® (pegabtanib) by Eyetech & Pfizer
- – DuraSeal™ (PEG hydrogel) by Confluent Surgical

THE UNIVERSITY OF ALABAMA IN HUNTSVILLE

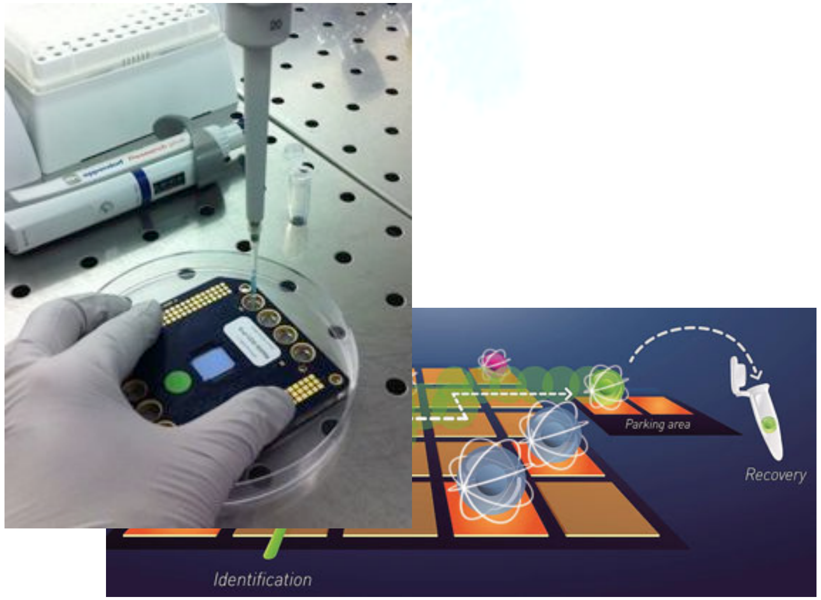


Lesson 1. The road from bench to market can also be faster...

Netval

Experiences that changed my vision

MENARINI silicon biosystems



Management Team
Distributors
Careers
Contact Us

MENARINI group

Management Team

GIUSEPPE GIORGINI
President and Chief Executive Officer

ROBERTO GRITTI
Financial Officer

GIANNI MEDORO, PhD
Chief Technology Officer

NICOLO MANARESI, PhD
Chief Scientific Officer

RAIMO TANZI
Chief Commerical Officer

BARBARA BAGGIANI
Chief Marketing Officer

FARIDEH BISCHOFF, PhD
Chief Clinical Development Officer, North America

2. A manager with experience in the business is fundamental

2. So what?

- There are different business models applicable towards innovation in LS:
- trade-off between Radical Innovation and Incremental Innovation
- A (LS) scientist is not a manager→ A manager is mandatory→ the TEAM

- Networking, networking networking!
- Accelerator programs
- Financial Resourses and Financial Institutions
  - Family Offices
  - Business Angels
  - Government Grants
  - National and International VCs

3.

What does a Life Scientist expect when approaching TTOs

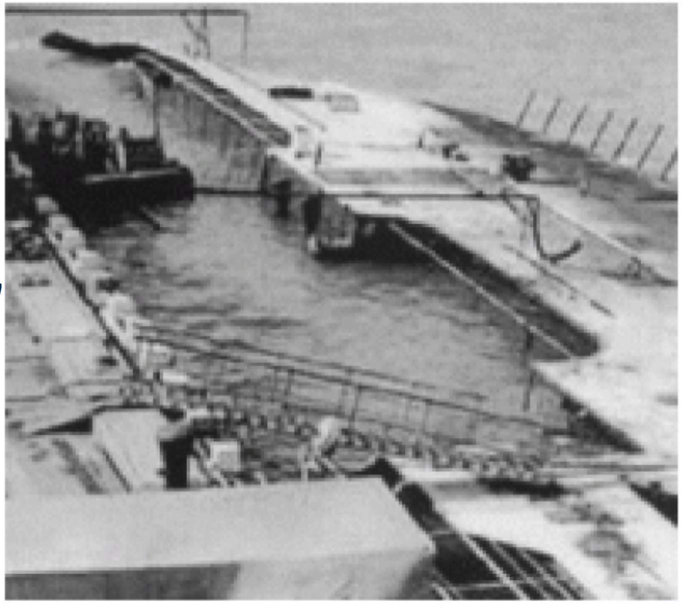
What does a Life Scientist expect when approaching TTOs

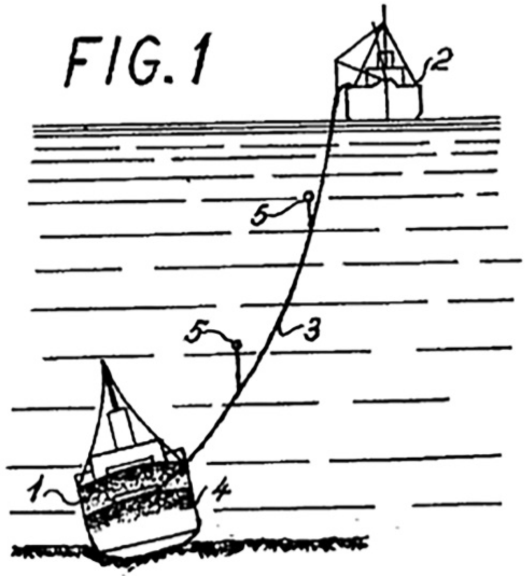
- *Someone that understands his/her invention*
- *A <u>long lasting</u> relationship*
- *A relashionship between <u>equals,</u> which <u>complements</u> his/her <u>skills</u>*
  - *<u>IP strategy,</u>*
  - *<u>Money for valorization</u>*
  - *<u>Legal, business models and competences</u>*

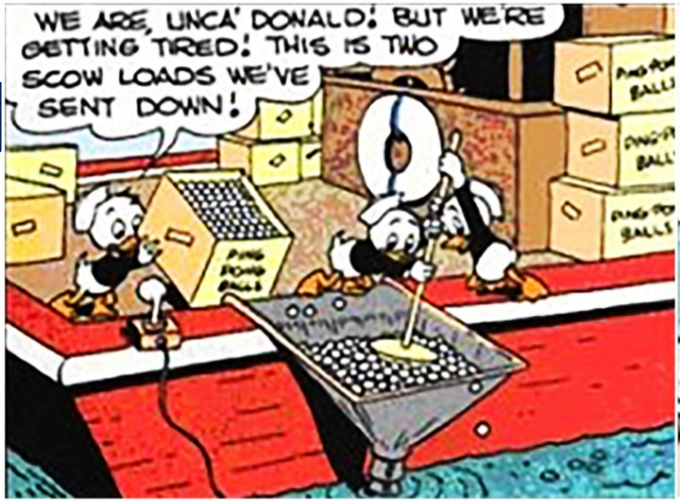
4.

My involvement in a pharmaceutical lawsuit

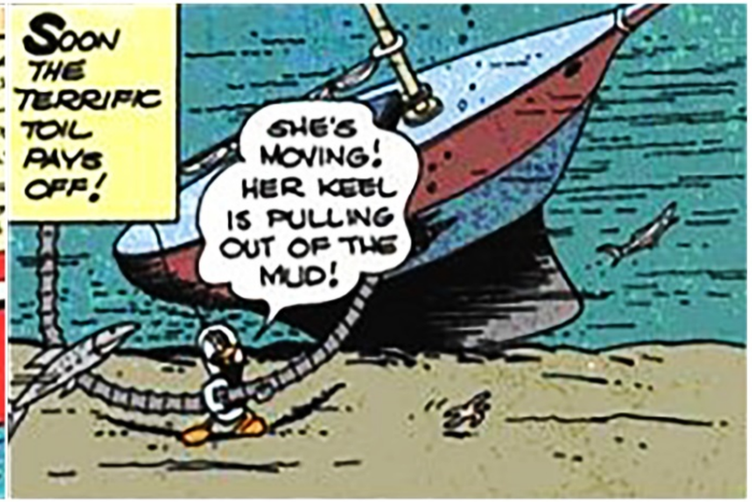
Patentability…







© Disney



© Disney

…and freedom to operate ?

Heus, J. 2017, *Importance of intellectual property generated by biomedical research at universities and academic hospitals, Journal of Clinical and Translational Research*, 10.18053/jctres.03.201702.005

4. So what?

- The way data are recorded can make the difference
- Knowledge based Value is not only IP
- Legal: how to be prepared?...

Happy birthday NETVAL!