

20 September 2018, Berlin

Embassy Room

IPR Policies

Dr. Alison Campbell (chair)

Dr. Jörn Erselius

Dr. Jérôme Van Biervliet

Alice Frost

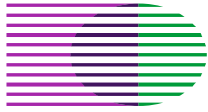
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IPR Policies

Dr. Alison Campbell

Chair of AUTM & Director of Knowledge Transfer Ireland



KTI

Knowledge Transfer Ireland
Where Research & Business Connect

Connect at knowledgetransferireland.com

IPR POLICIES: PANEL DISCUSSION

AESIS Conference
Berlin, 20 September 2018



Our discussion topic

Which IPR policies and IPR agreements are best capable to stimulate that university discoveries are used in an industrial setting in such a way that the outcome for society is optimised?

Panel

- Jörn Erselius
 - Managing Director, Max Planck Innovation, GERMANY
- Jérôme Van Biervliet
 - Head of Business Development, VIB, BELGIUM
- Alice Frost
 - Director, Knowledge Exchange, Research England, UK
- Panel Chair: Alison Campbell
 - Director, Knowledge Transfer Ireland, Chair AUTM, IRELAND

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IPR Policies

Dr. Jörn Erselius

Managing Director of Max Planck Innovation, Germany



Jörn Erselius

Societal Outcome of Academic-Industrial Collaborations

AESIS, September 20, 2018 Berlin

Max-Planck-Gesellschaft (Max Planck Society)

Largest basic research organization in Germany:

- 83 Max Planck Institutes (MPIs)
 - 29 Life science section (BMS)
 - 34 Chemical, physical, technical section (CPTS)
 - 20 Social sciences and humanities (GSHS)

- Financing:
 - ≈ 80% federal and state funds (50:50)
 - + donations, membership fees

budget: ≈ € 1,7 billion + third party funds (public and private)

- 17.200 staff, including 5600 scientists
+ 4.700 junior/visiting scientists



Max-Planck-Innovation GmbH (MI) – MPG Technology Transfer

- MI is a 100% subsidiary of the Max Planck Society
- MI handles most technology transfer matters for MPG (patenting, licensing, start ups, support of collaboration agreements, ...)
- MPG/MI has no written IP policy
 - however, there is a common understanding how IP and commercialization should be handled and there are certain guidelines for inventors, founders, etc.
- Lately shift from “maximizing” commercial value to (societal) impact
- Contradiction: policy makers want more impact but measure technology transfer of academia by numbers (number of patents, licenses, income, start ups)
- Biggest political pressure on start ups – “founder friendly” terms (equity, license terms) expected
- IP practice: flexibility !
 - most important is the transfer of research results into industry, not optimizing profit however, terms should be fair...

Benefit for Society – Equitable Licensing

- One important aspect of social impact is equitable licensing, i.e. helping to make products – mainly medical treatments - available in developing countries through favorable licensing terms by academia
- Specific terms for developing countries (low price, non assert etc.) are very difficult to negotiate with pharma companies (except waiving royalties), but these terms are usually not the limiting factor in commercializing early technology
 - MPG would not hinder the development of an important drug for developing countries because of unsatisfactory licensing terms
- Funding needs to be available to translate basic research finding at least to a proof of concept (done at MPG e.g. through the Lead Discovery Center) and later on also for drug development
- Several case studies from MPG show the complexity of equitable licensing

Anti Malaria Drug Artemisinin

- Still more than 500,000 people - mostly children - die from malaria every year
- Malaria is treated with Artemisinin (part of a combination product), extracted from the plant *Artemisia Annua* (sweet wormwood)
 - Nobel Price in Medicine 2015 for Prof. Tu Youyou
- WHO mainly contracts crop growing (18 months) to farmers in the Golden Triangle
 - Sweet Wormwood as alternative income source to Opium Poppy
- Due to crop failure and speculation the availability and price of Artemisinin fluctuates
 - Artemisinin (demand 150–300 tons/a) is not suitable for long term storage



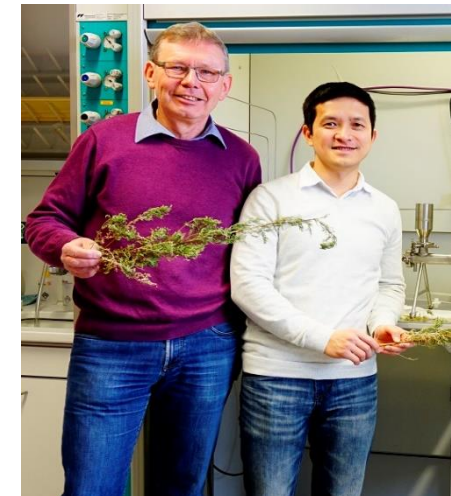
Semi Synthetic Artemisinin (SSA)

- PATH Project on SSA as fall back option in case of shortages
 - Co-financed by Bill and Melinda Gates Foundation
 - Amyris produces Artemisinic Acid (precursor) from yeast
 - Sanofi-Aventis uses a photochemical batch (370kg) process to manufacture Artemisinin
 - Industrial production plant (up to 60 tons/a) went operative 2013
- Sanofi met market resistance
 - Price of SSA is higher than price from plant extractions
 - Competitors denied to buy SSA from Sanofi
 - Plant was sold to Huvepharma (Bulgaria) in 2016 that produces about 20 tons SSA/a



Artemisinin related research at Max-Planck-Institutes

- Prof. Peter Seeberger (MPI for Colloids and Interfaces) developed a high yield continuous flow process to convert Artemisinic Acid into Artemisinin in 2011
 - Improved process (2013) directly produces APIs (like Artesunate, Artemether)
- Prof. Andreas Seidel-Morgenstern (MPI for Dynamics of Complex Technical Systems) added improved continuous plant extraction and crystallization process
- Humanity in Science Award 2015 for Prof. Seidel-Morgenstern and Prof. Seeberger

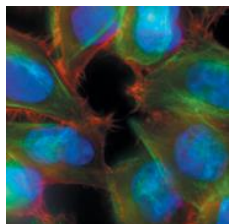
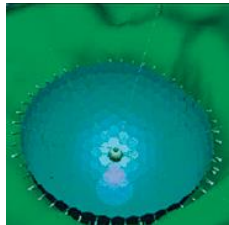


ArtemiFlow GmbH



- Startup ArtemiFlow GmbH was founded by Prof. Seeberger in 2012
 - Collaboration and funding proved to be complicated in a politically complex environment
 - Use of Artesunate as cheap cancer drug could be a second market
 - Unsuccessful negotiations to found a Joint Venture in Vietnam 2015/2016
 - Subsidiary in collaboration with tobacco farmers from Kentucky (US) planned 2018
 - Negotiations of license agreement ongoing, MPG renounces from royalties in developing countries
- By the way: in April 2015 FDA's Center of Drug Evaluation and Research (CDER) Director Woodcocks called on pharma manufacturers to switch from batch to continuous production
 - Prof. Seeberger founded another startup related to pharma production in continuous flow called Fluxpharm in 2016
 - First project: cheap production of Efavirenz (HIV)





Many thanks for your attention!

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Miltefosine – an Early Product Development Partnership (PDP)

- Miltefosine (hexadecyl-phosphocholin) is the only oral drug approved for the treatment of leishmaniasis
- It was developed as anti-cancer drug (Miltex®), approved in early 90s by Asta Medica
 - Hans-Jörg Eibl, MPI Göttingen; Clemens Unger, University Göttingen; Jürgen Engel, Asta Medica
- At the same time US and British scientists (Simon Croft) showed that Miltefosine could be a potential treatment for Leishmaniasis
- They started a collaboration with the WHO, which later became a PPP between WHO, academia and Asta Medica (later Aeterna Zentaris)
- Clinical trials in India, approved in 2002 in India and subsequently in other countries
- Today also used in animals (dogs)
- Compound with less side effects (Oleyl-Phosphocholin) was, despite many efforts by MPG (e.g. collaboration with Dafra, Belgium and Novartis Animal Health), never developed



VPM 1002, BCG-based Tuberculosis Vaccine



- Scientists at the Max Planck Institute for Infection Biology in Berlin (Prof. Kaufmann) genetically modified BCG (Bacillus Calmette–Guérin) so that it primes the immune system more strongly against the tuberculosis bacterium
- may be used as a replacement for the BCG vaccine in newborns as well as for boosting BCG vaccinations in adults
- Currently in phase II/III clinical trials (South Africa, India)
- The vaccine candidate was licensed by MPG to Vakzine Projekt Management (VPM, founded 2002, initiative of the BMBF to promote vaccine development in Germany)
- Further close collaboration between VPM and Max-Planck-Institute
- VPM started collaboration with Serum Institute of India (which lately acquired VPM)
- The Serum Institute of India is the world's largest vaccine producer by number of doses produced
- Approval hopefully within the next few years

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IPR Policies

Dr. Jérôme Van Biervliet

Head of Business Development VIB, Belgium

SCIENCE MEETS LIFE

VIB: from Science to Value

IP policies & practice of creating societal impact
Aesis Seminar



Jérôme Van Biervliet
Head of Business Development
Head of Discovery Sciences

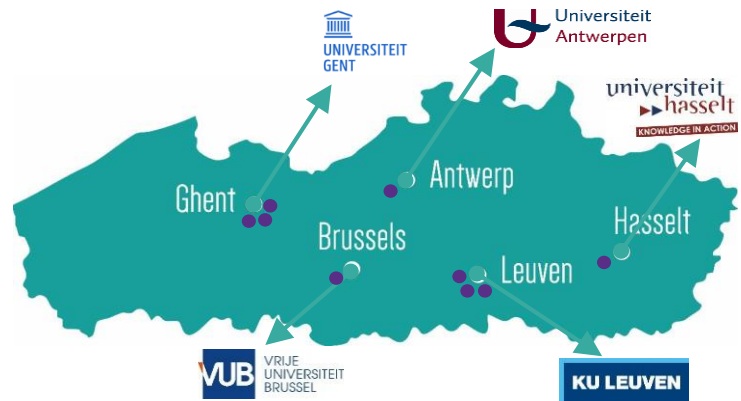
VIB's mission

Conduct frontline life science research
"Excellence in Science"

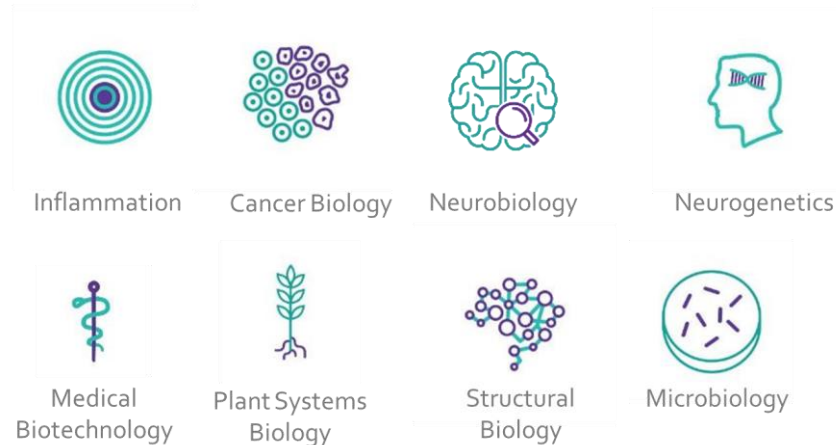
Translate results into benefits for society
"Excellence in Science Innovation and Entrepreneurship"

VIB's road to success

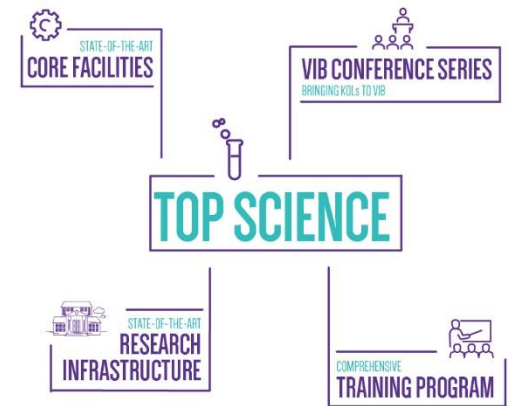
Independent Research Institute
in a framework with Universities



Working in dedicated fields of
Molecular Life Science research



With central policies
fostering **Top Science**



Institutional Scores: Medicine

Institution	Country	Papers	Indicator value
Broad Institute of MIT and Harvard	USA	1314	49.2%
Howard Hughes Medical Institute	USA	3732	47.2%
The Rockefeller University	USA	1174	39.5%
Flanders Interuniversity Institute for Biotechnology	BEL	947	39.4%
Dana Farber Cancer Institute	USA	5565	39.2%
Harvard-MIT Division of Health Sciences and Tecnology	USA	743	38.5%
Wellcome Trust Sanger Institute	GBR	1081	38.5%
Cardiovascular Research Foundation	USA	510	38.5%
American Cancer Society	USA	617	38.3%
Centro Nacional de Investigaciones Oncologicas	ESP	677	37.8%
Institute of Cancer Research	GBR	1785	37.8%




Howard Hughes Medical Institute



Economic impact of VIB


START-UPS

1.17 B € CAPITAL INVESTMENT
823 DIRECT EMPLOYMENT




INFRASTRUCTURE

BIO-INCUBATOR LEUVEN	BIO-INCUBATOR GHENT	BIO-ACCELERATOR GHENT
9,000 M ²	6,500 M ²	18,000 M ²
15 COMPANIES/TENANTS	10 COMPANIES/TENANTS	4 COMPANIES/TENANTS
280 EMPLOYEES	225 EMPLOYEES	550 EMPLOYEES





INTELLECTUAL PROPERTY

588 TOTAL NUMBER OF PATENT APPLICATIONS
253 TOTAL NUMBER OF ACTIVE PATENT FAMILIES




SUPPORT BIOTECH ECOSYSTEM

INTERNATIONAL SCHOOLS 92 GHENT PUPILS 70 LEUVEN PUPILS	FLANDERS.BIO / VIB MBI LIFE SCIENCES & HEALTH 20 GRADUATIONS / YEAR
ACCESS TO TALENT 5 UNIVERSITIES 4 STRATEGIC RESEARCH CE	




INDUSTRIAL INCOME

89.4M € TOTAL OVER LAST 5 YEARS



INWARD INVESTMENTS

900M € CAPITAL INVESTMENT
650 DIRECT EMPLOYMENT



AGREEMENTS WITH INDUSTRY

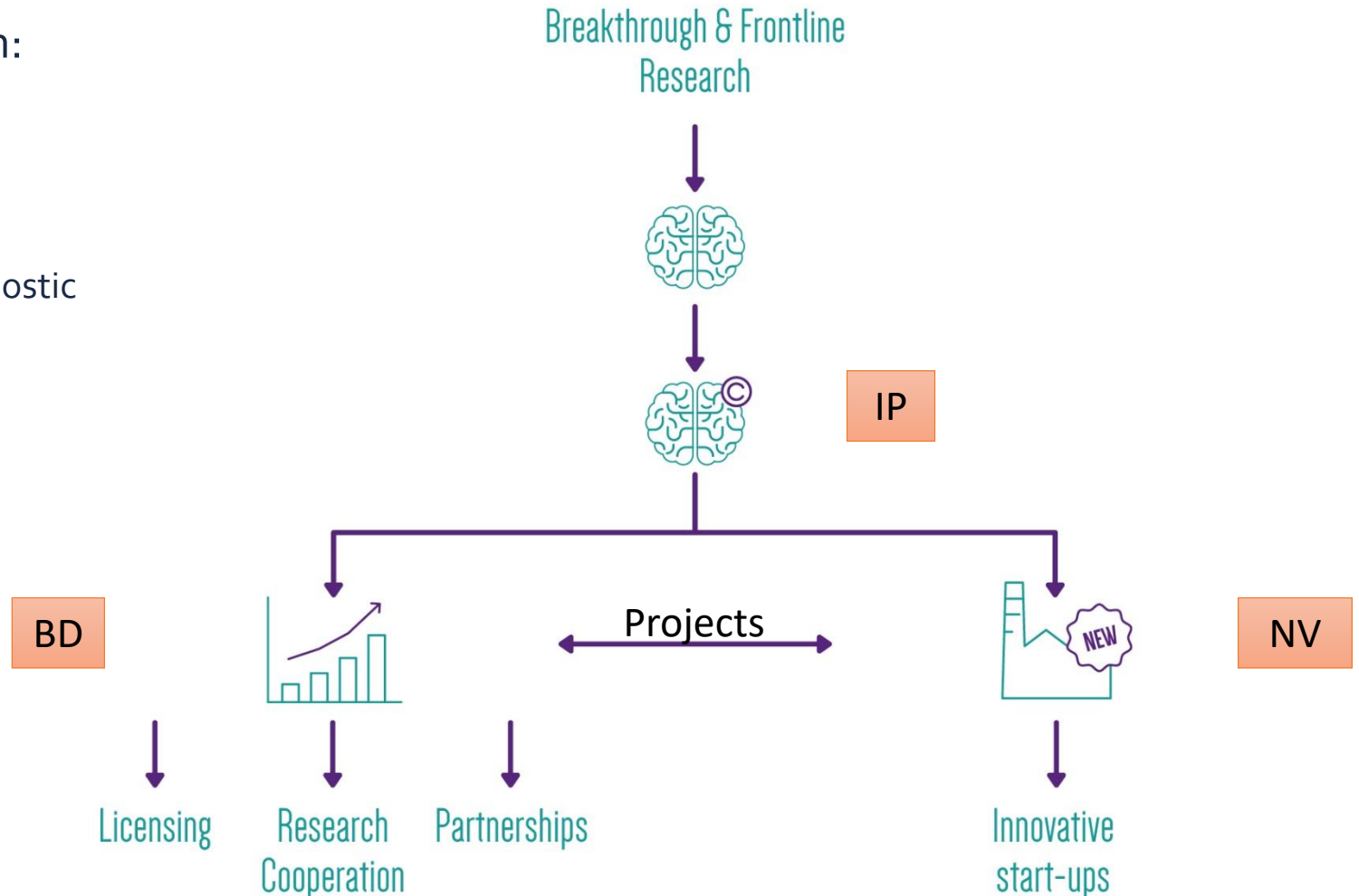
+100/YEAR



Turning knowledge into value

A creative and entrepreneurial approach is key

- VIB Innovation and Business team:
 - ▶ creating synergy
 - ▶ IP, BD, New Ventures
- All have industry experience
 - ▶ Mix of therapeutics, agro and diagnostic expertise
- Projects: creating options



VIB creates significant added value for society



> **1200 partnerships** with industry



- 588 patent applications
- 297 patents granted
- 253 patent families under management



> **M€ 300 industrial revenue**



- **20 spin-offs and inward investments: +/- 1,500 jobs**
- VIB spin-offs attracted **B€ 1.2 capital investment** (>50% international)

VIB start-ups – very visible impact

1,2B€
total investment

3,9B€
Ablynx

+ Non-Equity
Deal-money

823
employees



VIB's instruments to increase value

De-risking innovation is key to attract investors and business partners

Proof of concept (PoC) funding:

- Validation of IP
- In-licensing assets
- Combination of IP/assets



VIB Discovery Sciences:

- From innovative targets towards novel pharmacology
- Industry-trained discovery team

VIB seed capital:

- Flexible financial instrument
- Endorsement of VIB's commitment

V-Bio Ventures:

- Early stage venture fund
- EIF cornerstone
- 76 M€
- Increase output of novel innovative ventures

'IP Policy' is more a collection of (best) practice

Possibility to drive value creating activities & financial means

- IP practice:
 - ▶ Proactive scouting, coaching towards valuable inventions, scientist-to-scientist discussions
 - ▶ Budget available for filing, prosecution, defence
 - ▶ Strategic positions to allow more time to develop high value composition-of-matter IP / IP platform for technology
- Partnership with universities:
 - ▶ Clear accountability
 - ▶ Exclusive right to set approach to IP and commercialize
 - ▶ Share returns
- Business development:
 - ▶ Flexibility but with the aim in mind – reserve possibility to exclusively license to partners
 - ▶ Co-develop under an option agreement
- New venture creation :
 - ▶ Have investor requirements in mind
 - ▶ Build POC



Thank you!

Backup – topics for discussions

- IP policies imposed by EU projects
- IP practices that can help accelerating collaborations with partner institutes
- Societal impact through industry / economic activities
- Other programs reach societal impact otherwise:
 - ▶ Academic diffusion
 - ▶ Collaboration with charities
 - ▶

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IPR Policies

Alice Frost

Director Knowledge Exchange, Research England, United Kingdom



**Research
England**



UK – national IP policy and institutional IP practice

Alice Frost
Director of Knowledge Exchange

20 September 2018
AESIS Societal Outcome of
Academic-Industrial Collaboration,
Berlin

UK – background

- UK Research and Innovation – 9 research and innovation councils (7 Research Councils, Research England and Innovate UK): £6bn pa budget funding universities, institutes and businesses
 - Research England: university research and knowledge exchange £2.2bn pa budget – REF and KEF
- UKRI outcomes: knowledge, economy, society
- RE funding/policy on knowledge exchange and research including impact
 - All disciplines, all types of HE institutions, all types of partner, all types of impacts

UK Government policy on IP

- 2018 Response to Parliament Public Accounts Committee:

“Government is still not doing enough to safeguard the economic benefits of its research assets...ensure that clear accountabilities are in place to safeguard IP”

- Sponsorship of UK IP Office: toolkits and guidance
- Funding and requirements on funders, primarily UKRI

“the exact mechanism chosen to protect and exploit IP depends on the nature of the opportunity, so the Government does not dictate the nature of these arrangements.”




- RE/UKRI – approach to IP

- Obligation on grant recipient to exploit – universities, institutes and businesses
- Supporting linkages, capacity and capabilities in research and innovation system eg
 - for RE/universities – £250m pa Higher Education Innovation Fund (HEIF) and £100m Connecting Capability Fund
 - Industrial Strategy Challenge Fund, Catapults etc
- Accountability and transparency: eg REF impact case studies and assessment; national data eg Higher Education Business and Community Inter-action survey

Current policy focus

- Regulation is fairly low priority
 - 78% of university IP only 1 user
 - Diverse technologies – let technology flow through best route
 - No “one size fits all”
- Transparency and trust eg
 - RE & universities working together – with Government:
 - Reviews: McMillan, Rees on A2F for commercialisation
 - Evidence of effective performance: KEF metrics on achievement, KE Concordat on process



Effective IP practice ie getting the technology into use more important than formal policies?

Societal outcomes???

- Universities and charitable status; EC state aids economic/non-economic
- Businesses and investors have private interests, but economic development is a public good
- Subsidising businesses if there is no market failure, not vfm for public funding
- Achieving outcomes through openness - or protection; sustainable approaches to open innovation
- Delivering specific societal outcomes eg social innovation or social enterprise
- Specific IP terms eg non-exclusive licensing, reversionary rights
- Etc etc
- !

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Chaired by: Alison Campbell

Recommendation

Next up:

12.45-13.45	Lunch	Elements Restaurant
13.45-15.00	Measuring outcome of academic industrial collaborations	Emporio I Room
	Conditions for effective collaboration with industry	Embassy Room