



CBD and ABS: from scientific needs to public perceptions – road models for the Pharmaceutical Industry

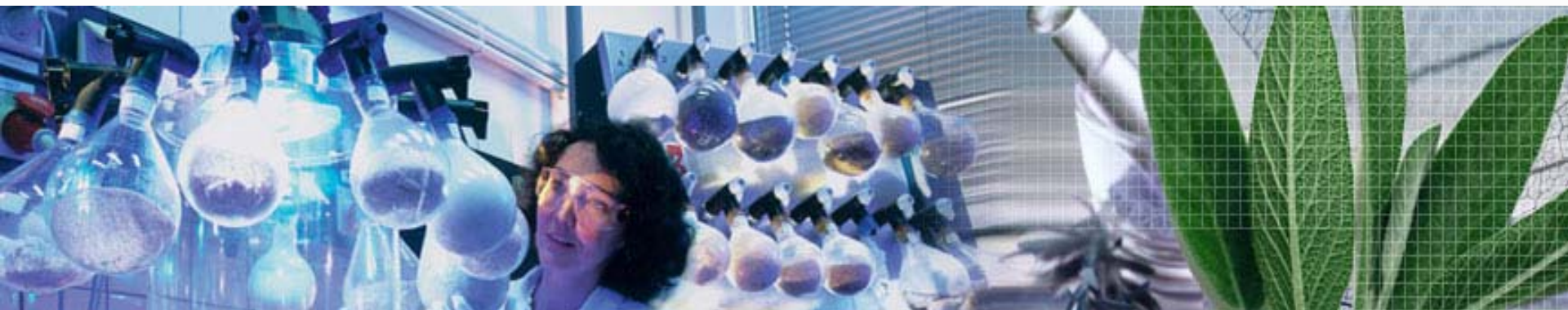
Dr. Thomas Henkel, CEO

JBA high level meeting on CBD and ABS,
Feb. 8-9, 2007





InterMed Discovery is dedicated to discover and develop innovative products for the life science industry based on natural products (NP)



IMD - The Company

- ❑ MBO of Bayer HealthCare R&D with a world leading proprietary Natural Products technology platform
- ❑ Founded 1.2.06 as privately owned venture with presently 22 staff
- ❑ transfer of all BHC R&D natural product related assets into IMD
- ❑ New location at the BioTech center (BMZ) Dortmund in the center of Northrhine Westfalia, Germany
- ❑ Customers come from pharmaceutical, agrochemical and food industry

The strong foundation

Organisms

- ❑ large proprietary collection of microbial genetic sources
- ❑ rigid pre-selection and life cycle management
- ❑ world wide network of suppliers

Work up

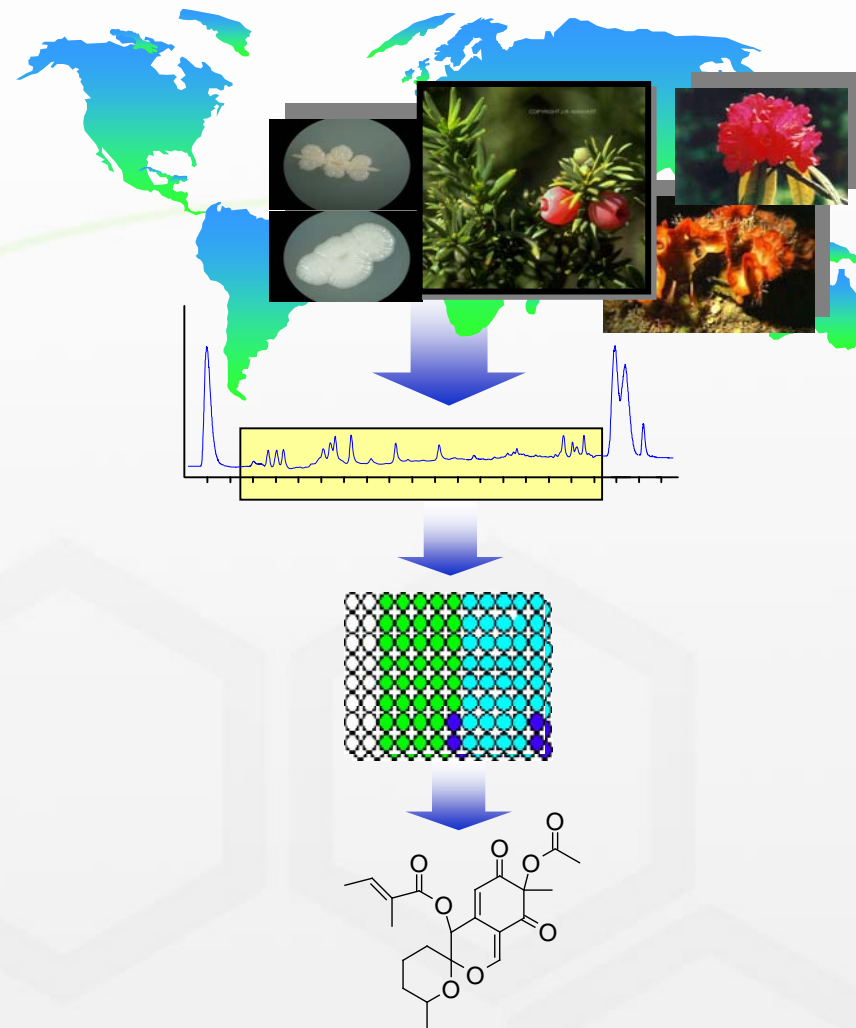
- ❑ proprietary technology platform
- ❑ world wide largest pure NP compound library

Logistics/biol. Testing

- ❑ standardized and automated process chain
- ❑ integrated data base concept

Chemical characterisation:

- ❑ Dereplication
- ❑ high quality structure elucidation with systematic data base support



IMD represents a unique integration of know how and processes combined with proprietary sample collections with high opportunity for value generation

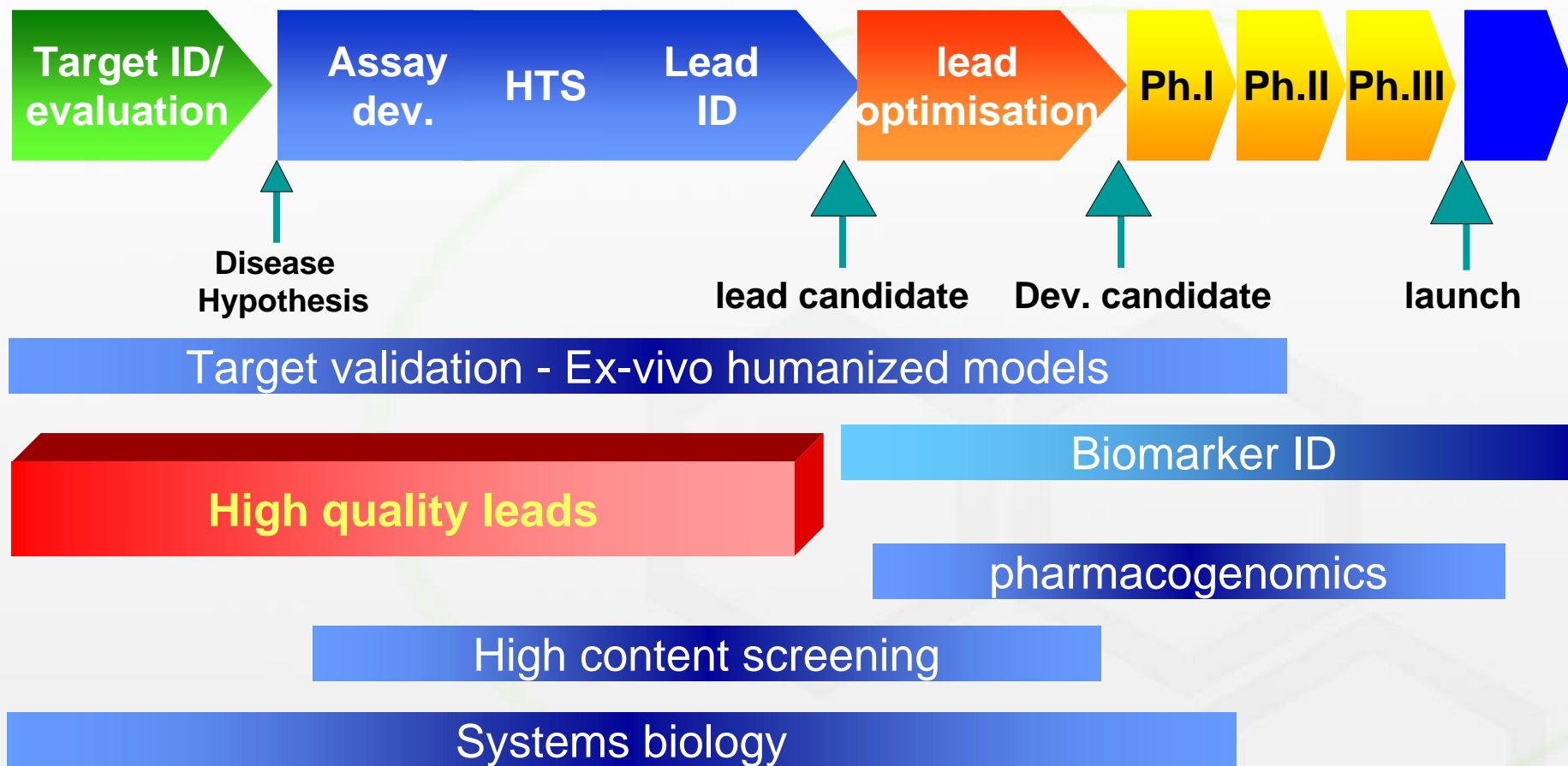
CBD and ABS:

from scientific needs to public perceptions – road models for the Pharmaceutical Industry

- **finding new products in the Life Science Industry and the role of Natural Product research**
- **Public perceptions**
- **best practice - some examples**
- **conclusion**

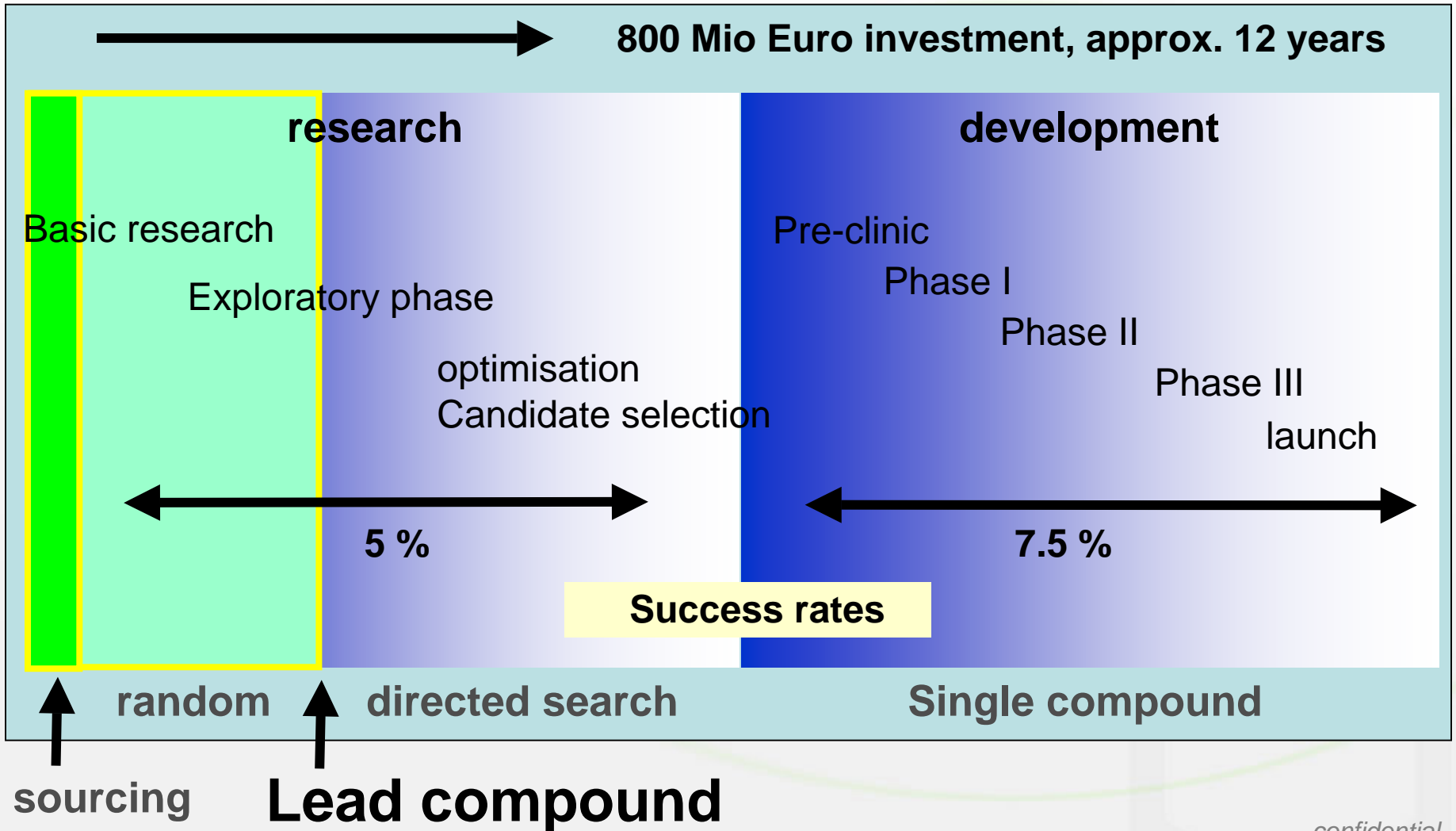
The life sciences R&D challenge

Capitalize on Innovative Technologies and new leads

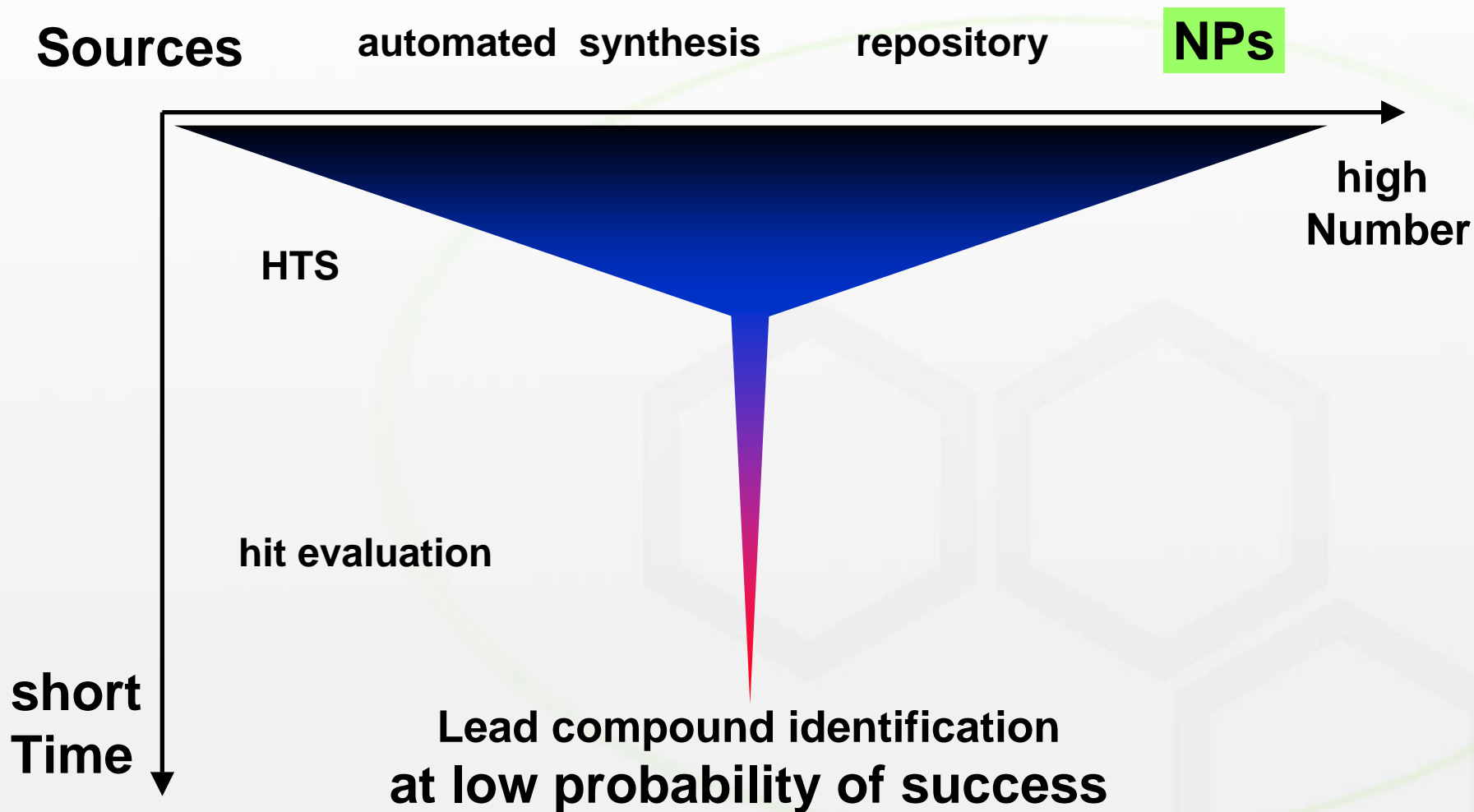


→ You need more than just compounds

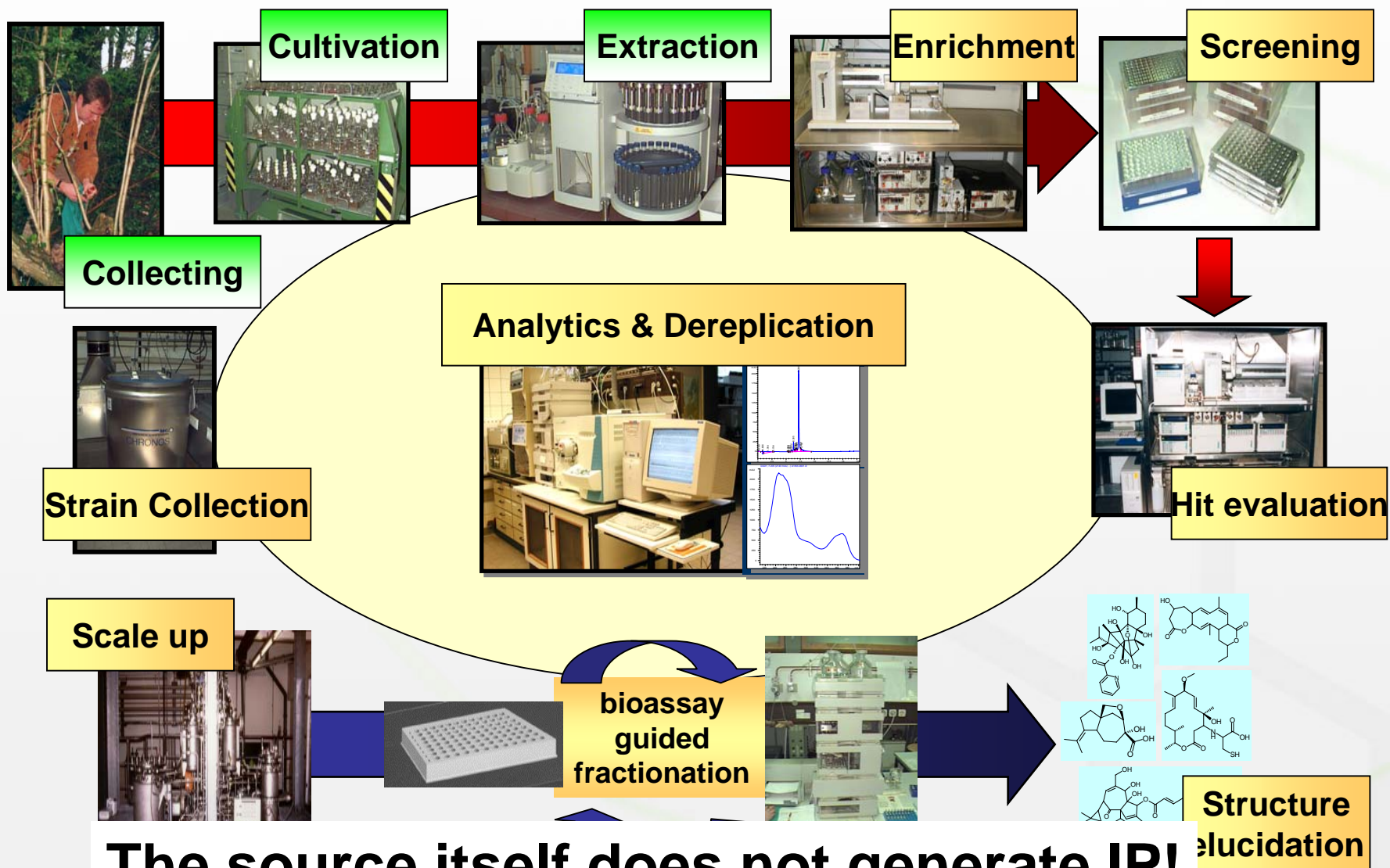
Research and development of new drugs - high risks and investments



Screening Workflow



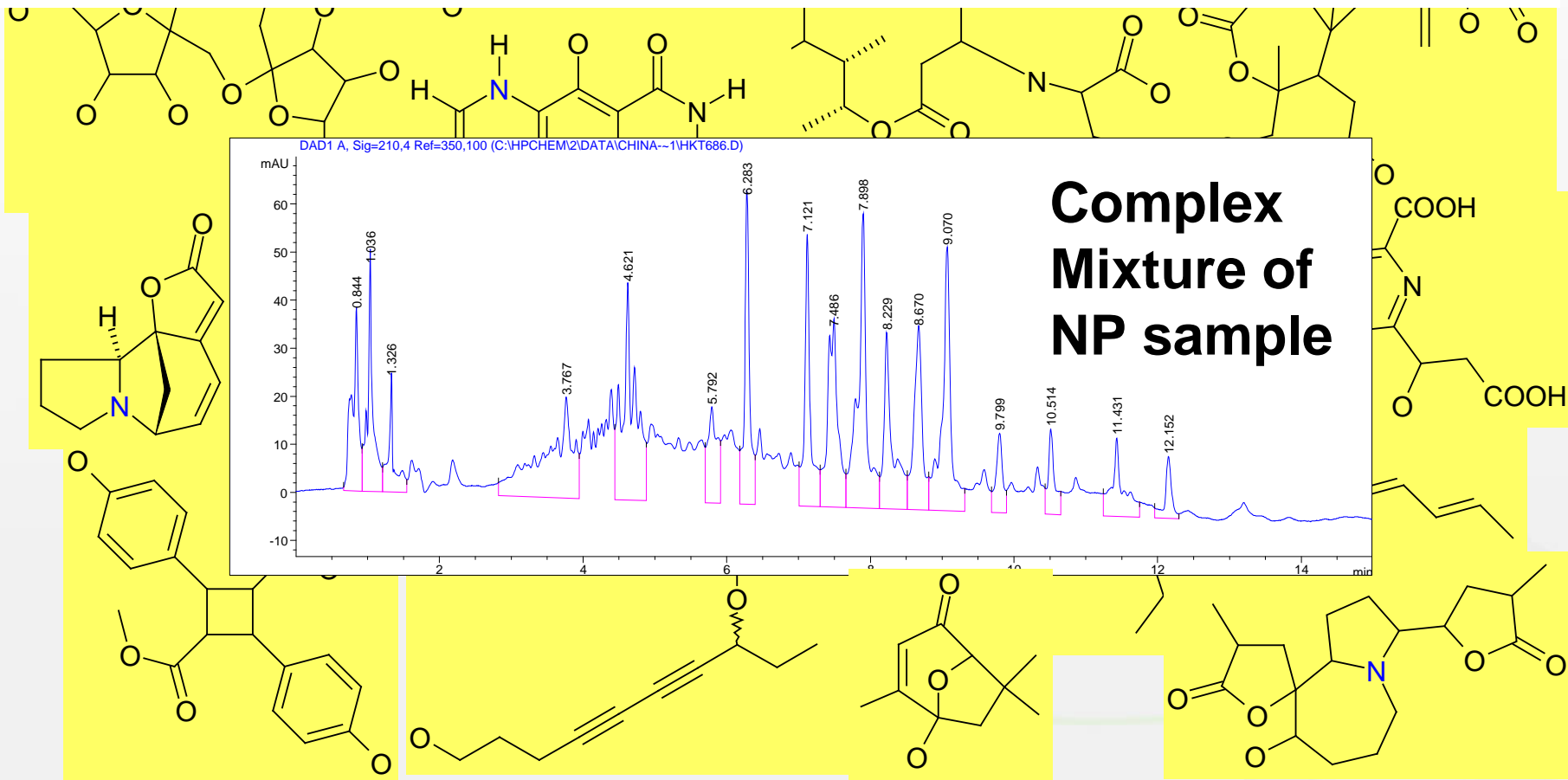
NP Research is expensive and risky



The source itself does not generate IP!

biological complexity translates in high technical requirements to generate success –

Productive value generation requires top tier set up which is not easy to be established “in the woods”



Nature's unlimited Reservoir

„Life Counts, M. Gleich et al.“

Amount of	
bacteria:	5×10^{30}
Animals:	1×10^{18}
known species:	$1,75 \times 10^6$
unknown species:	1×10^8 (estimate)

per one human body exist	
trees	500
birds	50
animals total	167.000.000

- rich source for innovative chemical compounds
- only small part of reservoir investigated up to now
- ➔ too much to investigate – where should we start?
- ➔ value (scientific and commercial) of TKnowledge is limited

Multiple sources for identical compound

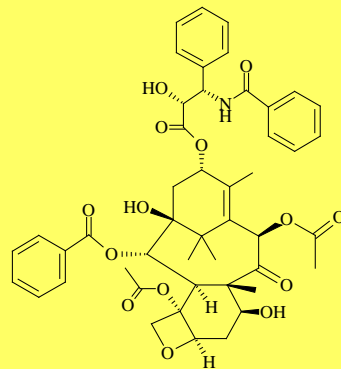
- There are 8 taxus plant species from different parts in the world (NA, Europe, Asia!) reported to produce paclitaxel and 16 congeners
- even a fungus appears as a producer!



Taxus (Eibe)



Alternaria



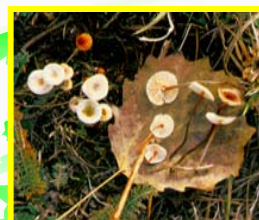
Strobel et al. (1996)
Dahiya (1998)

Who owns this finding regarding ABS?

Multiple sources for identical compound (2)



fungi



bacteria

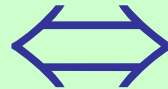
- micro-organisms producing identical compounds are spread all over the world
- Different “endemic” plants of the same family produce identical types of compounds
- species are distributed according to habitat properties rather than “country borders”

sustainability - in our all interest

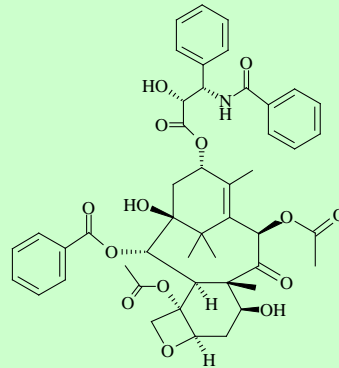
- A real threat of endangered species (tiger, rhino) lies in the increased usage of traditional medicines but not form use of ethical drugs
- Safety and quality issues as well as cost of goods (COG) aspects make sustainable production for drugs obligatory



Taxus (Eibe)



Taxus cell culture



Example Paclitaxel: Currently different sustainable processes are in place (cell culture, needle harvest etc.)

Sustainability issues do not limit drug development!

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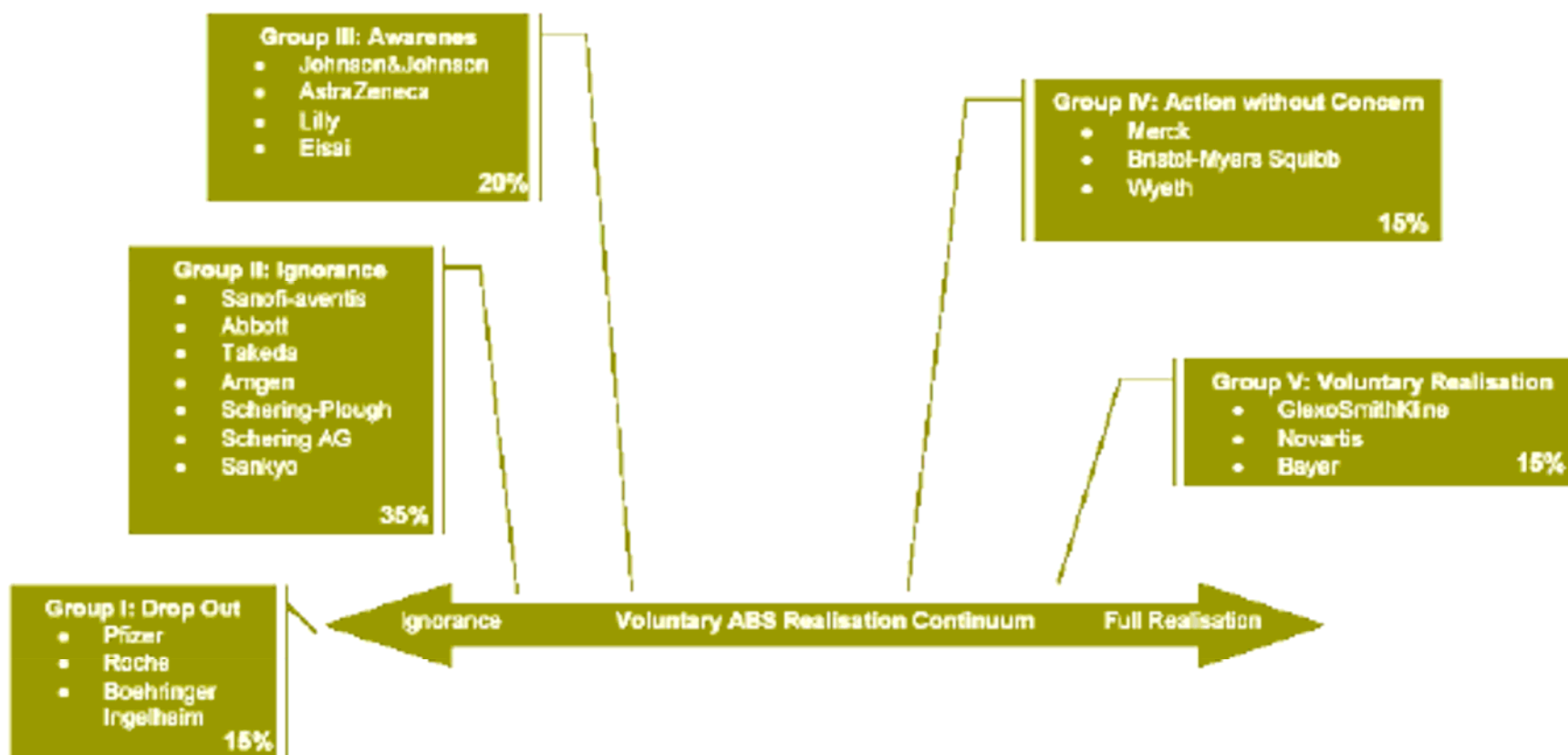
Public perceptions

- The image of the Pharma industry in particular, as well as the life science industry as a whole is bad
- There is increasing pressure from the developing countries and NGOs to change behavior, business terms and general policies at an international level (TRIP, WTO, UN-EP)
- e.g. bio-prospection is quite often regarded as bio-piracy without reflection of the details

Governing Biodiversity - The Realisation of Access and Benefit Sharing under the Convention on Biological Diversity

August, 25th 2005, Roskilde University, Denmark

Figure 17: The ABS Realisation Continuum



Percentages relate to the reference parameter of 20 cases studied

Governing Biodiversity - The Realisation of Access and Benefit Sharing under the Convention on Biological Diversity

August, 25th 2005, Roskilde University, Denmark

Citations:

Conclusion 1: In the realm of biodiversity governance, voluntary business measures based on corporate responsibility are inappropriate to safeguard access and benefit sharing.

Conclusion 2: An internationally binding protocol is required to enhance the implementation of ABS.

Conclusion 3: ABS loses its wind before it even gathered way.”

Governing Biodiversity - The Realisation of Access and Benefit Sharing under the Convention on Biological Diversity

August, 25th 2005, Roskilde University, Denmark

Citations:

“Perspectives

Companies from the industrialized North are the primary economic beneficiaries of genetic resources that are the property of the South.

... will ABS deliver for biodiversity?

Between 1991 and 2000, projects channeled about US\$ 2.7 million to conservation purposes in Costa Rica being ... rather insignificant compared with ...eco-tourism which accounts for US\$ 650 million per year

Do the international negotiations for an ABS regime simply come too late? ... it indicates an important point of critique of ABS: the mechanism is not capable of sufficiently tackling the root causes of biodiversity loss.“

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The author's comments:

- Most of the Pharma industry did not reflect ABS properly since they lost general interest in this matter
- The benefit of bio-prospecting of the Pharma industry is overestimated – there is no cost benefit scheme known to the author
- The life science industry has, if any, only very limited responsibility for the loss in diversity through environmental damages

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Protection of Traditional Knowledge (TK)

- “Shaman Pharmaceuticals” was founded in the US in the ‘90 targeting the increase of probability of success in drug finding via making use of TK in conjunction with a fair compensation of the provider
 - Shaman developed compensation and reimbursement schemes reflecting at least some of the issues regarding TK
 - different projects were reported as a success story; the business idea was rewarded to be innovative and followed with high interest
 - however, “Shaman pharmaceutical” went bankrupt
- **the value of TK as factor for a regular income stream appears to be overestimated**
- **drug discovery is a difficult business**

Example for best practise:

Statements and Procedures for the active integration of the Convention on Biological Diversity (CBD) proposed by the **German Association of Research-Based Pharmaceutical Companies (VFA)**

“General Statement

The German Association of Research-Based Pharmaceutical Companies (VFA) states

- 1. to support the intentions of the Convention on Biological Diversity*
- 2. to confirm its sincere interest and support in conservation of biological diversity and sustainable use of its components*
- 3. to offer constructive proposals for adequate multi-factorial compensation of each party´s contribution in co-operations between receivers and providers of genetic resources (Receiving Party and Providing Party, respectively)*
- 4. that the interests of all participating parties need to be respected and realised in order to vitalise the CBD*

The VFA´s understanding of such collaborations under the CBD is that those need to result in exploitable outcomes. To enable the Pharmaceutical Industry as a Receiving Party to optimally fulfil the above general criteria, several elements need to be prepared. ...”

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enabling the utilisation of natural products through ABS



plants

insects

fungi

bacteria

Marine organisms

- ⇒ **ABS generally will not result in significant revenue streams for provider countries and will not be able to protect bio-diversity**
- ⇒ **However, locally ABS can induce immediate and significant impact and progress in R&D**
- ⇒ **Interest of the parties should be allowed to be balanced bilateral – the “UN Watchtower” will highly likely not work on its own**
- ⇒ **compensation has mutually to be agreed in adequate balance to the real value generation - adequate sharing of risks and benefits has to be insured**



Thank you!

