

Ein Unternehmen
der Life Science-Stiftung
zur Förderung von
Wissenschaft und Forschung



asceni  - on

Life Sciences into Business

Equitable Licensing: Medical Research in the Public Interest

**Bringing „Charitable Aims“
into Practice**

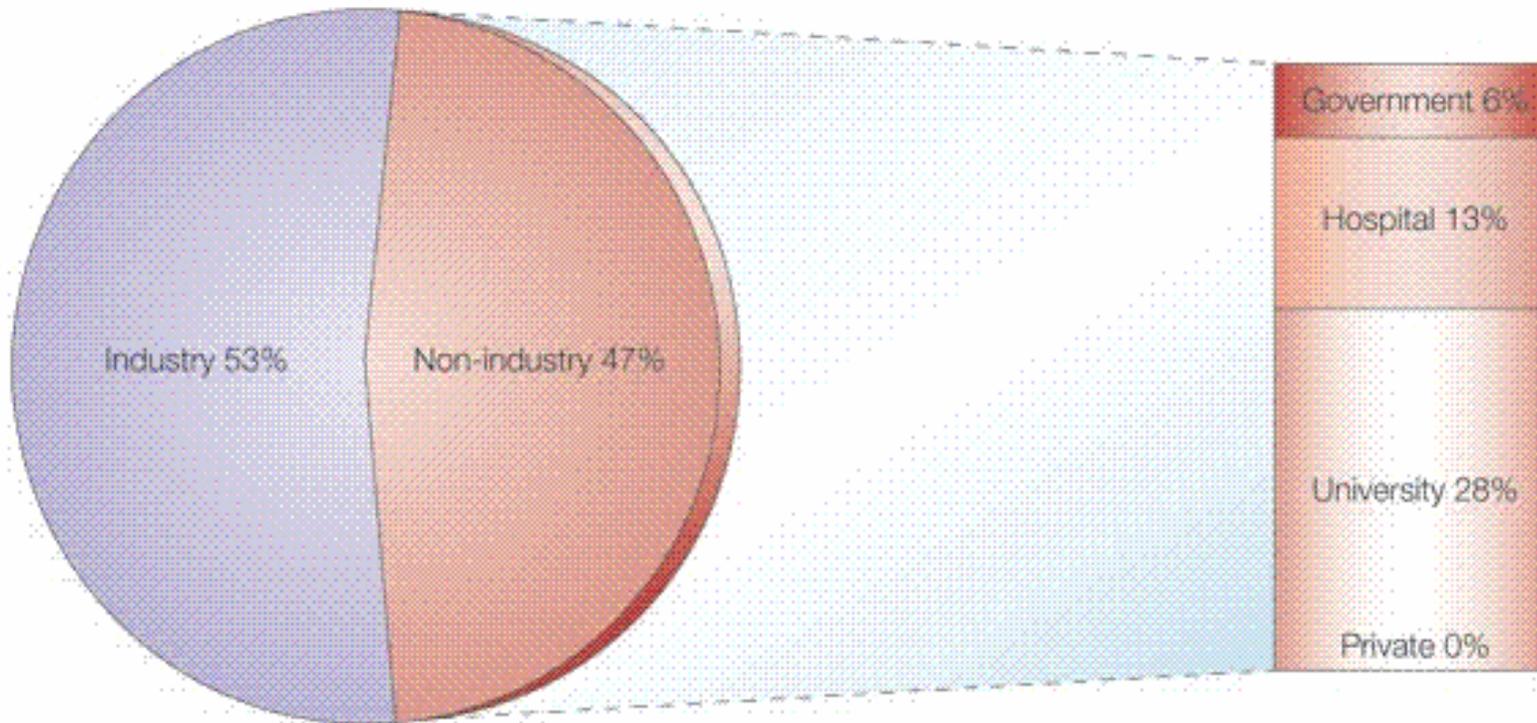
Dr. Christian Stein, Ascenion GmbH, 23.4.2009

- **About Us**
- **The Philadelphia Consensus Statement**
- **Charitable Aims: Contribution of University Technology Transfer**
- **Examples for Standard Clauses**
- **Charitable Bodies Active in Drug Discovery**

- Founded in 2001
- Fully owned **subsidiary of the Life-Science Foundation for the Promotion of Science and Research**
- Focus on life sciences
- Marketing of around **600 technologies** and materials of public research institutions
- Closing an average of **60 commercial agreements**
- Holding equity in 16 spin-offs
- Team of 20 specialists with multiyear experience and sector specific expertise
- Offices in Munich, Berlin, Braunschweig, Hamburg, Hanover, Neuherberg



Academic Research in Drug Development



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Nature Reviews | Drug Discovery

- No access to certain drugs in poor countries
- Some diseases (e.g. AIDS, TB) are widespread in poor countries
- Treatment is not affordable at prices charged in industrialized regions

- **Ideal:**
 - global access to medical treatment for all countries
- **But:**
 - Health problems in developed countries are different from those in developing countries
 - Charitable aims versus profit/return on development/investment costs

Proposals

The Philadelphia Consensus Statement proposes three major changes to university policies on health-related innovations.

Universities shall

- promote equal access to research
- promote research and development for neglected diseases
- measure research success according to impact on human welfare

Promote equal access to research

- Granting rights to generic companies to manufacture and export innovations to developing countries
- Price reductions
- Non-patenting requirements in low/middle income countries
- Participation in patent pools
- Inclusion of licensing terms in exclusive technology transfer agreements that ensure low-cost access to health-related innovations in the developing world
 - Model terms: *Equitable Access License (EAL)*
 - *Global Access Licensing Framework (v1.1)*: A proposal to guide the adoption of licensing policies on every university campus.
 - Chaifetz et al., *Closing the Access Gap for Health Innovations: Open Licensing, Globalization and Health* (Feb. 2007).
 - Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach*, Berkeley Technology Law Journal (2005).

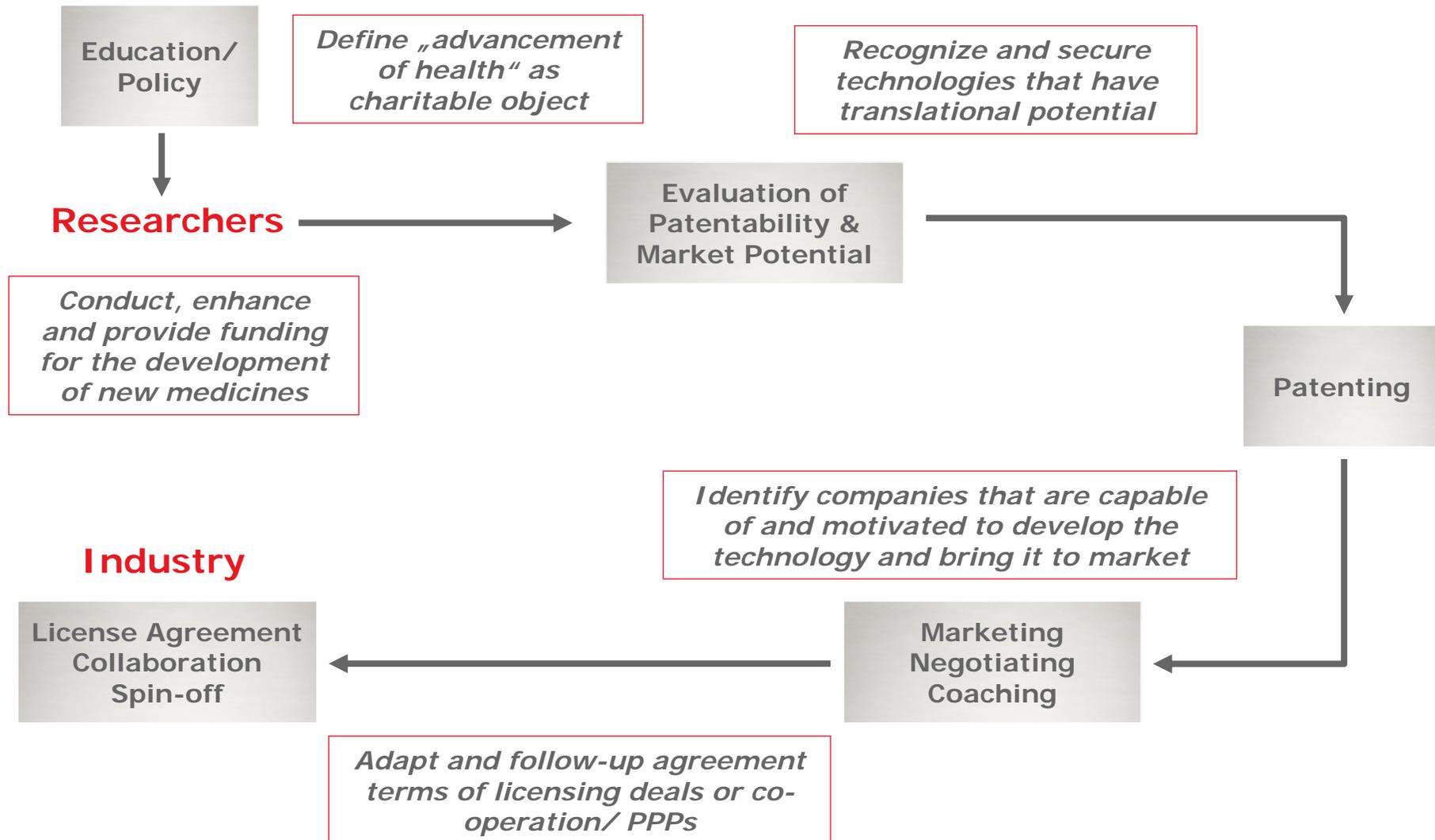
Promote research and development for neglected diseases

- Adopt policies promoting in-house ND research
- Engage with nontraditional partners to create new opportunities for ND drug development (e.g. public-private–partnership)
- Carve out an ND research exemption for any patents held or licenses executed.

Measure research success according to impact on human welfare

- Public statistics on university intellectual property practices related to global health access.
- Collaborate with other universities and consortia to develop more robust technology transfer metrics that better gauge access to public health goods and innovation in neglected-disease research.

Contribution of University Techtransfer



Licensing agreements

- Define terms (e.g. developing countries)
- Terms to secure manufacture and supply of product developing countries
 - Manufacture and supply by licensee
 - Manufacture by licensee and supply by distributor
 - Manufacture and supply by sub-licensee
 - Manufacture and supply by university or its alternative licensee (compulsory license, EU Compulsory Licensing regulation)
- Obligation to supply end-product to developing countries at „cost-based“ price (Prevent re-selling to developed countries)
- No or fair royalties for sales in developing countries

Reservation of rights for humanitarian purposes

For public research institutions, a reservation of humanitarian rights in commercial technology licenses is one mechanism to help them meet their mission to serve the public benefit through both, commercial and humanitarian channels.

Adapted from A. Benett, UC Davis and PIPRA „Reservation of Rights for Humanitarian Uses“, Handbook of Best Practices, 2007

Reservation of Rights in Exclusive Licensing Agreements

- Nothing in this Agreement will be deemed to limit the right of The Regents (the University)... to make and use the Invention ... and associated technology and allow other educational and nonprofit institutions to do so for educational and research purposes.
(The University of California)
- Stanford retains the right, on behalf of itself and all other nonprofit academic research institutions, to practice the Licensed Patent and Technology for any purpose, including sponsored research and collaborations. Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution.
(Stanford university)

Source: A. Benett, UC Davis and PIPRA „Reservation of Rights for Humanitarian Uses“, Handbook of Best Practices, 2007

The University of California

- 1.40 “Humanitarian Purposes” means (a) the use of Licensed Products covered under Compound Patent Rights (“Compound Products”) for research and development purposes by any organization or other third party, anywhere in the world that has the express purpose of developing the Compound Products for use in an Economically Disadvantaged Country (EDC), and (b) the use of the Compound Products by any organization or other third party for Commercial Purposes in an Economically Disadvantaged Country.
- 1.42 “EDC” means all countries listed on the United Nations Conference on Trade and Development list of “Least Developed Countries” in effect as of the Effective Date of this Agreement which are set forth on Appendix I hereto.

Source: A. Benett, UC Davis and PIPRA „Reservation of Rights for Humanitarian Uses”, Handbook of Best Practices, 2007

The University of California

- 2.14 Licensee's commercial use of the Compound Patent Rights to make, use, sell, offer for sale and import Compound Products in EDCs will be royalty free and the Licensee will be required to give away the Compound Products for free or at cost.

Source: A. Benett, UC Davis and PIPRA „Reservation of Rights for Humanitarian Uses“, Handbook of Best Practices, 2007

The University of California

- 2.15 Notwithstanding other provision of rights granted under this Agreement, The Regents [the university] hereby reserves the right to license the Compound Patent Rights to any third parties for solely Humanitarian Purposes. Such licenses for Humanitarian Purposes will expressly exclude the right of the third party licensee to export or sell the Compound Products from an EDC into a market outside of the EDC where Licensee has introduced or will introduce a Compound Product and where Patent Rights exist. In any such license, the third party licensee's commercial use of the Compound Patent Rights to make, use, sell, offer for sale and import Compound Products in EDCs will be royalty free and the third party licensee will be required to give away the Compound Products for free or at cost. For avoidance of doubt, the third party licensee may be permitted to export Compound Products from the EDC of origin to other EDCs and all other countries mutually agreed to by The Regents and Licensee.

Source: A. Benett, UC Davis and PIPRA „Reservation of Rights for Humanitarian Uses“, Handbook of Best Practices, 2007

The Public Intellectual Property Resource for Agriculture (PIPRA)

Definitions

- “Humanitarian Purposes” means (a) the use of Invention/Germplasm for research and development purposes by any not-for-profit organization anywhere in the World that has the express purpose of developing plant materials and varieties for use in a Developing Country, and (b) the use of Invention/Germplasm for Commercial Purposes, including the use and production of Germplasm, seed, propagation materials and crops for human or animal consumption, in a Developing Country.
- “Commercial Purposes” means to make, have made, propagate, have propagated, use, have used, import, or export a product, good or service for the purpose of selling or offering to sell such product, good or service.
- “Developing Country” means any one of those countries identified as low-income or lower-middleincome economies by the World Bank Group at the time of the effective date of this agreement and all other countries mutually agreed to by Licensor and Licensee (the current list of countries is typically given in an appendix to the agreement.)

Source: A. Benett, UC Davis and PIPRA „Reservation of Rights for Humanitarian Uses“, Handbook of Best Practices, 2007

The Public Intellectual Property Resource for Agriculture (PIPRA)

Reservation of rights

- Notwithstanding other provision of rights granted under this agreement, University hereby reserves an irrevocable, nonexclusive right in the Invention/Germplasm for Humanitarian Purposes. Such Humanitarian Purposes shall expressly exclude the right for the not-for-profit organization and/or the Developing Country, or any individual or organization therein, to export or sell the Germplasm, seed, propagation materials or crops from the Developing Country into a market outside of the Developing Country where a commercial licensee has introduced or will introduce a product embodying the Invention/Germplasm. For avoidance of doubt, not-for-profit organization and/or the Developing Country, or any individual or organization therein, may export the Germplasm, seed, propagation materials or crops from the Developing Country of origin to other Developing Countries and all other countries mutually agreed to by Licensor and Licensee.

Source: A. Benett, UC Davis and PIPRA „Reservation of Rights for Humanitarian Uses“, Handbook of Best Practices, 2007

Charitable bodies active in drug discovery



Science Funding

Creative Research

Technology Transfer

Programme related investment

'To foster and promote research with the aim of improving human and animal health'

Investments

Capital growth of endowment

Equity & Equity
Long/Short
Absolute Return & Buyout
Healthcare & Venture
Property & Infrastructure
Private Equity

Thank You for Your Attention!



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