

**OPERATIONAL ISSUES OF HEALTH
PUBLIC-PRIVATE PARTNERSHIPS**

MEETING REPORT
**Dealmaking and
Intellectual Property
Management for
Public Interest**



Initiative on
Public-Private
**Partnerships
for Health**

**ALLEVIATING THE HEALTH CONSEQUENCES OF
POVERTY BY ENHANCING PUBLIC-PRIVATE COLLABORATION**

Dealmaking and Intellectual Property Management for Public Interest

**Bethesda, Maryland, USA
29–30 November 2004**

Report of a meeting organized by:
the Initiative on Public-Private Partnerships
for Health (IPPPH)

with:

The Centre for Management of Intellectual Property
in Health Research and Development (MIHR)

Hosted by:

Aeras Global TB Vaccine Foundation



Initiative on
Public-Private
Partnerships
for Health



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Author: Cathy Garner, Board Trustee and Senior Adviser, Centre for Management of Intellectual Property in Health Research and Development (MIHR)
Managing Editor: Karin Holm, Senior Program Officer, Initiative on Public-Private Partnerships for Health (IPPPH)
Contributing Editor: Richard Mahoney, Interim Chief Executive Officer, MIHR
Copy Editor: Sean McGrath, Ornex, France

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Global Forum for Health Research

1-5 route des Morillons
P.O. Box 2100
1211 Geneva 2, Switzerland
Tel: +41 22 791 4260
Fax: +41 22 791 4394
Email: info@globalforumhealth.org
Website: www.globalforumhealth.org

**Centre for Management of Intellectual Property
in Health Research and Development**

Oxford Centre for Innovation
Mill Street
Oxford OX2 0JX, United Kingdom
Tel: +44 (0)1865 812041/811109
Fax: +44 (0)1865 726965
Email: admin@mihhr.org
Website: www.mihhr.org

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Preface

This document summarizes a workshop entitled, “Dealmaking and Intellectual Property Management for Public Interest,” organized by the Initiative on Public-Private Partnerships for Health (IPPPH) jointly with the Centre for Management of Intellectual Property in Health Research and Development (MIHR) and held on 29–30 November 2004, in Bethesda, Maryland, USA, at the offices of the Aeras Global TB Vaccine Foundation.

To promote health equity and achieve the UN’s Millennium Development Goals, new drugs and vaccines to combat diseases that predominantly affect populations in developing countries are needed. Not-for-profit ventures to promote the development of new drugs, vaccines, diagnostics, and other health products have been created in recent years to address this need. These ventures are often called public-private partnerships (PPPs) because they usually involve public and foundation funding and collaborate closely with pharmaceutical and biotechnology companies and academic institutions to help develop products that have significant public health value but that, in most cases, have little commercial value.

The workshop brought together a diverse group of practitioners to address issues raised at a consultation on intellectual property management for PPPs that took place in Geneva, Switzerland at IPPPH offices on 25 June 2004. The earlier consultation identified priority issues for the November workshop and was based on a draft version of the IPPPH publication “Public-private management of intellectual property for public health outcomes in the developing world: the lessons of access conditions in research and development agreements,” by Antony Taubman of the World Intellectual Property Organization, written in a personal capacity.

The joint IPPPH/MIHR workshop also used the Taubman paper as background information and attracted thirty-five participants from the Canada, South Africa, Switzerland, the United States, and

the United Kingdom. Participants included senior management, legal counsel, program officers, and commercial and business development professionals from the major PPPs involved in the development of new medicines for the treatment and prevention of diseases affecting the poor in developing countries. Also there were attorneys in private practice, university scientists, professors in law and medical schools, university technology transfer professionals, representatives from donor agencies, UN and international organizations, and from private and national research institutions.

The workshop focused on how intellectual property management can help support the development of needed new products and their availability in the developing countries. Case studies brought theory to life and there was vibrant discussion throughout the meeting.

IPPPH has facilitated numerous similar forums and workshops on topical issues, bringing together key players and decision makers in the field of PPPs for neglected diseases. MIHR is committed to providing opportunities for shared learning and capacity building in the management of intellectual property. We hope that the ideas generated and the contacts forged at the workshop will stimulate further exchanges among the public and private sectors to help improve health among the poor in developing countries.

Cathy Garner

*Author, and Board Trustee and Senior Adviser
Centre for Management of Intellectual Property in
Health Research and Development*

Karin Holm

*Managing Editor and Senior Program Officer
Initiative on Public-Private Partnerships for Health*

Roy Widdus

*Project Manager
Initiative on Public-Private Partnerships for Health*

1. Introduction

Thirty-eight participants took part in a two-day workshop to assess the challenges and opportunities in making deals and building partnerships between public and private sector organizations to improve access to health technologies for neglected diseases. The workshop examined the terms and conditions negotiated by public-private partnerships (PPPs) engaged in product development that enabled them to facilitate product development and help ensure product supply and access to the poor in developing countries.

The workshop used as a background document, an IPPPH paper on IP frameworks, written by Antony Taubman,¹ and focused on a number of “case illustrations” presented by PPP representatives. Participants split into two working groups to address specific issues and conduct discussions in greater depth.

The discussions focused on:

- Deal-making to match objectives
- Segmentation of markets and division of rights
- Pricing
- Dispute resolution, arbitration and enforcement
- Milestones
- Partnership building
- Negotiating with universities
- Constraints on access and availability
- Success criteria
- Future actions

¹ Antony Taubman, “Public-private management of intellectual property for public health outcomes in the developing world: The lessons of access conditions in research and development agreements,” IPPPH, Global Forum for Health Research, June 2004, ISBN 2-940286-19-1.

2. Overview: A Framework for Dealmaking and IP Management

Dr Antony Taubman presented an overview² of his 2004 paper. The report argues that

Successfully bringing a new drug or vaccine to the public requires a diverse blend of inputs and contributions, in terms of intellectual, material and financial resources. These include background IP and know-how, provision of research facilities and funding, the specific research outcomes and innovation that form the basis of a new drug, access to platform technologies and manufacturing capacity, drug development capacities, including the capacity to manage clinical trials and regulatory approval processes and investment in downstream development, and capacity to disseminate drugs to the public while providing necessary clinical support and health infrastructure. The market for finished drugs is also hybrid and diverse in character, in many countries combining price subsidies, public procurement programs and various incentive structures.

Dr Taubman stated that in many cases there needs to be a unique, tailor-made or “sui generis” form of IP management for the product development PPPs. Product development is a complex process, with interaction among many different organizations. He noted that a new discipline of public-sector IP management is emerging.

Dr Taubman presented an analysis of the policy process, indicating the linkage between the legal framework of deals and negotiation at the micro (institution to institution) level in relation to international legal agreements at the macro (e.g. international treaties) level. Because there are limited commercial markets for health technologies addressed to neglected diseases, PPPs must use new and innovative strategies to achieve their objectives. His presentation highlighted the need to share “best practices” in building partnerships and constructing deals. He also noted the need to identify appropriate measures of success for PPPs – a recurring theme of the workshop.

Although each deal has specific characteristics, Dr Taubman noted that there are often common features. He concluded that public-interest IP management should be based on pragmatic conceptions of:

- Strategies to achieve access by the poor
- The complementary roles of public and private sector research
- Appropriate incentives for the private sector
- Appropriate oversight of public sector resources
- Effective management of product development know-how

² Antony Taubman, “Public health research for neglected disease burdens: a framework for reflecting on dealmaking and IP management,” PowerPoint presentation (see Annex 1.1).

3. Facilitating Development of Candidate Products

The framework was further elaborated through three case studies from the Medicines for Malaria Venture (MMV), the International Partnership for Microbicides (IPM) and the Global Alliance for TB Drug Development (TB Alliance). (The presentations by MMV and TB Alliance can be found in **Annexes 1.2 and 1.3**).

The cases illustrated the use of licensing terms to help ensure achievement of public sector objectives. In particular, each case demonstrated the potential for the segmentation of the market to provide both incentives for the private sector and product access by the public sector. Market segmentation was achieved geographically and by field of use.

For example, the MMV deal for the OZ synthetic peroxide antimalarial project (Annex 1.2) involved an assignment of a patent from a US university. The patent included claims for treating cancer and schistosomiasis, which are retained by MMV. The compound was licensed to an Indian company, Ranbaxy, with a provision for reversion of the rights to MMV should Ranbaxy fail to meet certain milestones (such as meeting public sector demand in target developing countries at affordable prices).

Likewise, further segmentation of the market into a “traveler’s market” and a private sector sales worldwide provides potential commercial incentives for Ranbaxy once they meet the criteria for public health interest.

In the case presented by IPM, involving the in-licensing of TMC120 from Tibotec, the strategy was to limit the licenses by geographical areas. This strategy is not without potential problems because a division between developing and developed countries may not take into account the issue of affordability within countries. For example, there are very wealthy individuals in even the poorest countries who can afford to buy a drug at developed country price levels.

The TB Alliance license agreement with Chiron for PA824 was described as a traditional license deal with exclusive rights, options and royalties. Chiron has rights only in developed countries, whereas the TB Alliance has rights in developing countries, thus ensuring that the PPP can explore a number of options to achieve its public sector mission.

4. Options and Conditions for Accelerating Development

The deals were discussed in more detail by working groups that considered the following aspects:

- Issues and options arising – what worked and what didn't work – lessons learned
- Role of the PPPs – comparative advantage, financing options, etc.
- Analysis of partnerships – the keys to making a partnership successful
- Inputs to make the PPP dealmaking more efficient and effective.

Reports from the two sub-groups highlighted the following:

- To guide the formulation of terms and conditions of deals, there is a need for clarity about PPP objectives and about ultimate measures of success.
- There is a need to address the difficulties in segmenting the market. For example, it will be good to understand whether to define territory based on “average” income such as GNP/capita or on numbers or percents of low-income earners. Working group members identified difficulties with this issue for China, India, and the middle-income countries of Latin America.
- Also, it will be important to address difficulties in defining “public sector” and “private sector” health providers, especially in developing countries. A subsidiary issue to defining sectors is to understand the implications of parallel trade of products produced under a PPP license.
- It would be good to examine pricing issues further and to develop definitions of “affordable” by, for example, developing an affordability index. The discussants noted that lowest cost may not be compatible with sustainability.
- Many participants felt that it was important to handle potentially contentious issues early in the

development process. When products are already being produced and access conditions are vital, it may be difficult to resolve controversial matters. However, for early-stage in-licensing of compounds that require considerable further R&D, it may be necessary to postpone the discussion of contentious issues either because the program may not be successful or simply because the uncertainties are too great to negotiate a meaningful agreement.

- There is a need for clear processes of dispute resolution and arbitration.
- The participants noted that liabilities in the manufacturing stage could be particularly challenging in formulating workable agreements.

In addition, both working groups saw benefits in sharing information across the PPP community, especially with regard to working through the deals and the type of terms and conditions that could be invoked to ensure the greatest opportunity for meeting the ultimate objectives of the PPPs.

The working groups also identified the need for an educational effort by the PPPs in raising awareness of their role and their approach to the development of drugs and vaccines for neglected diseases. In particular, the working groups identified the need to raise awareness with three important groups of stakeholders.

- **Universities.** As a key source of early-stage discoveries, it was important for PPPs to ensure that appropriate constituencies within the university sector were made aware of the underlying mission and goals of the PPPs. This awareness-raising would facilitate greater understanding of the PPP's need for fast response, for an understanding of the special considerations in deals concerning products for neglected diseases, and for recognition that the PPP's missions are aligned with the social mission of the universities. A poll among participants demon-

strated that nearly half of all the PPP deals are with universities – an indicator of the importance of academia to PPPs.

A variety of approaches can be used for awareness raising:

- For the technology-transfer managers, it is possible to use the newly formed interest group, Technology Managers for Global Health, within the Association of University Technology Managers (AUTM). This group can provide a conduit for information and feedback between universities and PPPs.
- To reach senior officials of universities, PPPs can communicate with groups such as the Association of American Universities (AAU) and the National Association of State Universities and Land Grant Colleges (NASULGC). Also, a forum convened by a prestigious organization such as the Gates Foundation would be helpful in reaching university presidents.
- For scientists and researchers, articles in *Nature* and *Science* would be appropriate.

In addition, there is a need to support a growing interest among technology-transfer offices and universities to operate against metrics aligned with both their social and economic goals. There is scope to also increase the awareness of technology transfer managers about the relative market value of technologies for neglected diseases.

- **Companies.** There is a need to raise awareness among companies of detailed aspects of the limited markets available for many products for neglected diseases and of the potential for segmentation of markets by territories and by fields of use. Those companies having a more in-depth understanding of neglected diseases tend to be more flexible in deal making. However, there is often a reluctance of Big Pharma to license IP because its development model is primarily based on ownership and tight management of intellectual assets. The deals with Big Pharma tend to be for future delivery of affordability rather than for the in-licensing of products for development. There was a notable difference in the attitude of biotechnology companies to those of Big Pharma; biotech companies were on the whole readier to make deals.
- **Developing Countries.** There is an urgent need for developing countries to participate fully in the development, manufacture and introduction of drugs and vaccines for their own populations. MIHR is addressing this need especially with respect to IP management capacity building including the definition of best practices. PPPs can be important partners for developing country research and development institutions and can facilitate the development of appropriate skills in those countries.

5. Access to Medicines: What Can Product Development Partnerships Control?

The second day of the workshop concentrated on the issues of deals for supply and access. The discussion was launched with an overview of the development process for drugs and vaccines with special attention to IP issues. Dr Roy Widdus³ reviewed the range of PPPs involved in delivering medicines to people in need. He emphasized that the product-development PPPs are generally highly product-specific but that in fact the common systems for drug distribution were not product-specific.

The product-development PPPs have goals relating to health impacts but they need the engage-

ment of many parties to ensure that these impacts are realized. Achieving impact on neglected diseases requires success on two fronts: availability and access. Availability has to do with issues such as the development of drugs and vaccines from basic R&D, and their licensure, manufacture, and procurement. Access extends far beyond R&D and is affected by many factors including poverty, governance, effectiveness of distribution systems, education of the population and others. It was noted that hepatitis B vaccine was not available to developing country people until 10 to 20 years from its availability in the developed world.

³ Roy Widdus, “Access to Medicines: What can product development partnerships control?” PowerPoint presentation (see Annex 2.1).

6. Securing Product Availability and Access

Three cases – from IAVI, MMV, and the Concept Foundation (see Annex 2.1, 2.2 and 2.3) – were presented to illustrate the terms and conditions that could be employed to help ensure availability and access.

These cases demonstrated the importance of professional IP management by the PPPs. Several common lessons emerged. PPPs need to be clear about:

- Ownership to ensure they have the appropriate level of influence and control of the product to achieve public sector goals.
- The retention of key rights such as march-in rights which can help to ensure the continued development and availability of the product, if a private sector partner should not continue with a project regardless of the reasons.
- Milestones which provide quantifiable indicators to measure progress, allow for review and reassessment of partnerships, and for appropriate actions in the case of difficulties.
- Expectations on pricing of the product to the public sector, although it was agreed that this can be an especially difficult matter.
- Defining and reaching agreement on appropriate enforcement and dispute resolution procedures.
- Issues of product liability.
- The ownership and use of clinical trial and other regulatory data.

The discussion of these cases showed that there are a variety of effective approaches to the issues. There was broad agreement that employment of effective approaches is essential to strong project management. Strong management capabilities are needed in forming and operating partnerships with Big Pharma, because sometimes Big Pharma has found that PPPs may have significant resources but were not sophisticated in their approach. PPPs can improve their capabilities by sharing experiences.

The participants identified several issues that require further examination:

- Understanding of cost and price. For example, it is necessary to know what is included in cost to be able to compute a cost-plus price.
- Managing risk, i.e. scientific, operating, financial, competing products, etc.
- Liabilities, indemnification and insurance, e.g. clinical trials and product liability.
- Appropriate jurisdiction for dispute resolution.
- Balancing the building of mutually beneficial relationships with “tough-nosed” enforcement of milestones.
- Developing consistent, transparent and workable polices and criteria for closing down partnerships that are unlikely to succeed.

The discussion led to the identification of concerns about the need to provide private sector partners with realistic estimates of sales. For example, UNICEF vaccine procurement has been hampered by poor estimates that had led to skeptical views by companies about other public sector demand projections. The discussion also returned to the role of the PPPs in assisting other organizations that will prepare the way for the adoption and sustained use of the new products. The discussion also touched on the possible conflict between the goal of “lowest possible cost” and the desirability of collaborating with developing countries in establishing product development capabilities and manufacturing facilities. Finally, several participants noted that material transfer agreements (MTAs) can be valuable for controlling the direction of development before entering into a full-blown, long-term development contract.

The Malaria Vaccine Initiative (MVI) noted that their recent successful clinical trials were obtained sooner than expected. They have to speed up their activities concerned with product introduction. In relation to milestones, MVI staff explained that they had adopted a strategy of specifying a rapid succession of milestones, thus giving them increased opportunity to identify and act on problems.

7. Measures of Success

The final session of the workshop dealt with defining ways to track progress and measure success. This topic had often been touched upon during the meeting, and this session provided an opportunity to go into more depth.

The participants identified the following criteria for measuring success:

- Cost vs. accessibility.
- Survival – to what extent does the product add to a healthy life rather than just survival.
- The extent to which a new product is adopted by government health systems.
- The number of culled or unsuccessful product development projects versus ones continuing through the development pipeline in the portfolio.
- The extent to which a PPP changes the R&D environment and attracts others into the effort.
- Catalyzing the adoption by developing countries of PPP models and of technologies for neglected diseases.
- Defining the customer and presenting a “complete product” offering to donors which ensures that all aspects which contribute to success are understood and delineated within proposals.

8. Conclusion

There was broad enthusiasm for a second meeting to be scheduled for the fall of 2005. Dr Jerry Sadoff, head of the Aeras Foundation, offered to host the event. In the meantime, there were a number of other actions that could contribute to a wider understanding and appreciation of the issues.

- Follow up on the AUTM links to ease deals with universities.
- Pool resources across the PPPs in relation to deal-making and partnership building.
- Highlight the PPPs mission and approaches at suitable events such as the Gordon Conference

to be held in Oxford in September 2005, and the Licensing Executive's Society and AUTM conferences.

- Share information on deals including a web-based environment for appropriate exchange of information.
- Document additional case studies for inclusion in the forthcoming second edition of MIHR Handbook.

The meeting was concluded with thanks to the Aeras Foundation and to the organizers, and with sadness at the imminent closure of IPPPH.

Presentations Day One

1.1 Antony. S. Taubman, “Public health research for neglected disease burdens: a framework for reflecting on dealmaking & IP management.”

1

Public health research for neglected disease burdens: a framework for dealmaking & IP management

Workshop on: Dealmaking and IP Property Management for Public Interest

29 November 2004: A.S.Taubman



2

Public health research for neglected disease burdens: a framework for *reflecting on* dealmaking & IP management

Workshop on: Dealmaking and IP Property Management for Public Interest

29 November 2004: A.S.Taubman



3



Public-Private Management of Intellectual Property for Public Health Outcomes in the Developing World

The Lessons of Access Conditions in Research and Development Agreements

www.bpph.org

4

Public interest IP management for neglected disease burdens

- How to sustain the policy space for public and public-private innovation processes?
- What practical lessons, what skill sets for working within that space?
- Do Public-Private Partnerships (PPPs) give practical insight for *public-private partnership*?
- What options for new pathways, further options, broader development pipelines and innovation structures to meet neglected needs?

5

Working within the policy space



Individual management partnerships

Institutional policy

National policy settings

National legal frameworks

International policy + legal framework

6

Optimal outcomes within the policy space

- What's the best interface between public and private inputs in medical research and development?
 - Seek to define optimal structures and interventions to overcome neglect and deficiencies in available public health technologies.
- Interface is shaped in part by IP laws, standards and management strategies. The IP system conventionally analysed as a legally-determined "balance" of public and private interests
 - framed in legislation, influenced by international standards
 - strong calls for flexibility to allow this balance to be set.
- Debate has focused on how IP standards relate to broader public policy objectives and other international law principles.
- Yet the balance is always dynamic. Actual beneficial impact achieved through the concretion over time of many distinct acts in the practical exercise of rights, interests and legal safeguards.
- Policy overview informed by practical insights from experiments in public-private partnership innovation structures

7

Multilateral Development Goals

- Goal 6: Combat HIV/AIDS, malaria and other diseases
- Goal 8: Develop a global partnership for development
 - Target 17: In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries
 - Target 18: In cooperation with the private sector, make available the benefits of new technologies

8

DNDi: "The gap is growing: more resources needed now for neglected diseases"

- Invest more in neglected diseases ... that fall outside the realm of market forces... accompanied by transfer of technology to disease-endemic regions
- Translation of basic research into molecules that can be tested in patients
- Strengthen existing capacities in neglected disease endemic regions to facilitate clinical trials
- Secure the market for, and thus the use of, new medicines
- Encourage industry to be more engaged in neglected diseases and to find innovative ways to share their enormous resources, expertise, laboratories and compound databases
- "Access to the technological expertise and research facilities of industry is crucial, but without the solid support of governments we will not be able to push our drug development projects through the pipeline."

9

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10

10/90 report - 2003-04

1. The imperative need to correct the 10/90 gap in health research and set priorities taking into account the global burden of diseases and their determinants
2. Build the capacity of health research systems in developing countries
3. Create international research networks and public-private partnerships
4. Increase funding for health research by developing countries
5. Governance and monitoring progress in health research

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10/90 report - 2003-04

- The imperative need to correct the 10/90 gap in health research and set priorities taking into account the global burden of diseases and their determinants
- Build the capacity of health research systems in developing countries
- Create international research networks and public-private partnerships
- Increase funding for health research by developing countries
- Governance and monitoring progress in health research

12

Promoting Innovation for neglected health needs

- What structures work?
 - Legal and policy frameworks, "partnerships"
- What incentives induce the necessary resources?
 - money, research expertise, development expertise, risk exposure, clinical trial capacity, infrastructure
- What kinds of innovation are needed? Basic research or incremental/applied/tailored development?
 - New compounds (access to compound libraries/ GR/TK)
 - New forms of compounds (more chemically stable salts, metabolically stable for better in vivo delivery, etc)
 - New delivery technologies for (dry vaccines through microsphere technology)
 - Adapted technologies for limited infrastructure (cancer diagnostic for self-administration)

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Managing Innovation for neglected health needs

- Is there a distinct, emerging skill set for public interest IP management?
 - Public-private partnerships "must be as aggressive in the way they use IP as any commercial unit, but for a different purpose - namely to pursue their social objective of getting quality, affordable products to developing country patients"
 - "creative IP arrangements that do not scare off companies but also allow the PPP enough control to ensure their ultimate objective"
 - Kettler & Towse, OHE, 2002
- How to capture "best practice"?

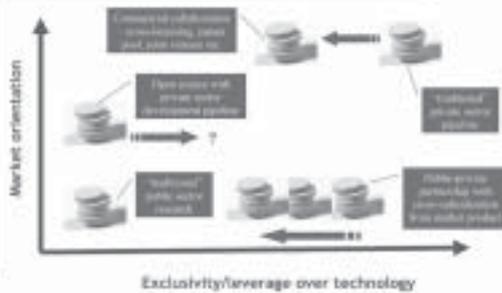
14

Managing Innovation for neglected health needs

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 - Kettler & Towse, OHE, 2002
- How to capture "best practice"?

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garnering and focussing the resources to meet neglected needs: what role for IP?



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Public-private partnerships (PPPs)

- A distillation/microcosm of the broader policy challenge (not the only model to explore)
- interplay between
 - yoking commercial interest to bring industry resources to bear, and
 - forms of exclusivity to induce investment of resources on priority health needs, and to sustain the control of the funding/public interest partner over technologies (background and new technologies)

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- Original antimalarial compound (artemisin/quinhaosu) derived from a natural source
- Progressively developed into more stable and useful derivative forms ('incremental innovation?')
- Patent estate held by a public-private partnership with strong public health mandate
 - What kind of innovation should be recognized by the patent system?
 - How is this asset best managed to achieve public health outcomes?

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Two key demands ...

- Public interest management of knowledge to deliver new public health outcomes:
 - what are the lessons of practical experience?
 - what structures or partnerships, what ways of blending incentives and safeguards, what forms of IP management and leveraging have been effective?
 - "work in progress," but a vital new skill set is emerging
- Enlarging the base of innovation, and broadening the drug development pipeline:
 - bolstering indigenous innovative and drug development capacity in developing countries
 - empowering developing countries to extract maximum benefit from their research activities, leveraging access to technology
 - respect for and recognition of traditional medical knowledge

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garnering and focussing the resources to meet neglected needs: what role for IP?

- Resources, tangible and intangible:
 - knowhow, research and product development capacity, clinical trial expertise, regulatory infrastructure, background/platform technologies and research tools, investment of public and private capital
- Applying these resources towards unmet needs:
 - generating new resources
 - private: incentives, market interventions
 - public: additional funding, infrastructure development
 - better applying existing resources
 - leveraging access to technologies
 - drawing on drug development skills and R&D infrastructure

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Managing IP for public health outcomes throughout the drug development pipeline

- Consider distinctive aspects of R&D in the public health domain, with respect on how IP issues are managed:
- strong public interest and public-funded/philanthropic input
 - corresponding strong public interest expectations
 - intensive and lengthy regulatory process: need for risk management
 - need to generate resources both for initial research and for subsequent product development: distinct incentives may be required
 - different markets and government mechanisms for regulating and disseminating products
 - "parallel pipelines" - serving related, but distinct need groups
 - market sector, non-market, social-marketing opportunities
 - brokering delivery of complete technology packages
 - need for drug delivery platforms, up-streams, impact of research tools

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What 'lessons' from the PPPs; who for?

- Broad international debate on the innovation structures needed to address neglected disease burdens
 - Global Forum
 - WHO Commission
- Growing body of experience with practical initiatives - new ways of blending inputs and capacities, spanning public/private, market/philanthropic/government sectors
 - each one a direct practical initiative, focused on a concrete public health goal, marshalling resources and capacities to that end
 - need for mutual learning, "best practice(s)" ideas (not templates)
 - evolution of a distinct discipline of public interest management of IP for public health outcomes
 - but each initiative can also be construed as a practical experiment in "innovative innovation," with potential lessons for policymakers
 - hope that new policy initiatives can be grounded in this experience

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What 'lessons'; and who for?

- Detailed lessons poorly recorded & not widely understood.
 - too busy doing the real work;
 - long time-lines, intermediate results at best;
 - complex array of inputs, not easily analysed;
 - hard to separate 'clinical' IP management from political context;
 - each partnership arrangement has unique characteristics - not ripe for cutting and pasting;
 - confidentiality for commercial reasons or other sensitivities.

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What 'lessons'; and who for?

- review of actual agreements may shed light on
 - formal aspects of partnerships and how mutual expectations are defined
 - how differing roles and the different allocation of resources, rights and responsibilities are determined
 - how management of IP issues can bridge between differing perspectives of funding and industry partners and reinforce shared objectives.
- broaden understanding of practical ways to resolve public policy dilemma of balancing private incentive to generate needed public health products against the goal of guaranteed access to those in need.

25

Focus on precise objectives

- Concentrating on concrete outcomes
 - which target groups, which disease burdens, what kind of dissemination strategy?
 - creates more likelihood of practical mechanisms that deliver beneficial new public health interventions
 - frees up other (richer) markets, other (more profitable) indications for private partner to serve
 - enables cross-subsidization
 - saves costs and resources in clinical trials and use of test data
 - IP policy question of validity of secondary uses, incremental innovation

26

Planning for access

- Access to new treatments has two steps:
 - Creation of R&D outcomes that would otherwise not exist (due to lack of market interest)
 - promotion of widest possible actual availability of a product once clinically proven and viable
- But PPP agreements factor in long-term access guarantees at the early stages of research
 - price ('reasonable', 'social marketing,' 'public sector')
 - performance (defined markets, timing)
 - reserve rights to access IP - all the necessary IP, not just the research IP

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Focus on downstream distribution

- The model for downstream distribution can determine basic choices over:
 - ownership of IP
 - access to background, related IP
 - provisions on licensing new technologies (such as favorable conditions for target markets)
 - undertakings on specific steps to make new product available
 - guarantees on access for third parties - e.g. to test data, background technology, capacity building

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Access to technology packages

- Creative IP licensing in PPPs provides access to technologies and other resources beyond the scope of the sponsored research
 - practical delivery of the finished product requires more than access to a single technology produced by the research
- Structuring alternative access pathways in case an industry partner is unable or unwilling to meet performance standards:
 - background technologies: manufacturing processes, adjuvants, excipients
 - test data and support for regulatory approval
 - technology transfer and capacity building

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Ownership of IP vs access to IP

- A pragmatic approach to ownership; not an end in itself
 - withhold ownership from industry partner until financially established
 - retain ownership of IP for target markets, permit industry partner to retain ownership elsewhere
 - leave ownership to industry partner as element of overall trade-off
 - with guarantees on access to new IP and background IP
 - limits the costs and liabilities of maintaining an IP portfolio

30

Legal agreement or technology partnership?

- optimal partnering depends in part on formal legal agreements
- but should reflect common understanding of shared values and objectives, recognition of and respect for distinct interests and operational constraints, and the establishment of realistic expectations of the two partners.
- accept that immediate interests, overall goals, cultural values diverge, lack of confidence and mutual understanding can itself impede or prevent the attainment of shared objectives and the most fruitful pooling of resources.
- practical experience may also lead to a reassessment of the assumptions and structures that underpinned the partnership, and may lead to insights about rights, undertakings, flexibilities and clarifications, as well as the overall mix of incentives and inputs, that could make the project more successful

31

Access conditions

- Technology development and access obligations:
 - research and creation of new technology per se, or the availability of necessary technology and associated data
 - may establish obligations on the research/industry partner to undertake research and development, and to make available background IP, know-how and associated data (including technical know-how or skills and resources required for product development, clinical trials and regulatory approval know-how, as well as the data on safety and efficacy produced by clinical trials).
 - provisions may amount to a positive undertaking - such as an agreement to undertake research or to provide technology, or an obligation to license or transfer IP rights in the event the research/industry partner fails to, or has insufficient interest to, develop and disseminate covered technology in a particular market.

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- Downstream technology dissemination provisions:
 - set conditions for how the covered technology is to be distributed or marketed by the research/industry partner
 - setting a price or criterion (such as "reasonable price" or "public sector price") for determining the price for distribution in a certain market;
 - may stipulate more generally that the pharmaceutical will be "reasonably available" or otherwise comply with similar criteria; and
 - may provide distinct requirements for how the pharmaceutical is to be distributed in distinct markets, such as an undertaking to cross-subsidize developing country or public sector distribution on the basis of preferential pricing.
 - other conditions defining how access to the covered pharmaceutical should be granted on the basis of market or non-market mechanisms.

33

Agreements differ widely:

- different strategic judgments and assessments about the most effective incentive structure, and the negotiating dynamics that yield a particular agreement.
- nature of the contributors brought by the two parties - whether the public partner is providing background IP, for example, and funding may support a stand-alone research program or supplement an existing program.
- External, more objective factors, including market and infrastructure issues:
 - size and characteristics of patient population for the target disease,
 - availability of sustainable financing from private and public sources,
 - cost and cost-effectiveness of gene vaccines and drugs,
 - health care delivery systems, including drug or vaccine distribution and delivery plans,
 - economics and structure of the relevant industry sector, and
 - pattern of ownership of and freedom to use necessary background technology.
- availability of alternative interventions (e.g. for a new malaria drug, there could be competing drugs, preventives such as potential vaccines, insecticide-treated bednets, and new insecticides), and,
- broader policy settings and regulatory factors

34

What drives choices?

- lengthy time-frame: convincing guarantees of access that will be effective over time while being responsive to changed circumstances
- price: specific formulae for particular markets, pricing standard using general criteria, or no price requirements at all (access defined in other ways, or reliance on competition to ensure adequate or reasonable access)
- technology access guarantees: not just covered technology, but whole technology package (background IP, test data, knowhow, improvements)
- technical assistance - comprehensive tech transfer

35

Need for practical mechanisms that deliver effective, affordable new treatments for diseases of the poor

- a challenge at two levels - a pressing policy issue and an immediate practical need
- develop and understand hybrid forms of IP management that give to funding agencies, government authorities and philanthropic initiatives
 - bargaining power, control, freedom to operate, and the capacity to catalyze new resources and negotiate access to the panoply of technologies needed to deliver affordably a new drug that is safe and effective
 - offering private-sector players enough legal clarity and workable commercial structures that enable commitment of product research, development and manufacturing resources.

36

- No template or model provisions: each process has unique characteristics
- Understand the complex dynamics that shape successful technology partnering for public health outcomes.
- What is the right mix of ownership, access and control of IP?
 - What degree of engagement of commercial interest and exclusivity is needed to achieve project goals?

37

- Public-interest IP management is based on a pragmatic conception of:
 - public interest guarantees of access,
 - public funded and private sector research,
 - private incentives
 - safeguards for investment in product development,
 - deployment of product development know-how
- coherently combined and channelled into delivering actual public health outcomes for neglected health needs.

1.2 Richard Wilder, “Dealmaking/IP Management Case Illustrations: MMV- “OZ Project.”

1

Dealmaking and Intellectual Property Management for Public Interest

29-30 November 2004

MMV - “OZ Project”
Richard Wilder
Sibley Austin Brown & Wood

Sibley Austin Brown & Wood LLP
1000 15th Street, NW
Washington, DC 20004

2

MMV Mission

- MMV mission to accelerate discovery, development and delivery of medicines for the treatment and prophylaxis of malaria.
- MMV-developed medicines must be readily available and affordable in developing countries.
- MMV enlists collaborators - universities, government agencies, private sector - as it does not have capability to conduct discovery, development, and delivery of medicines.

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3

General IP Principles - Development

- It is not necessary for MMV to own IPR – either background IPR or program IPR – to further its mission.
- Typically, background IPR is owned by the collaborator that developed it and brought it to the program being funded by MMV.
- During the development phase of a program (before marketing approval has been granted by regulatory authorities):
 - Background IPR will be licensed on a non-exclusive, royalty-free basis to the other collaborators and to MMV.
 - Program IPR may be owned by either the collaborator that invented it or by MMV, with licenses being granted to the other parties on a non-exclusive, royalty-free basis.

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4

General IP Principles - Post-Development

- Focus is on ensuring that manufacture and distribution on terms and conditions required by MMV and terms to manufacturer/distributor may include:
 - ownership or exclusive rights in background and program IPR in both developed and developing countries; or
 - exclusive rights in background and program IPR only in developed country markets, with IPR in developing country markets being held by MMV; or
 - IPR be held by no parties in no or very few developing country markets – in essence allowing generic manufacture and distribution in such countries.
- Rights revert to MMV if terms and conditions not met.

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5

OZ Project Motivation

- Many existing antimalarials are losing effectiveness due to resistance.
- Artemisinin - isolated from Chinese wormwood (*artemesia annua*) plant - and its semisynthetic derivatives, are increasingly expensive and have short half-life.
- Synthetic compounds containing the active peroxide bond of artemisinin sought, but to date attempts have failed
 - low oral activity (a defect shared in part by the current artemisinin derivatives);
 - neurotoxicity; and
 - difficult synthesis, expensive.

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6

Status of Project

- Exploratory work, beginning in 2000, led to selection of OZ-277RBx 11160 as lead compound to enter development. Discovery team included:
 - Dr Jonathan Venter, University of Nebraska Medical Center, USA
 - Dr Reto Hres, Swiss Tropical Institute, Switzerland
 - Dr William Chanana, Monash University, Australia
 - Dr Hugues Maitre, F. Hoffmann-La Roche, Switzerland
- May 2002 - Roche handed over project - development phase - to Baschary.

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Project - Development Phase

7

- Ranbaxy Laboratories Limited have successfully completed scale-up and produced 30 kg of high purity GMP grade material.
- Preclinical toxicology and formulation work started in the fourth quarter 2003.
- Phase I trials done in UK, including single rising dose, multiple rising dose and food effect, all in one protocol
- Phase II-Proof of Concept in Thailand starts in November

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Ownership of IPR

8

- Initially program IPR was to reside with the University of Nebraska, but did not want to absorb the cost, so right to patent was passed to MMV
- U.S. Patent No. 6,486,199 was issued to MMV November 26, 2002 (first and only patent owned by MMV) claiming:
 - The Compound
 - Pharmaceutical composition
 - Method of preventing or treating malaria comprising administering the compound
 - Method of manufacturing a composition for prophylaxis and treatment of malaria
 - Method of treating cancer
 - Method of prophylaxis or treatment of schistosomiasis
- PCT Applications pending

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Allocation of Rights

9

- Background IPR owned by parties necessary to make and sell product including program IPR licensed to MMV and is sub-licensable by MMV to third parties.
- Ranbaxy has obligation to make product available at affordable cost
- Ranbaxy has license under background and program IPR MMV has rights in
- MMV has rights in any improved formulations developed by Ranbaxy
- Profits - if any - are shared by Ranbaxy with MMV
- MMV Shares income with University of Nebraska, Swiss Tropical Institute and Maastricht University (but not with Roche)

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Conclusion

10

- MMV has Rights it needs to further its mission
- Intent is to finish development with Ranbaxy and into manufacture for distribution
 - Manufacture by Ranbaxy for malaria-endemic countries at affordable prices
 - Ranbaxy has rights in so-called "traveler's market" and for other indications - obligation to pay royalty to MMV if profits made in those markets and by MMV to some partners if profits made
- Necessary rights retained by MMV to ensure goals can be met

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1000 AVENUE OF THE AMERICAS, SUITE 2000
NEW YORK, NY 10018-6090

1.3 Gerald J. Siuta, “Dealmaking/IP Management Case Illustration: Global Alliance for TB Drug Development Licenses PA-824 from Chiron Corporation.”

Topic	Outline information
Desired candidate product	The nitroimidazole PA-824 and related compounds for the treatment of tuberculosis.
Background intellectual property and its holder(s)	PA-824 demonstrated <i>in vitro</i> activity against both drug-sensitive and multidrug-resistant strains of TB. Originally a by-product of 1990s cancer research at PathoGenesis Corporation (acquired by Chiron), PA-824 has three key characteristics: it is novel, bactericidal, and sterilizing.
Partners in the ‘deal’	In 2002, the Global Alliance for TB Drug Development received a worldwide exclusive license to PA-824 and related compounds from Chiron Corporation for the development of a new drug for the treatment of tuberculosis.
Your organization’s objectives and assumptions	To accelerate the discovery and/or development of affordable, new anti-TB drugs that will shorten treatment, be effective against multi-drug resistant strains, and improve treatment of latent infection.
Objectives of partners and their incentives for making the deal	To participate in the development of a potential new treatment for TB.
IP and other issues arising	Issued patents and patent applications on PA-824 and related compounds.
General observations	Provisions have been made for possible further collaboration with Chiron at later stages of development, including a grant-back option to Chiron for manufacture and commercialization of products in developed markets. The parties have agreed that no royalties will be due under this agreement for drugs marketed in less developed economies, including impoverished countries with a high burden of tuberculosis.

Presentations Day Two

2.1 Roy Widdus, "Access to medicines: What can product development partnerships control?"

1



Access to medicines: What can product development partnerships control?

Roy Widdus, Ph.D

Initiative on Public-Private Partnerships for Health
Global Forum for Health Research
Geneva

Bethesda, November 2004

2

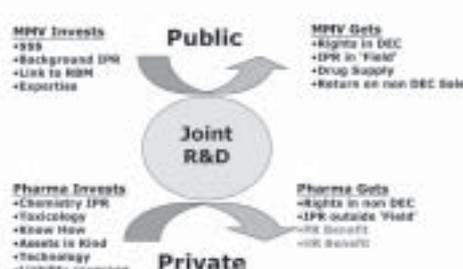


"What has been the experience of industry with PDP negotiations of 'access provisions' in agreements so far?"

- "Well, the public sector has never been very good at projecting uptake of new products"
 - PDPs (wrongly) equated with 'the public sector'
 - PDPs (wrongly) judged to be capable of speaking on behalf/"delivering" the public sector agencies
 - Public sector deficiencies (correctly) identified

3

The win/win proposition:



Public

MMV Invests
• \$\$\$
• Background IPM
• Link to R&M
• Expertise

MMV Gets
• Rights in DEC
• IPM in "Field"
• Drug Supply
• Returns on non-DEC Sales

Joint R&D

Private

Pharma Invests
• Chemistry IPM
• Toxicology
• Know How
• Assets in R&D
• Technology
• Liability coverage

Pharma Gets
• Rights in non-DEC IP
• IPM outside "Field"
• R&D Savings

The "deal" is sustained by balancing incentives/costs for each partner

4

Visual R&D is essentially project and portfolio management through relationships and contracts



5

Impediments to better health in developing countries

Ideal situation

Research → Product and manufacturing development → Regulation → Introduction strategies → Health Wide Appropriate use system

Current reality for the poor

- Unattractive return on investment for commercial product R&D
- No planning for product use and initial cost
- Weak health services infrastructures

6

The 'Bench-to-Bush' Mission of PD-PPPs such as MMV



7

Many people will lack access to essential drugs

Percentage of population with regular access to essential drugs (1997)



8

Determinants of Access to Pharmaceuticals (WHO)

Availability, i.e., whether a satisfactory product has been developed

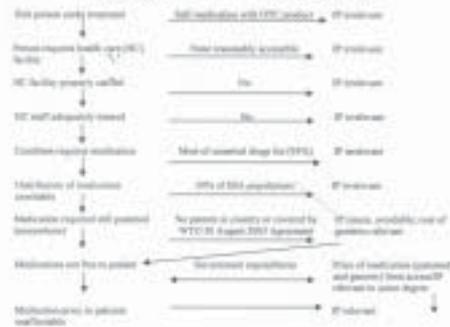
- Basic research
- Discovery
- Development

Accessibility, including:

- Drug quality, rational selection, appropriate prescribing and use
- Distribution system effectiveness and efficiency
- Economic factors, i.e. cost, pricing, procurement and financing
- Knowledge and 'health-seeking' behaviour of 'consumer'

9

IP and access to medicines: A consumer perspective



10



Adoption versus routine use

- It is important to differentiate responsibilities for routine use from those things that will accelerate adoption
- 'One time' versus ongoing

11

What aspects of access to medicines are under control of product development partnerships

- The choice of which candidate products to develop, that
 - Can influence manufacturing costs, to some extent, and
 - Can also influence supply/storage and the, distribution difficulty, ease of administration and likely compliance, which are factors in access.
- The choice of development partners
 - These vary in policy and priorities in addressing the needs of poorer developing countries.
- Manufacturing costs (to some degree)
 - Can retain the right to ensure the cost manufacturers, but cannot benefit after cost of goods if difficult to manufacture.
- Whether to seek regulatory approval as a product sponsor, or to leave this to the drug manufacturer
- Which access conditions
 - Populations targeted for potential supply, i.e., countries, markets
 - Level of manufacturers (to some degree by choice of manufacturers)
 - Price charged (to some degree, to some degree through 'most-favoured' conditions)
- Specifying ownership of IP (at least) generated during the agreement (i.e., leveraging its investment)
- Antidumping and investment questions regarding the candidate product's linked public health utility, in low and middle income countries.
 - The investor states that as opposed to the minimum required for the same trade it requests applications for efficacy and safety, but may include studies of its own (involvement and safety in disadvantaged groups, efficacy in pregnancy, etc.)
 - It requested substantially to research, conduct of these studies may delay sales introduction and potential public health impact. However, obtaining them early on all candidate products is financially unrealistic.

12

What aspects of 'access to medicines' are not under PDP control?

- Health systems issues
 - Reach of health services
 - Staffing of health services
 - Consistency of health personnel
 - Efficiency of health services/product distribution
- Public/private mix in health services, which can affect quality of care
- Environment practices and efficiency
- Allocation of resources for health systems
 - Allocation of government resources for product purchase
- Purchasing power of consumers
- National policies regarding product choice and drug pricing, and the speed of their formulation
- Policy recommendations of international agencies and the speed of their formulation
- Regulatory approvals sought, if PDP does not choose to itself be a sponsor for regulatory approval
 - Where and with what timing approvals are sought will be at the option of the manufacturer.
- Manufacturing costs and pricing, if the PDP calculates it is not advisable to attempt to produce

13



Identifying 'access' partners:

- Who sets policy
 - Global, bilaterals, national, etc
- Who will purchase the envisaged product?
 - 'Internationals', government, cooperatives, individuals,
- Distribution channels?
 - Public, private, mix
 - Pricing considerations

14



Supply/access conditions in agreements

- Will benefit from considering adoption issues in advance
- Who are 'gatekeepers' for adoption/use?
 - International/bilateral/national
 - Who could delay adoption & why?
 - Who are potential allies?
- Some things can go into agreements
- Some things PDPs cannot really control need early attention to influence in a favorable direction

What will get you into trouble in anticipating adoption.....

- The “unknown unknowns”
 - Those things just not thought about
 - Can reduce the likelihood of these through sharing experience
- “Those things you know that just aren’t so”
 - Beware overly optimistic assumptions

2.2 Labeeb Abboud, “Dealmaking/IP Management Case Illustrations: IAVI Securing Access

1

Dealmaking and IP Management
for Public Interest

Securing Access

International AIDS Vaccine Initiative
November 30, 2004

2

Overview

- IAVI mission and strategy
- Portfolio and Partners
- Assumptions and Incentives
- IP Ownership and Access
- Issues in Negotiations
- General Observations

3

Mission and Strategy

- Mission: To develop a safe, effective, accessible preventive HIV vaccine for use throughout the world
- Strategy:
 - Advocacy
 - Policy
 - R & D
 - Engaging Developing Countries

4

Portfolio and Partners

- Portfolio:
 - Today: HIV vaccine capable of attenuating infection (MVA/DNA; DNA; AAV; SFV; VEE; Ad35/11)
 - Tomorrow: HIV vaccine capable of preventing infection. Preference is for a single administration product
- Partners:
 - Academic institutes (US, EU, Kenya)
 - Biotechs (US, EU)

5

Assumptions

- Potentially relevant technology was not being pursued due to development risks/funding
- Access commitment + March-in rights would be effective to ensure Access
- We would obtain reasonable commercial terms for rights to required third party IP, manufacturing, and distribution

6

Partner Incentives

- Funding at early stage, and potential revenues
 - May reduce their risk for development activities
- Platform development
- Credibility to investors and potential partners
- Access to technical expertise
- Access to clinical trial sites
- Political benefits of working with an NGO

IP Ownership

7

- Background IP
 - Partner:
 - Owns
 - Licenses
- Program IP
 - Partner owned
 - Jointly owned pro rata
 - Ownership determined by inventorship

Access/Supply

8

- Access commitment for Developing World
 - March-in rights:
 - Abandonment or failure to exercise commercial efforts in Developing World (or Public Sector)
 - Time period
 - Failure to offer at agreed upon price
 - Automatic trigger/Right of first refusal
- Non-exclusive license
 - Public sector of Developing World
 - Developing World
- Exclusive license
 - Developing World
 - Worldwide

Issues in Negotiations

9

- IP
 - Use of Program IP and Data
 - regulatory filings, comparative studies, publication, confidentiality
 - Third Party Improvements
 - Expense of FTO and IP
 - Technology transfer
 - Re-importation
- Other
 - Program Management/Control
 - Clarity of roles
 - Decision making process
 - Financial Terms

General Observations

10

- Necessity for PPP involvement to develop technology
- Partner's perceptions of PPPs:
 - Lack of sophistication
 - Deep pockets
- Challenges:
 - Required Third Party IP
 - Technology transfer to Developing Countries
- Importance of Trust and Communication

2.3 Article about the Concept Foundation serving as Dealmaking/IP Management Case Illustrations by Joachim Oehler, “The Role of Milestones in Licensing Deals to Assure Access to Health Products in Developing Countries.”¹

Executive Summary

IP management to optimize public sector benefits needs to balance the commercial interests of private sector manufacturers with the needs of the public sector to obtain access to products at lowest possible costs. Most of the intellectual property (IP) oriented towards generating public sector benefits in the healthcare sector and biotechnology results from R&D in public-sector research centers and international organizations. Through adequate management of the resulting IP the public sector can benefit from its R&D investments through availability of the most modern products at conditions that are beneficial for the developing world, thus eliminating the otherwise significant access barriers.

An important tool of adequate IP management between public sector and private sector partners is the detailed definition of contractual milestones when it comes to licensing out IP from the public sector to private sector companies with the goal of producing products based on or incorporating the IP. This article describes in detail the considerations that lead to successful milestone definitions and discusses important factors related to pricing to the public sector; territory and exclusivity; regulatory work and data; time to market; royalties; and terms and termination of licensing agreements.

One of the underlying assumptions for everything that is outlined above is that milestones are not cast in stone. Milestones should and need to remain adjustable throughout the lifetime of a license agreement according to project development, changes in the market environment, and other factors that can't be anticipated completely. When it comes to the detailed specifications of individual milestones, it does not really matter if you are choosing an absolute or a relative goal, and which definitions to finally select. What matters is to get the commitment of a private sector company to realize public sector targets. It is important to have a working set of adequate milestones in place, to

define review periods for performance assessment by your contract partner, and to be ready to be open to and to accept milestone revisions when new, solid evidence requires a change of rules to keep the product and public sector goals alive. Such result oriented milestones require very intensive preparations, detailed knowledge of processes related to the development and marketing of the product, detailed knowledge of markets, realistic anticipation and forecasting of product potential, the persistence for quantitative forecasting and for establishing a master plan for the entire product roll-out, and a mission-driven mindset to establish the optimum public sector goals and to prevent the public sector from losing out to commercial thinking.

Successful public-private partnerships are being built on value propositions from the public sector to the private sector partners that take advantage of the inherent capabilities of public sector organizations. It is the task of the public sector IP manager to identify the relevant capabilities that are important to a particular public-private partnership, and turn these capabilities into specific value propositions that help the private sector partner to realize its commercial goals, but without sacrificing any potential benefit to the public sector. In this context, it is especially important to overcome the common phenomenon of further “marginalization of the poor” in the small and smallest countries of the developing world. In a commercial environment it is market attractiveness that rules priorities. In a public-sector context, the poor in the smallest countries have the highest needs to get access to affordable products. Adequate and successful IP management of public-sector generated IP needs to bridge these two opposites. The experiences of the Concept Foundation, which are the platform for this article, show that this is possible.

1. Introduction: The Importance of Contracts

For parties entering into agreements of any kind, the primary assumption of contractual relationships is that the principal subject of their deal will be realized successfully. In terms of assumptions and remedies, contractual agreements differ consider-

¹ Oehler J. 2004. The Role of Milestones in Licensing Deals to Assure Access to Health Products in Developing Countries. *IP Strategy Today* No. 10-2004. Pp. 59-70. www.bioDevelopments.org/ip

ably in quality and substance for cases when unforeseen and adverse effects prevent the contractual partners from reaching their goals. Too many contractual relations go sour because when everything seems predictable partners rush into agreements without carefully thinking about contingencies.

Without an early elaboration of clear provisions for contingency planning and crisis management, this “honeymoon” trap is why many contractual agreements contain unclear, foggy language and omit definitive, detailed, and enforceable conditions concerning not only the contractual rights but also the obligations of each partner and the specific countermeasures to be taken should one party run into difficulties in fulfilling its part of the deal. Instead, “best efforts” clauses or provisions for consultations to solve problems case by case are used so as not to spoil the initial enthusiasm when the agreement is being established. This can be a sure recipe for disaster when the unforeseen strikes, especially if the mechanisms to settle disputes over differing opinions about contractual performance are not clearly specified.

A typical contract specifies the subject matter, the rights and obligations of each party under the agreement, and the duration and terms. Licensing agreements between two organizations identify, among many issues, the nature and scope of the intellectual property or product that is licensed, specify the territorial grant to the licensee where the licensed product would be made available, and the terms under which the Licensor receives financial compensation from its licensee(s).

A practical example is the use of technical know-how or the results of scientific research that represents the particular intellectual property of a Licensor and is to be licensed out to a commercial company able to create a product from this IP and to distribute this product to consumers and users. The interests of both parties in this arrangement are straightforward and advantageous for each partner – it is a win-win situation. This ordinary, idealistic assumption prevails at the beginning of any licensing deal. All too often, however, reality thwarts the goals of the initial agreement for the times planned or forecasted, and the contractual partners are left with a subset of the original targets.

Such contracts between private and public sector entities must also consider that the commercial

interests of private sector companies are on the whole oriented towards maximizing profitability. Accordingly, it should not be expected that private sector businesses will automatically provide the best services to the public sector or that they will focus on the generation and use of intellectual property to maximize public sector benefits. To prepare for situations when the original targets of a license agreement are delayed or not achieved, and to avoid situations when projected public sector benefits are delayed or unrealized, it is good practice to establish contractual milestones that regulate target achievement under the license and set incentives for keeping to timelines and performance goals. This allows both the Licensor and licensee(s) to focus resources on their efforts to perform as initially agreed.

Additionally, it is very useful to spell out the level and conditions of fines (monetary or otherwise) to be paid when a partner does not fulfill obligations. This should include a mechanism to prevent prolonged periods of quarreling over differing opinions and arguments over performance that would halt product development or marketing efforts and ultimately hurt the public sector.

Most important milestones cover:

- Pricing to the public sector
- Territory and exclusivity
- Regulatory work and time to market
- Royalties
- Terms and termination of the license agreement

2. The Great Divide in Business Models: Public Sector-Industry

The discussion between the public sector and industry is a cross-cultural event, no matter how well public sector players think they understand industry. In such a cross-cultural environment, there is nothing more dangerous and productive of misunderstanding than to “assume the obvious”, since what is obvious for one person with a public sector background will not necessarily be the same for the other partner. Do not leave obligations and contractual performance to “best efforts” and “common sense”! It is much better for both partners to specify in writing exactly what the public sector wants to achieve with a commercial partner, detailing when and how this will be achieved and

specifying related penalties. If the agreement specifies only best efforts and unspecified performance, disaster threatens!

Value Propositions Stimulate Collaboration

To manage intellectual property for maximized public sector benefits requires balancing the expectations of the public sector to obtain products at the lowest possible prices, excellent quality, and in sufficient quantities, with the expectations of private sector companies to generate a satisfactory rate of return on their manufacturing and marketing efforts.

Important value propositions for pharmaceutical companies are:

- *Save time to market:* An earlier market entry means higher market share opportunities for the company and ultimately more sales. Example: Pharmaceutical and/or clinical research using an existing network of public-sector institutions in parallel speeds the generation of results needed for drug regulatory approval without the lead time required to approach new, unfamiliar trial sites and train in GCP (Good Clinical Practices).
- *Save resources:* Reduced need for internal company resources means a lower cost burden for the licensee and improves the bottom line. On the other hand, when investment levels are maintained more parallel activities are possible with the same amount of resources, helping to increase the company's commercial output. Example: existing public-sector distribution networks, formal or informal, allow a product to reach a large public-sector market very quickly without the costly buildup of a supply chain.
- *Save investments:* A reduced need for investments means better cash flow utilization within the company, which is very important for investors.

Any plan for a value proposition must deal specifically with the nature of the partnership, and a successful proposal must present an **authentic and actual value** to a potential partner. These authentic and actual values need to be based on the set of capabilities, which actually are the platform for all actions that results in value creation, that the public-sector organization could offer and on what needs of the private-sector partner could be met by a public-sector partner. Such genuine values include the examples above: "save time to market", "save resources", and "save investments." As these demonstrate, it is important to look behind the

immediate and apparent "face" value of individual capabilities in the public sector to be able to identify and compose the true value contributions. Indeed, an authentic value proposition is more often composed of several contributions from various capabilities than a single value factor.

It is very helpful to understand all the specific values at a very early stage of approaching potential licensing partners that drive an industry and that are particularly important for the potential licensee. A detailed analysis of these values and alignment with existing public-sector capabilities help to identify the value propositions that public-sector organizations could offer their private sector partners.

3. The Most Important Milestones

3.1 Principles

The management of intellectual property for maximized public sector benefits has three key aspects:

- Definition of the geographic coverage for marketing the product (i.e., territory)
- The claim for product exclusivity by the private sector licensee(s)
- The definition of the preferred public sector price or other public sector benefit

These headlines seem very straightforward. It is easy to imagine that the partners in a license arrangement agree on a set price for the product for public sector distribution, agree on the names of the countries where the product could be sold, and that as a result the private sector company as licensee obtains the exclusive rights to marketing and sales of the product in this territory. However, in real life, this does not necessarily mean a maximization of public sector benefits.

Some key questions need to be answered to safeguard the maximization of public sector benefits:

- How well will we reach smaller countries with our product?
- How well will we reach the rural population in developing countries that, by all experience, normally remains underserved?
- Who will be the beneficiaries that can obtain the product at a special public sector price?
- How can we assure that we obtain the product at prices that public sector agencies can afford?

The principal way to address these issues is to set contractual milestones that prevent the marginalization of the poor in smaller countries, regulate public sector access, and set the geographic coverage for all countries in a territory (even in countries and regions that commercially are not interesting enough to generate sizeable returns on investments and would therefore normally not be served). Finally, there needs to be a clear framework to compute the manufacturing cost.

Due to commercial pressures, there is an inherent danger of putting the private sector and its commercial interests before those of the public sector. This danger mainly results from attempts to simplify the private sector partner's participation because of fears about failing to make a deal. While simplifying agreements is good practice, establishing specific contractual milestones and clarifying them under the terms of an agreement are not necessarily complications. Success requires focusing on the targets to achieve and on the issues to exclude. A tight focus will secure simplicity of the provisions and regulations without overburdening an agreement.

When it comes to public sector benefits, making a product available or how quickly it reaches markets does not constitute progress. It is how many people the product will reach, how easily it will be available, and who can afford the product at what pricing level that defines success. The goal is to reduce morbidity and mortality to the greatest possible extent. For the public sector, This is the ultimate benefit of product development. The necessary achievements for obtaining this outcome need to be clearly specified as milestones in the agreement. Accordingly, we will take a closer look at territory, exclusivity, and pricing.

3.2 Territory and Related Aspects

A typical license agreement will specify the grant of the license in one of its early paragraphs. Language such as "LICENSOR grants COMPANY the rights to manufacture and sell the PRODUCT into the PRIVATE SECTOR and PUBLIC SECTOR markets of the TERRITORY" is commonly used. The terms LICENSOR, COMPANY, PRODUCT, PRIVATE SECTOR, PUBLIC SECTOR, and TERRITORY are used according to the definitions in the introductory "Whereas" chapter to the agreement.

Under this wording, the license grant is established as a right of the licensee to the product. However, it doesn't specify the obligation to sell into the territory. This is a very important issue of practical IP management for public sector benefits. While it is reasonable to assume in case of a "one-product, home market" manufacturer that the licensee will introduce the product into this (single) market, it is not necessarily true that a licensee will introduce the product into all markets of a multi-country territory, especially the public sector. This failure to reach all the desired markets may result from various factors that were not known or were underestimated at the time when the license agreement was established.

Between the signing of a license agreement and the commercial rollout of the product, a considerable period of time may be needed for product development, manufacturing scale up, and drug regulatory approval for a pharmaceutical. Depending on the capabilities of the licensee, this time period may well extend over several years. During this time the company's business and the business environment may change significantly, and resources that originally were available for dealing with the product may have been partially redirected to other, possibly more profitable, products and projects. Markets that initially seemed very attractive may lose their appeal over time compared to other opportunities since recognized by the company.

Changes in the business environment and business focus may affect the licensee's commitment to serve the public sector as originally envisioned for the entire territory. To avoid negative consequences for public sector availability and public sector access to the product in the territory, it is only prudent to establish the license grant as an obligation to sell the product into the public sector of the territory – not just as a right of the licensee. This can be accomplished in various ways:

- One possibility is to separate the grant of the "rights to manufacture the product" from the "obligation to sell the product into all countries of the territory". Emphasis here should be on all countries in the territory.
- Another possibility is to assign milestones to the execution of the sales rights for the product under which the licensee would gain access to other countries. Only after showing defined success according to the milestones the licensee

would be granted additional sales rights for other countries.

- Public and private sector rights to selling the product could be dealt with in separate regulations that capture the priority for the public sector organization of having the product introduced into the public sector to a satisfactory level (to be defined by an adequate milestone) in one country before additional rights to markets – public and private- in other countries would be granted.

The license grant could specify, as example, the rights of a Brazilian manufacturer to produce and sell the product in Brazil, its home market, and the rights to sell it in other Latin American countries when certain conditions are met. A wide range of options for these conditions are available and could be specified in the license agreement, such as:

- *Market share*: licensee will gain the rights to sell into other countries after establishing a market share of 20% in the specific market segment, as reported by IMS.¹
- *Market position*: licensee will gain the rights to sell into other countries after positioning the product among the top 3 products within its category in the Brazilian market, as measured by analyst reports.
- *Sales volume*: licensee will gain the rights to sell into other countries after an annual sales volume of 5 million units is realised in the Brazilian market, as measured by cumulative sales reports from distribution agents.
- *Public sector penetration*: licensee will gain the rights to sell into other countries after the total output/annual output into the public sector in Brazil has reached 10 million units, as measured by procurement orders from public sector agencies.

In addition to the milestones for gaining the rights to sell in additional countries, the remaining countries in the licensed territory could be prioritized in order of importance for the licensee, or eventually the Licensor as well. Each country on the list will then be characterized by individual milestones that need to be reached by the company before it could sell in an additional country. These country

² IMS is an international firm that publishes reports on pharmaceutical sales by conducting pharmacy audits and other means.

priorities and milestone definitions should be set initially when signing the license agreement, with the option to revise the priorities and milestones after a certain period.

It is unwise to leave country priorities or milestone definitions open and uncovered for the sake of higher flexibility (e.g. saying, that the next country priority will be set shortly before reaching the last defined milestone in the actual country of activity, or a similarly flexible model that postpones decisionmaking). This carries the risk that it might get more and more difficult to reach the necessary consensus between licensor and licensee about country priorities and milestone definitions, especially the closer the country of choice is to the bottom of the priority list. The licensee might then no longer desire to sell in a particular country, and especially into the public sector, due to various, possibly hidden reasons, which would run contrary to the goals of the public sector organization at that time. In a flexible licensing model, if milestones had not been mutually defined before such a situation emerges, the private- sector company would not violate the license agreement if the necessary consensus about milestone definitions cannot be reached between the contract partners, and could walk away from its responsibilities to serve a particular country.

On the other hand, priorities and milestone definitions may change over time in a fast moving business environment and they might not be considered valid after several years in the lifetime of a license agreement. This is a common perception when it comes to the definition of priorities and milestones, especially among advocates of “real-time” implementation. Given the need to eventually define priorities and milestones, to protect public sector access to the product everywhere as far as possible, and the inherent dangers of leaving important parts of an agreement initially undefined pending a mutual understanding at a later time, it is close to irresponsible to skip over these definitions and omit them from the initial version of the signed license agreement. One can provide for a regular update of the details of these conditions, when a changed environment, for example, calls for revisions. At that time, however, it would be up to the licensee to demonstrate the need for changes and to prepare a detailed proposal of what to change and how to change it. Unless the proposed changes bring up compelling and convincing reasons for the licensor, the original definitions of priorities and milestones will prevail. The originally anticipated

public sector goals and benefits remain in force without alteration and are still to be realized by the licensee.

Initially defining contractual priorities and detailed milestones is, of course, a painful process that requires very intensive preparations so that the essential aspects of public sector needs are not overlooked. This phase of desk research and information collection is among the most important phases for adequately preparing license agreements serving public sector interests. For initial negotiations between parties, it is most appropriate to roll out the terms of a licensing arrangement in all related details, even though it may be difficult and resource-intensive to formulate all of them. Calls from the contract partner or one's own tendencies to postpone detailing specifications or omit the necessary depth of description for the benefit of simplifying and quickly reaching an agreement are not beneficial for establishing the necessary framework of an efficient and ultimately effective public sector oriented licensing arrangement. If it is not possible to reach an agreement on staggered priorities with detailed milestones in the beginning of the contract relationship, how can these differences satisfactorily be ironed out later?

3.3 Avoiding the Marginalization of the Poor in Small Countries

For commercial companies, large markets dominate priorities and occupy the top spots of territorial ranking, while small countries regularly end up at the bottom of the priority list. In a commercial environment, market attractiveness rules priorities. The needs of the poor and of public sector agencies in small countries do normally not represent attractive markets for companies that are expecting to generate sizeable commercial returns out of their manufacturing and marketing efforts. It is necessary for a Licensor to ensure that product access is not limited to larger markets only and that small countries will also be covered to avoid further marginalizing the poor.

When it comes to the territorial grant of a license agreement aimed at maximizing public sector benefits, this particular issue needs to be considered thoroughly by the licensor. The prospect of substantial profits from product sales into the private markets of any territory is an important issue for awarding the licensee commercial advantages under the license agreement. However, the territorial grant must not only cover large countries and

their sizeable private markets -as main incentive that the public sector would be reached as well –, but needs to also include small countries and their public sector markets that normally would remain uncovered by the private sector partner. It is vital for an effective territorial grant to contain a mix of large and small markets to balance the commercial potential for the licensee against the humanitarian need of the public sector to provide access for the poor to affordable and effective products also in those countries that are commercially not attractive. This particular need is left to the protection of the licensor as the guardian of public sector interests.

It is a good practice, therefore, not to grant sales rights in large countries to a single licensee without including the obligation to also serve the markets and the public sector in the smallest countries. Should a single licensee be unable to cover all the markets of a region, an appropriate segmentation of the entire region needs to ensure that two or more licensees each get a profitable share of it to assure that the public sector in the smallest countries will also be served. As outlined above, this goal needs to be adequately supported by specific milestones.

The upfront definition of territorial milestones is often skipped or neglected to the public sector's disadvantage. One very common reason for this is that the primary needs of the public sector are spread over a wide territorial area and/or over a variety of minority groups in dire need for services. Satisfactory coverage requires a multitude of distinctive priorities and characteristic milestone definitions, which places a burden of initial definition on the license partners, especially the licensor as guardian of the public sector interests.

One strategy for expanding territories is for the licensor to generate sales to public sector agencies in countries that are not covered by the initial territory grant but very much need the product. This approach has the following advantage: the licensee can focus on the obligations and related milestones under the license agreement without dilution through multiple targets, while the licensor seeks to serve public sector agencies outside the territory. If desired, this additional market may be assumed by the licensee.

An issue for special consideration is the setting of a quantitative goal for public sector sales. The licensor could use absolute or relative target figures for the size of the public sector sales. A good target

figure is the market share percentage reached after a certain time from product launch. Another possibility is to define the sales growth reached in the first years on the market. You could use the sales volume after 1, 3, or 5 years on the market to characterize the expected – and initially agreed upon – success of product introduction. You could specify, for example, that the product should be among the top three products within the specific market segment in its third year of introduction.

Competitiveness in the private sector is an important success factor for any product. Licensees need to gain highest levels of competitiveness in private sector markets for being able to reach their commercial objectives. This will – in return – support a very competitive manufacturing cost structure, which ultimately provides the public sector with lowest possible cost. It is therefore adequate to also express public sector goals by measuring private market targets.

Another way to set milestones for performance in the public sector would be to set sales volumes in the private and public sector in relation to each other. A powerful milestone definition is to specify, for example, that public sector sales reach 40% (or any other agreed upon ratio) of the sales volume for the private market within three years after product launch.

With respect to public sector availability, it is mandatory to specify expected launch dates for the product. For example, the license agreement could stipulate that the product be made available in the public sector not later than two years after signing the agreement. In case a product requires initial sales in the private market for any reason, an adequate requirement for public sector introduction could be “...not later than *X* years after private sector launch.” For multi-country territories, individual requirements for each country would need to be established and defined.

Remedies for unmet milestones need to be part of the license agreement. One effective remedy is to significantly increase royalties on sales in the private market when a milestone has not been reached.

3.4 Exclusivity

Exclusivity is one of the first things that companies ask for. It is important to link such requests with specific milestones. Such milestones can be:

- The volume of sales reached in (a) market(s) after a certain time period from launch or signing the agreement.
- The level of market share reached against competition.
- The level of market share established in a new market segment, measured against the total product potential.
- The level of coverage of different regions in a large market or across different countries of a region.
- The latest date of product launch into a market that will secure product/technology exclusivity for the company in general, for a selected territory, etc.

Equally important to setting specific milestones is to specify penalties and fines for the licensee if these milestones haven't been reached. Examples are:

- Temporary increase of royalties on private sector sales until the milestone condition has been reached.
- Loss of exclusivity for the product or technology and conversion to a non-exclusive license in general or for a specific territory.
- Loss of exclusivity and territory to a competitor.
- Payment of a fine in a predefined amount for the failure to introduce a product into a country under exclusivity for the licensee.

It is good practice to evaluate the request for exclusivity against the level of public sector benefits that a potential licensee could deliver. Again, it is unreasonable to expect that a private sector company will concentrate major resources on serving the public sector as long as there are no specific obligations in a license agreement or adequate milestones have not been defined. Since the request for exclusivity is made to protect the commercial potential of a market place, the public sector partner has the right in a *quid pro quo* to ensure the protection of public sector needs. It is especially important for the public sector partner to understand, and eventually to regulate in the license agreement, what kind of resources – qualitatively and quantitatively – the private sector company will make available and mobilize to work in the public sector segment of the exclusive territory.

3.5 Pricing for the Public Sector

A key issue for the public sector in developing countries is the affordability of products that are brought into the market. Prices must ensure the widest possible availability. Price calculations are done differently in the pharmaceutical industry than in the public sector. Pharmaceutical companies commonly use a retrograde calculation scheme. They base product prices on the perceived purchasing power of the target segment in a market. Manufacturing costs are not a major factor for the price calculation. Overhead and marketing costs are usually higher than production costs and need to be well offset by product pricing. Adequate product positioning into affluent markets to a large extent determines achievable margins and operating profitability. The public sector, in contrast, mostly uses the cost-plus model for price determination. Manufacturing and organizational infrastructure contribute significantly to costs. Sales and marketing costs are kept at the lowest possible levels so as not to burden the product price. A reasonable but small rate of operating profit is added on top of these costs to determine the product price. With the purchasing power of the public sector under severe limitations, a price determination along the lines of a cost-plus model is the method of choice.

An effective license agreement needs to employ a detailed cost calculation model. The aim of this cost calculation model is to understand all directly and indirectly attributed product costs that contribute to final cost. By applying this tool and marking up the ex-factory product price with a mutually accepted profit margin for sales into the public sector, a reasonable platform for the determination of the lowest possible public sector price can be achieved. For indirect costs it is necessary to determine if the cost burden on the product is fairly allocated. Private sector pricing of the product is entirely up to the discretion of the manufacturer and not a public sector concern.

It is good practice to mandate the regular submission of manufacturing cost reports and product cost calculation details on an annual basis. Furthermore, it is important for the Licensor to reserve the rights to have these cost reports audited by independent auditors.

Should a manufacturer be unable to match expected price levels for the public sector when the company begins manufacturing and is still at the beginning of the learning curve, it is necessary to

set a definite time line for when expected price levels must be reached. Adequate penalties have to be in place for this case. It is important to recognize that a license agreement can not be a tool to force a manufacturer to produce a product below cost, however, the detailed agreement on the manufacturing cost calculation model and the overall pricing structure for the product will eliminate related concerns.

The licensor should define which institutions are the public sector organizations that can obtain the product at the preferred price. For pharmaceutical products, it should be clearly defined if these public sector organizations are only ministries of health, government purchase organizations, public sector hospitals, and similar institutions, or if non-government agencies with charitable functions, social marketing organizations in a country, international organizations with a humanitarian mission, and other institutions are also potential beneficiaries. The license should define how these agencies and organizations will be informed about the availability of a preferred public sector price for the product.

3.6 Regulatory Work and Time to Market

Pharmaceuticals are subject to drug regulatory approval by health authorities. The time needed for the regulatory approval process prolongs the period for a product to reach a market. It is a good practice to stipulate in the license agreement when the licensee must bring the product forward to registration, and it is best to specify within what time period after signing the license agreement the licensee has to forward a complete registration filing to the relevant authorities. For a multi-country territory it is vital to specify the sequence of registration filings in the various countries and the maximum time allowed between individual filings.

It is also advantageous to specify how much time may pass after a registration approval has been obtained until the product is actually launched into the public sector. This prevents the unusual, but realistic scenario of a licensee “sitting” on its rights and not utilizing them for the benefit of the public sector.

4. Conclusions

4.1 Setting Tough Milestones for a Tough Industry

Finally, some thoughts about milestones for the cautious few who feel uncomfortable with the idea of setting tough milestones in a tough industry.

One of the underlying assumptions for everything that is outlined above is that milestones are not cast in stone. Milestones should and need to remain adjustable throughout the lifetime of a license agreement according to project development, changes in the market environment, and other factors that can't be anticipated completely. When it comes to the detailed specifications of individual milestones, it does not really matter if you are choosing an absolute or a relative goal, and which definitions to finally select. What matters is to get the commitment of a private sector company to realize public sector targets. It is important to have a working set of adequate milestones in place, to define review periods for performance assessment by your contract partner, and to be ready to be open to and to accept milestone revisions when new, solid evidence requires a change of rules to keep the product and public sector goals alive.

Such result oriented milestones require:

- Very intensive preparations
- Detailed knowledge of processes related to the development and marketing of the product
- Detailed knowledge of markets
- Realistic anticipation and forecasting of product potential
- The persistence for quantitative forecasting and for establishing a master plan for the entire product roll-out
- A mission-driven mindset to establish the optimum public sector goals and to prevent the public sector from losing out to commercial thinking

In a process oriented sense, milestones represent and define the Standard Operating Procedures (SOPs) of organizations that have voluntarily subjected themselves to certification procedures, such as ISO. Why shouldn't the public sector also define such SOPs for important targets of a license agreement? It is crucial to recognize that public-private partnerships are NOT the magic solution for tasks that have not been well enough specified! In this sense, public-private partnerships (PPPs)

should not represent a poor substitute in absence of specific targets for public sector benefits.

4.2 Achievements of the Public-Private Partnership Model: The Work of the Concept Foundation to Close the Medicines Access Gap Specific to Developing Countries

The role of Public-Private-Partnerships (PPPs) as an innovative approach to the discovery, development and distribution of health products, drugs and vaccines for developing countries has been emphasized repeatedly in various publications, and around 86 PPPs (see www.ippph.org for a complete list) have been established worldwide in the meantime. However, PPPs' accomplishments as indicators for the PPP model to succeed in its goal are rarely publicized, partly because most of these entities are relatively young. Half of these partnerships have been established in the past few years since 1999 (www.ippph.org). This is a very short period of time in a pharmaceutical R&D or health care environment where normally times to market are ranging from not less than 10 to around 12-15 years on average.

The Concept Foundation (www.ConceptFoundation.org) was established in 1989 through an initiative funded by WHO's Special Programme of Research, Development and Research Training in Human Reproduction (WHO/HRP), with the support from PATH/PIACT and additional funding by the World Bank and the Rockefeller Foundation. The mission is to "Provide access to top quality reproductive-health products for developing countries at lowest possible prices and realize maximum public sector benefits through the management of intellectual property and technology transfer for contraceptives and pharmaceuticals that otherwise would not be available to the public sector with the intended quality and prices". Concept Foundation has accumulated extensive experience with project management of health technologies development and with technology transfer to roll-out new technologies in the developing world.

The R&D process for product development of new drugs, vaccines and also diagnostics in the diseases of poverty is a crucial step towards ultimately eradicating the disease burden in the poorest regions of the world. Many PPPs concentrate their efforts on the product development approach, and the larg-

est product development PPPs have successfully raised (in combined figures) more than half a billion US dollars in recent years to acquire the R&D funds needed to fuel their development work. However, product delivery is an equally important, if not even a more decisive, factor of access to medicines, and most product development PPPs are not active in delivery of their products into local health infrastructure. There are no significant experiences reported with the downstream issues involved in bringing products into markets there where they are most needed.

Future concerns for product development PPPs to solve will be how to handle and finance downstream issues for introduction and launching new products in diseases of poverty to close the medicines access gap for public health services when public health factors, such as:

- adequate health infrastructures,
- disease surveillance,
- compliance monitoring,
- education and training of health workers and medical staff,
- improving health care facilities,

and similar issues come into play, besides further important soft factors such as

- physical distribution networks,
- satisfactory supply volumes,
- adequate volume forecasting,
- minimizing product waste at the point of treatment,

and others, to name but a few of the most important issues to deal with.

As we know well from the experiences in pharmaceutical industry, a significant and decisive part of the cost structure for new medicines is related to bringing a new product to markets through effective and successful programs of marketing and distribution. While nobody would expect the need to create market demand (= invest marketing dollars) for new products to fight diseases of poverty, the inability of the poorest regions high in demand for effective medicines to pay for new products and the supply, distribution, as well as surveillance problems to reach all who need treatment, will demand huge additional investments and other type of public-private partnerships at work on the downstream issues before all goals are being reached.

These efforts must include reaching lowest possible manufacturing costs for the ability to forward preferential pricing to public health services and closing the medicines access gap in the developing world, establishing sustainable manufacturing with a continuous system for quality monitoring and creating a business model, financially attractive to private pharmaceutical companies, to overcome the disincentives from poor expected return by operating in public sector markets. The achievements of the PPP business model exercised by Concept Foundation to realize these goals, dealing with the downstream issues around product delivery, demonstrate broad success in the principal goal to close the medicines access gap for developing countries.

ANNEX 3

Agenda

DAY ONE: MONDAY, NOVEMBER 29, 2004

- 8:30 am–9:00 am *Coffee*
- 9:00 am–9:30 am **Welcome, Purpose, and Meeting Format** – *Cathy Garner & Roy Widdus*
- 9:30 am–10:00 am **A Framework for Dealmaking and IP Management** – *Tony Taubman*
- 10:00 am–10:30 am **Securing development of candidate products**
Case Illustrations (10 min. each):
- Medicines for Malaria Venture: Synthetic peroxide antimalarials
 - International Partnerships for Microbicides: TMC 120 agreement with Tibotec/J&J
 - Global Alliance for TB Drug Development: PA 824 from Chiron & other illustrations
- 10:30 am–11 am *Coffee*
- 11:00 am–12:30 pm Working Groups: **Options and conditions for ensuring development**
- 12:30 pm–1:30 pm *Lunch*
- 1:30 pm–2:30 pm **Plenary:** Working Groups report back (20 min. each), questions
- 2:30 pm–5:30 pm **General discussion on dealmaking issues** (*Coffee around 3.30 pm*)
- 7:00 pm–9:30 pm *Dinner at nearby restaurants*

DAY TWO: TUESDAY, NOVEMBER 30, 2004

- 8:30 am–9:00 am *Coffee*
- 9:00 am–9:15 am **Access to Medicines: What can product development partnerships control?**
– *Roy Widdus*
- 9:15 am–10:00 am **Securing product supply/'access' conditions**
Case Illustrations (15 min. each):
- International Aids Vaccine Initiative
 - Other examples, incl. Milestones in Licensing Deals – Concept Foundation.
- 10:00 am–10:15 am *Coffee*
- 10:15 am–12:00 noon Working Groups: **Options and conditions for ensuring product supply/'access' conditions**
- 12:00 noon–1:00 pm *Lunch*
- 1:00 pm–2:45 pm **Plenary:** Working Groups report back (20 min. each), questions, and general discussion
- 2:45 pm–3:15 pm *Coffee*
- 3:15 pm–4:00 pm Discussions: **Ways of Measuring Success**
- Defining a 'win-win' deal
 - What else makes collaborations work?
 - Can we monitor deals and identify predictors of success or 'best practices'?
- 4:00 pm–4:30 pm **Useful Next Steps**

4.30 PM CLOSE OF WORKSHOP

List of Participants & Working Group Assignments

1. **Labeeb M. Abboud**, General Counsel, International AIDS Vaccine Initiative (IAVI), 110 William Street, 27th Floor, New York, NY 10038, USA
Tel: 1 212 763 4292; Fax: 1 212 847 1112; E-mail: labboud@iavi.org
2. **Usha R. Balakrishnan**, Director, Office of Corporate Partnerships, University of Iowa, 417 Gilmore Hall, Iowa City, Iowa 52242, USA
Tel: 319-335-3271; Fax: 319-353-2028; E-mail: usha-balakrishnan@uiowa.edu
3. **Chekhesa Clingman**, Technology Transfer Fellow, National Institutes of Health, Office of Technology Transfer, 6011 Executive Blvd., Suite 325, USA
Tel: 1 301 435 5018, Fax: 1 301 402 0220; E-mail: clingmac@mail.nih.gov
4. **Daniel T. Eksteen**, Business Manager, SAAVI, Medical Research Council, Francie Van Zijl Drive, Parowvallei, Cape Town, 7505 Tygerberg, South Africa
Tel: 27 21 938 0551; Fax: 27 21 938 0823; E-mail: daniel.eksteen@mrc.ac.za
5. **John Fraser**, Director of Technology Transfer, Office of Research, Florida State University, 100 Slinger Bldg., MC 2763, Tallahassee, FL 32306-2763 USA
Tel: 1 850 644 8637; Fax: 1 850 644 3675; E-mail: jfraser@research.fsu.edu
6. **Cathy Garner**, Chief Executive Officer, The Center for Management of Intellectual Property in Health R&D (MIHR), Oxford Centre for Innovation, Mill Street, Oxford OX2 0JX, United Kingdom
Tel: 44 186 581 2041; Fax: 44 186 572 6965; E-mail: cathy.garner@mihr.org
7. **Mike Goldrich**, Executive Vice President and COO, The International AIDS Vaccine Initiative (IAVI), 110 Williams Street, 27th Floor, New York, NY 10038 USA
Tel: 1 212-847-1108 Direct, 1212-847-1109 Executive Assistant, 1 212-847-1111 Switchboard
Fax: 1 212-847-1112; E-Mail: MGoldrich@iavi.org
8. **Michael Gollin**, Partner, Venable LLP, 575 7th Street, N.W. U Washington, DC 20004-1601 USA
Tel: 1 202 344 4000; Fax: 1 202 344; E-mail: magollin@venable.com
9. **Doug Holtzman**, Senior Program Officer, Infectious Diseases, Global Health Program, Bill and Melinda Gates Foundation, PO Box 23350, Seattle, WA 98102, USA
Tel: 1 206 709 3601; Fax: 1 206 709 3170; E-mail: douglasH@gatesfoundation.org
10. **Erik H. Iverson**, Associate General Counsel, Bill & Melinda Gates Foundation, PO Box 23350, Seattle, WA 98102, USA
Tel: 1 206 709 3669; E-mail: eriki@gatesfoundation.org
11. **Rita Khanna**, Legal Counsel, Aeras Global TB Vaccine Foundation, 7500 Old Georgetown Road, Suite 800, Bethesda, MD 20814, USA
Tel: 1 301 547 2900; Fax: 1 301 547 2922; E-mail: rkhanna@aeras.org.
12. **Ebi Kimanani**, Principal Program Developer, International Biomedical Research Institute, 25 Circle Beaconsfield, Quebec, H9W 5B6, Canada
Tel: 1 514 697 5902; Fax: 1 514 697 6597; E-mail: ebik@ibrinst.org or ebik@ebitendo.com

13. **Orin Levine**, CEO, GAVI's Pneumococcal ADIP, Johns Hopkins University Bloomberg School of Public Health, 615 N. Wolfe Street, Baltimore, MD 21205, USA
Tel: 1 443 287 0835; Fax: 1 410 614 1419; E-mail: olevine@jhsp.edu
14. **Dean Mason**, President and CEO, Sabin Vaccine Institute, 161 Cherry Street, New Canaan CT 06840-4818 USA,
Tel: 1 203 972-7907; Fax: 1 203 966-4763; E-mail: dean.mason@sabin.org
15. **Nigel J. McWilliam**, Director Business Development, CONRAD, 1611 North Kent Street, Suite 806, Arlington, VA 22209 USA
Tel: 1 703-276-4033; E-mail: nmcwilliam@conrad.org
16. **Benoît Merkt**, Attorney at Law, Lenz & Staehelin, 25 Grand Rue, 1211 Geneva 11, Switzerland
Tel: 41 22 318 70 00; Fax: 41 22 318 70 01; E-mail: benoit.merkt@lenzstaehelin.com
17. **Jon F. Merz**, Assistant Professor, Department of Medical Ethics, University of Pennsylvania School of Medicine, 3401 Market Street, Ste 320, Philadelphia, PA 19104-3308 USA
Tel: 1 215-573-8107; Fax: 1 215-573-3036; E-mail: merz@mail.med.upenn.edu
18. **Paul Model**, Attorney, Consultant/International Partnership for Microbicides, 1010 Wayne Avenue, Suite 1450, Silver Spring, MD 20910, USA, Mailing Address: Paul Model Esq., 477 Madison Avenue, 21st Floor, New York, NY 10022, USA
Tel: 1 212 751 8438; Fax: 1 212 888 7306; E-mail: paulmodel@modelesq.com
19. **Angeline Nanni**, Director of Vaccine Finance and Supply, GAVI's Pneumococcal ADIP, Johns Hopkins University Bloomberg School of Public Health, 615 N. Wolfe Street, Baltimore, MD 21205, USA
Tel: 1 443 287 0835; Fax: 1 410 614 1419; E-mail: ananni@jhsp.edu
20. **Jeremy Nuttall**, Director of Preclinical Development, International Partnership for Microbicides, 1010 Wayne Avenue, Suite 1450, Silver Spring, MD 20910, USA
Tel: 1 610 747 0682; Fax: 1 301 608 2241; E-mail: jnuttall@ipm-microbicides.org
21. **Uri Reichman**, Branch Chief, Infectious Disease and Medical Engineering Branch, NIH Office of Technology Transfer, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 USA
Tel. 1 301 435 4616; Fax: 301 402 0220; E-mail: UR7a@nih.gov
22. **Patricia Atkinson Roberts**, Senior Commercialization Officer, Program for Appropriate Technology in Health (PATH), 1455 NW Leary Way, Seattle, WA 98103, USA
Tel: 1 206 788 2345; Fax: 1 206 285 6619; E-mail: proberts@malariavaccine.org
23. **Theodore J. Roumel**, Senior Advisor, PhRMA, 1100 Fifteenth St., NW, Washington DC 20005, USA
Tel: 1 202 835 3593; E-mail: troumel@phrma.org
24. **Jerald C. Sadoff**, President and Chief Executive Officer, Aeras Global TB Vaccine Foundation, 7500 Old Georgetown Road, Suite 800, Bethesda, MD 20814, USA
Tel: 1 301 547 2900; Fax: 1 301 547 2901; E-mail: jsadoff@aeras.org
25. **Luis Salicrup**, Senior Advisor for International Technology Transfer, Office of Technology Transfer, National Institutes of Health (NIH), 6011 Executive Boulevard Suite 325, Rockville Maryland 20852-3804, USA
Tel: 1 301 435-5009; Fax 1 301 402-0220; E-mail: salicrul@mail.nih.gov
26. **Joshua Sarnoff**, Assistant Director, Glushko-Samuels IP Law Clinic, Washington College of Law, American University, 4801 Massachusetts Avenue, NW, Washington, DC 20016, USA
Tel: 1 202-274-4165, Fax: 1 202-274-0659, E-mail: jsarnoff@wcl.american.edu
27. **Gerald J. Siuta**, Consultant, Business Development, Global Alliance for TB Drug Development, 80 Broad Street, 31st Floor, New York, NY 10004, USA
Tel: 212-227-7540 (x204), Fax: 212-227-7541, E-mail: gerald.siuta@tballiance.org

28. **Peter Soukas**, Technology Licensing Specialist, Public Health Service, Office of Technology Transfer, National Institutes of Health (NIH), 6011 Executive Boulevard Suite 325, Rockville, Maryland 20852-3804, USA
Tel: 1 301 435 4646; Fax: 1 301 402 0220, E-mail: soukasp@od.nih.gov
29. **Kari Stoever**, Program Manager, Human Hookworm Vaccine, Albert B. Sabin Vaccine Institute, 161 Cherry Street, New Canaan CT 06840-4818, USA
Tel: 1 203 972-7907; Fax: 1 203 966-4763; E-mail: kari.stoever@sabin.org
30. **Antony Taubman**, Head, Traditional Knowledge (Global Intellectual Property Issues Division), World Intellectual Property Organization (WIPO), Avenue Giuseppe Motta, 52, P.O. Box 55, 1211 Geneva 20, Switzerland
Tel: 41 22 338 8429; Fax: 41 22 338 8120, E-mail: anthony.taubman@wipo.int
31. **Alastair West**, Finance Officer, World Bank, HDNHE, 1818 H St. NW, Washington DC, 20433, USA
Tel: 1 202 473 9256, Fax: 1 202 522 3234, E-mail: awest1@worldbank.org
32. **Roy Widdus**, Project Manager, Initiative on Public-Private Partnerships for Health, Global Forum for Health Research, International Center Cointrin (ICC), Block G, 3rd Floor, 20 Route de Pré-Bois, P.O. Box 1826, 1215 Geneva, Switzerland
Tel: 41 22 799 4088/4086; Fax: 41 22 799 4089; E-mail: roy.widdus@ippph.org
33. **Richard Wilder**, Attorney at Law, Sidley, Austin, Brown and Wood, 1501 K Street, N.W., Washington, D.C. 20005, USA
Tel: +1 202 736 8017; E-mail: rwilder@sidley.com
34. **Holly Wong**, Senior Director, Public Policy, International AIDS Vaccine Initiative, 110 William Street, 27th Floor, New York, NY 10038, USA
Tel: 1 212 763 5461; E-mail: hwong@iavi.org
35. **Katherine Woo**, Director, Scientific Affairs, Institute of OneWorldHealth, 580 California Street, Suite 900, San Francisco, CA 94104, USA
Tel: 1 415 421 4700; Fax: 1 415 421 4747; E-mail: kwoo@oneworldhealth.org

Working group assignments

Group A

1. Labeeb Abboud
2. Chekhesa Clingman
3. Daniel T. Eksteen
4. Cathy Garner
5. Michael Gollin
6. Carol Hooks
7. Rita Khanna
8. Ebi Kimanani
9. Dean Mason
10. Benoît Merkt
11. Paul Model
12. Jeremy Nuttall
13. Uri Reichman
14. Luis Salicrup
15. Gerald J. Siuta
16. Kari Stoever
17. Alastair West
18. Richard Wilder
19. Katherine Woo

Group B

1. Usha R. Balakrishnan
2. Candace Eastman or Wendy Taylor
3. John Fraser
4. Mike Goldrich
5. Doug Holtzman
6. Erik H. Iverson
7. John Kilama
8. Orin Levine
9. Nigel J. McWilliam
10. Jon F. Merz
11. Angeline Nanni
12. Linda Nyari
13. Jerald C. Sadoff
14. Joshua Sarnoff
15. Peter Soukas
16. Antony Taubman
17. Roy Widdus
18. Holly Wong

The Initiative on Public-Private Partnerships for Health (IPPPH) was created in 2000 to increase the effectiveness of public-private collaboration, particularly by helping those seeking to develop and improve access to health products to fight neglected diseases and other health problems in developing countries.

IPPPH operated until December 2004 as an initiative of the **Global Forum for Health Research**, an independent international foundation helping to correct the 10/90 gap in health research, under which selected activities on public-private partnerships continue. IPPPH received sponsorship and support from the Bill & Melinda Gates Foundation, the Rockefeller Foundation, the World Bank, and the Global Forum for Health Research.

Centre for Management of Intellectual Property in Health Research and Development (MIHR) was established in 2003 to advance new thinking and bring about innovative practices in the ethical stewardship of intellectual property which make a difference in social as well as economic respect.

MIHR provides advice on intellectual property policy development, training in developing countries, including education of scientists and officials in public sector health research and development, research into new practices in intellectual property management and publication of research results, information on resources to improve access to health products for people in developing countries, and coordination of technical assistance, especially for product development organisations. MIHR is an independent not-for-profit venture based in Oxford, UK, funded primarily by the Rockefeller Foundation.

Global Forum for Health Research

1-5 route des Morillons, PO Box 2100

1211 Geneva 2, Switzerland

Tel: +41 22 791 4260

Fax: +41 22 791 4394

Email: info@globalforumhealth.org

Website: www.globalforumhealth.org

**Centre for Management of Intellectual Property
in Health Research and Development (MIHR)**

Oxford Centre for Innovation, Mill Street

Oxford OX2 0JX, United Kingdom

Tel: +44 (0)1865 812041

Fax: +44 (0)1865 726965

Email: admin@mih.org

Website: www.mih.org