

Intellectual property rights, innovation and public health: prospective WIPO inputs

Preliminary
briefing to WHO
Commission

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Two key opportunities...

⌚ **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

WIPO as a UN specialized agency...

- ⌚ ... responsible “for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries in order to accelerate economic, social and cultural development, subject to the competence and responsibilities of the United Nations and its organs” ... including the WHO

... a twin responsibility:

1. promotion of innovation
 2. practical availability of the fruits of innovation
- ⌚ challenge for IP law and policy is to find the optimal linkage between these two goals, seen in two ways:
- a zero-sum trade off between public and private interests; damage control; IP as a necessary evil
 - a harnessing of public and private interests, an encouragement to deploy resources to society's needs:
 - ⌚ incentives to take risks, support research and invest in the development and dissemination of a finished product;
 - ⌚ remedies and other interventions when this fails

garnering and focussing 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

the role of IP in better applying resources to unmet public health needs

international



Level of initiative



individual project



Stages on drug development pipeline

the role of IP in better applying resources to unmet public health needs

The role of IP at distinct but inter-related levels:

- ⌚ Practical IP management and building capacity for effective negotiations with technology partners on IP issues
 - MIHR handbook, World Bank procurement guide
- ⌚ policies and strategies for IP management at the institutional or project level:
 - use of IP in technology partnerships to ensure guaranteed levels of access to new technologies for neglected diseases [e.g. various public private partnership agreements for public health outcomes]
- ⌚ National policy settings for public-funded or public-interest research
 - promoting active take-up and practical application of public funded research, with guarantees of public benefit [Bayh-Dole being one model]

the role of IP in better applying resources to unmet public health needs

Considered at distinct but inter-related levels:

- ⌚ Specific, targetted legislative initiatives to create incentives to meet neglected health needs
 - e.g. orphan drugs programs providing a menu of push and pull initiatives for drug development in the absence of sufficient incentives
- ⌚ National innovation policy and legal settings, including IP laws and their interaction with other aspects of the regulatory system
 - e.g. research exceptions, use of clinical test data, interplay between the patent system and drug approval
- ⌚ International cooperation, specific initiatives, standard-setting and legal framework
 - [e.g. Global Forum on Health Research, international treaties on IP]

Managing IP for public health outcomes throughout the drug development pipeline



Consider distinctive aspects of R&D in the public health domain, with impact on how IP issues are managed:

- strong public interest and public-funded/philanthropic input
- intensive and lengthy regulatory process; need for risk management
- need to garner resources both for initial research and for subsequent development: distinct incentives may be required

managing IP & setting incentives for public health outcomes throughout the drug development pipeline



Project planning for health outcomes:

- setting goals, strategies, and policies: determining questions of ownership, access and control over research outcomes
- surveys of existing technology as research inputs and patterns of ownership to identify potential partners and possible barriers
- assessment of freedom to operate and technology partnering and pooling options

managing IP & setting incentives for public health outcomes throughout the drug development pipeline



Initiating research on unmet public health needs

- Incentives for investment in research and other contributions
- Negotiation of terms and conditions research and development, including using IP in negotiating guarantees of development and access to finished product; negotiation or implementation of public interest safeguards ensuring adequate access to research outcomes
- Establishing and implementing publication and IP management policies for researchers

managing IP & setting incentives for public health outcomes throughout the drug development pipeline



Beyond the initial research: proof of concept and scaling up

- Incentives for pushing new candidates into the development phase
- IP arrangements in negotiations on financing and conducting clinical trials, and in attracting further investment, philanthropic support or allocation of public resources.
- Assessment of IP implications of moving beyond a pure research phase into preliminary stages of full drug development

managing IP & setting incentives for public health outcomes throughout the drug development pipeline



Clinical trials and regulatory approval:

Arrangements for generating, protecting and accessing clinical trials, incentives for investing in this process, and the legal settings that govern this; mechanisms for facilitating or reducing the cost of regulatory approval, such as push and pull incentives in 'orphan drugs' schemes.

Questions such as mutual recognition of regulatory approvals, sharing of data, negotiating access to clinical trial data

managing IP & setting incentives for public health outcomes throughout the drug development pipeline



Manufacture and distribution:

- Access to platform drug delivery and platform technologies,
- IP management strategies for effective global outcomes
 - differential ownership, control or licensing of IP rights in rich and poor countries, role of IP in tiered pricing, 'march in' rights and other forms of guarantees of access (including public or philanthropic funded research)

managing IP & setting incentives for public health outcomes throughout the drug development pipeline



Distribution and marketing phase

- Monitoring and enforcing access guarantees, IP implications
- Managing IP relevant to improvements and new indications, regulatory approval; implementing access conditions
- Regulating use of IP in the market place

managing IP & setting incentives for public health outcomes throughout the drug development pipeline



Ideally: each stage guided by an overarching conception of workable, equitable and effective arrangements for dissemination of the final product; leveraging the IP system to build in assurances of access (legal, regulatory, practical, commercial as needed)...

Some specific inputs:

Public sector IP policies

- ⌚ policies and practices to promote more effective deployment of public funds to create new medicines for neglected diseases, and to broaden the range of medical applications that are developed from basic research funded by public health programs
- ⌚ ownership and licensing of IP on public funded research, and access arrangements or guarantees built into research or funding contracts, whether as a funding policy or as a legislative requirement.

IP management for public health outcomes

- ⌚ Structures for public-private partnering and IP management strategies - combine public and philanthropic inputs with private sector drug development and regulatory management skills to create and disseminate new medicines for neglected diseases.
- ⌚ Practical dispensations of IP e.g. so access to wealthy markets offsets costs of drug development; guarantees new product immediately available developing countries at a public sector or social marketing prices.

Some specific inputs:

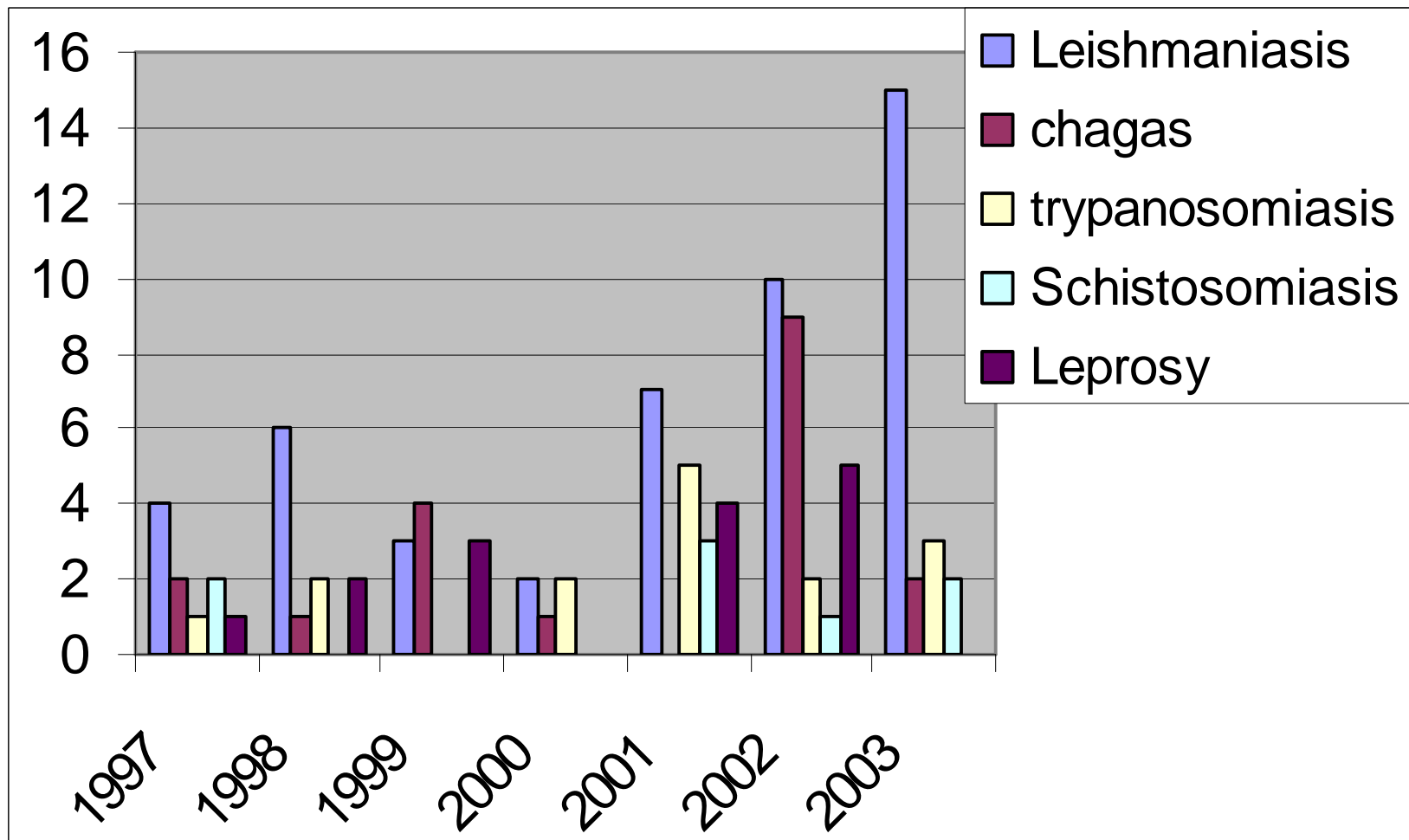
Practical lessons from orphan disease programs

- 🕒 practical experience and an array of policy mechanisms that could be drawn on in finding new or adapted forms of incentive structure for the public health needs of the poor: 'push' and 'pull' incentive structures, cross-subsidization, expedited approval, exclusivity
- 🕒 **Information on trends in research and development**
- 🕒 **Legal and practical IP issues confronting researchers**
 - legal and practical implications of patent pooling, patent exceptions applicable to medical research, and protocols/strategies for the use of 'research tools' and platform technologies, and the impact and extent of 'reach through' claims on products developed with research tools
- 🕒 **International dimension of enhanced incentive structures**
 - leveraging regulatory and market incentives in one area to promote beneficial outcomes elsewhere (e.g. "roaming" exclusivity, fast track or facilitated product approvals)

Seeds of hope?

- ⌚ Developing country researchers in medical fields figure disproportionately higher (10%) in published international patent applications in 2003, than in general (8%)
- ⌚ Health technologies prominent among the filings of leading developing country users of the international patent system (3 of top ten developing country users of the PCT)

International (PCT) applications published referring to neglected diseases/diseases of the poor



International (PCT) applications published referring to neglected diseases/diseases of the poor

