

**Human health and the IP system:
Innovation, access and public welfare**

Working draft: An overview of the issues

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Disclaimer: This paper is prepared as an informal working draft, as a potential background resource to assist in clarifying, categorizing and mapping current public health and IP issues. It does not express any formal position or offer any substantive assessment, and it is not envisaged that this paper or any possible future redraft would ever do so.

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The context of this paper: IP as an issue for global health policy

Crucial debates about public health issues – about how to secure resources for medical innovation, about the directions that health research takes, and about equitable access to the fruits of innovation – are increasingly paying close attention to the intellectual property (IP) system. This has precipitated a wideranging debate about the linkages between IP and innovation, equity and public health, a discussion touching on the theoretical policy role of the IP system and its actual practical impact, its costs and benefits as a set of policy instruments, its likely evolution, and potential avenues for its development and reform as a policy intervention.

Within the wide array of current debates over IP questions, arguably no set of issues assumes more fundamental significance than considering the extent to which the current operation of the IP system contributes to public health as an essential public good, and how the system can and should function better to promote public welfare in this crucial policy domain. But the debate can be complex and difficult, with much at stake – IP and public health issues arise at the uneasy intersection between science, economics, law, bioethics, and broader cultural and social questions.

The debate can touch on significant divergences in national systems, cultural values and economic conditions. Yet threats to public health are ultimately universally shared and the need for collective action is long recognized: as the drafters of the Constitution of the World Health Organization (WHO) observed, “[t]he achievement of any State in the promotion and protection of health is of value to all” and “[u]nequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger.”

With this background, effectively navigating the full array of issues and setting them in an overall policy context is a common challenge. This draft paper aims only to help clarify and classify current issues on IP and public health, without seeking to make assessments or take any position in these multiple areas of debate and policy analysis.

To some extent it may serve as a road map to the issues, but like a road map it does not predetermine the direction that is taken or the destination. There is, however, a special focus on patents, as the form of IP most frequently invoked in relation to public health.

This paper aims to serve this function by:

- Setting out general considerations on patents as an instrument of public policy relating to health (*Patents as an instrument of public policy*)
- Considering how current issues on IP and public health can be classified on various dimensions (*Mapping the policy landscape*)
- Surveying particular current issues on the international agenda (*Overview of current issues*)

I. Patents as an instrument of public policy: the health dimension

In principle, the overarching public policy role of the patent system is twofold:

- To promote innovation, through garnering and directing resources towards beneficial research and development that is a genuine and practically useful addition to technological knowledge
- To provide a transparent mechanism for the dissemination and accessible publication of this innovation, and the practical, equitable availability of the fruits of innovation

In short, **innovation** and **access**. Much of the extensive policy debate over the role of the patent system – since its inception in the pre-industrial age – boils down to how to find the optimal linkage between these two goals:

- At the level of principle, in terms of how various legitimate interests are accommodated in national laws and international treaties
- At the level of practice, measured in terms of actual behaviour and actual public welfare outcomes

Clarifying the health dimension

Getting the right linkage between these two goals is important for general public welfare, but it is vital for an effective practical contribution to public health outcomes, a policy goal of utmost importance. Much of the current debate about patents and public health boils down to specific concerns about how to attain these twin goals in a balanced way, at the level of principle and in practice; for instance:

- (i) Is the patent system effective in garnering private sector resources for needed health research?
 - providing incentives for risky investments, or raising barriers and imposing transaction costs?
- (ii) Is the patent system a suitable means of managing the science and technology yielded by major public sector investments in medical research?
 - promoting the transformation of upstream public sector innovation into practical products that reach the public who need them, or impeding access to research the public has funded?
- (iii) Is it helping to direct those resources to where they are needed, from an objective public health point of view?

- creating a rationale to address diverse disease burdens, or skewing research towards market opportunities?
- (iv) Is the patent system accurately recognizing genuinely valuable innovations?
- are patents over medical technologies mostly granted on legitimate inventions of potential value to society, or are patents also granted on relatively trivial developments and obvious extensions of known technology?
- (v) Even where the necessary innovations are made, does the patent system leverage access to those innovations?
- a necessary ingredient of equitable access to new medical technologies, or an unwelcome obstruction to equitable access?
- (vi) If the balance is less than ideal between private interest and public welfare in terms of effective and equitable health innovation, what interventions are needed?
- prior to patent grant, reforming patentability standards or tightening examination; after patent grant, closer regulation of competitive environment or direct interventions for public interest access; deploying public resources to support alternatives?

Policymakers naturally seek clear and precise answers to these pressing questions, as the basis for taking fundamental decisions about future directions in public health research, product development pipelines, and equitable access to medical technologies. But the answers may be complex and nuanced, and may well provoke more debate than they resolve. Typically, actual experience will range across a wide spectrum of possibilities, and examples can be found of both the success and failure of the patent system in attaining the goals set for it in the public health domain.

At the heart of the debate: how do private rights produce public goods?

The debate, at core, concerns how to promote the production of public goods – in this case, the public goods that consist of the sustainable, effective creation of useful new medical technologies, that can be ushered through an often extensive product development and regulatory approval process, to be accessible to the public as safe, effective and proven treatments that were not otherwise available to the public. The patent system has a long, sometimes controversial, history as a conscious policy intervention to promote the production of public goods. Some controversy may be expected, because of what can appear at first blush to be a counterintuitive or even paradoxical aspect of the patent system: it is a means of promoting the creation of public

goods by creating targeted legal exclusions from the public domain. Therefore private property rights are intended to serve as a means of promoting public welfare. Yet today's patent system is charged by its critics, especially in the public health domain, as inadequately accommodating the public interest dimension for the benefit of private interests. On the other hand, private interest is harnessed by the patent system as a conscious tool to promote overall welfare. The history of patent law has been dominated by a long debate about how optimally to balance between these sets of interests to ensure overall welfare outcomes.

The debate at core: principles and practice

The debate about public health and patents may be reduced to two, perhaps deceptively simple propositions:

- Is the patent system *in practice* living up to its principles *in theory*? If not, why not, and how can that be remedied?
- Or are there aspects of public health innovation and access, as policy issues, at odds with the principles of patent law and policy?

Past WIPO documents have discussed how at least some of the policy tensions may be managed through the ever more effective application in practice of the essential principles of patent law

The first step in dealing with managing policy tensions is to ensure these basic principles are optimally applied in practice. The criteria for patentability have been formulated precisely so the system is focused onto those inventions for which a patent right is most likely to serve the public interest: novelty safeguards the public interest against re-monopolizing public domain material; non-obviousness should ensure that patents are only granted in respect of truly inventive achievements; utility or industrial applicability underlines the need for patented technology to be of practical value. It is striking that many of the policy issues currently raised about the patent system do, directly or indirectly, invoke these core principles. For example, there are arguments that some gene related patents are either “mere discoveries” or are not truly inventive; and that some patents misappropriate traditional knowledge, and thus either lack novelty or are obvious. Accordingly, the most direct way of managing policy tensions is to hold the patent system to these core principles, and to increase the likelihood that each granted patent conforms to the public interest as defined in the patentability criteria.¹

¹ WIPO Patent Agenda: Options for Development of the International Patent System, WIPO document A/37/6 (August 19, 2002), at 28-34 (‘Managing Policy Tensions’).

What is distinctive about the life sciences?

Apart from certain categories of sui generis IP, at the level of fundamental principle, at least, IP systems tend to be technologically neutral, establishing broad principles that are then adapted and applied in practice as technological developments evolve. Yet it is a recurring theme in policy debate over patents and the life sciences that there may be some distinctive aspects of this area of technology that require special attention.

The *social and economic* factors that distinguish life sciences technologies include:

- The fundamental human interests at stake: health, food, the environment
- The concomitant high level of public funding and investment of other public resources into research, notably at the fundamental or discovery end of the R&D pipeline
- Ethical and policy issues about some technologies *as such* (e.g. stem cell technology)
- Ethical and policy issues about *patenting* some life sciences technology (e.g. genetically engineered mammals used in health research)
- Ethical and policy issues about how patent rights over life sciences technologies are exercised (e.g. humanitarian non-assertion undertakings or public private licensing structures)
- Economic and social impact of agricultural and medical sectors, and broader public sector role in these sectors
- Use made of genetic resources - human, agricultural, marine and terrestrial biodiversity – raising questions of ownership and control of resources, prior informed consent, benefit-sharing
- Social and economic development and North-South dimensions

The *technological and regulatory* factors that distinguish life sciences technologies include:

- The need for distinct regulatory mechanisms for certain life sciences technologies, such as pharmaceuticals and genetically modified organisms, to ensure safety, efficacy and biosafety
- The unique characteristics of gene technology – self-replicating, same platform spans different regulatory fields (e.g. human genes cloned through bacteria); a genetically engineered seed is a product (food), a means of reproducing the invention, and a means of disseminating the invention; may be difficult fully to disclose (e.g. new microorganisms or new plants) solely through written description

These factors have led to specific interventions for life sciences technology in the patent system to give effect to the same core patent principles, recalling that differential treatment of different technologies need not be discriminatory. Some of these symptoms within the patent system of perceived differences in life sciences technology include:

- Specific restrictions on some patentable subject matter such as methods of medical treatment exercised by some countries and regions
- The exercise of exceptions regarding morality and ordre public (not exclusive to life sciences, but significant reported cases in that domain)
- Budapest system for deposit of microorganisms for patent purposes
- Disclosure requirements for patents on inventions derived from genetic resources and traditional knowledge present in some national and regional laws (and raised in several international forums)
- The Doha compulsory licensing mechanism specifically for access to medicines
- ‘Bolar’ exceptions to patent rights, generally applied in relation to regulatory preparations for entry of generic medicines
- Implications of regulatory approval of medicines, including clinical trial data protection and linkages in some national systems between regulatory approval mechanisms and the patent system

II: Mapping the policy landscape

II.1 Mapping the issues: pre-grant and post-grant questions

The following discussion analyzes particular public health and IP issues within this wider policy context. To help get diffuse issues into context, the paper looks at the issues as they are arrayed along the innovation, product development and technology diffusion pipeline, while still taking a holistic view of the overarching public interest. In broadest terms, the issues can be divided between:

- A *pre-grant* cluster – the kind of issue that patent offices are concerned with – such as what inventions should be considered patentable, and how to interpret and apply core patentability criteria (novelty, inventiveness, utility) and exceptions to patentable subject matter (e.g. morality, ordre public exceptions); these principles have evolved as an expression of the public interest, with the intention of channeling resources toward beneficial innovations, raising the question of how patents as actually issued be aligned in practice ever closer to these principles?
- A *post-grant cluster* – the kind of issue that other regulatory authorities are concerned with, such as competition watchdogs, other government authorities or the courts – including such remedies and regulatory interventions as measures against abusive licensing practices or improper assertion of patent rights, government use authorizations and compulsory licensing orders.

To help illustrate the relationship between these two clusters, a current issue in public debate concerns ‘evergreening’: this term covers a range of alleged commercial practices and use of the patent system, essentially concerning attempts to maintain patent exclusivity over a pharmaceutical after the principal patent on a therapeutic compound has expired. This paper offers no substantive view on this or any other current debate. But it is worth noting that the analysis of such alleged practices splits into two general clusters, one essentially about the pre-grant situation and one essentially about the post-grant situation:

- The ‘pre-grant’ question of whether patent claims are approved on a new form, dose or delivery mode of a pharmaceutical that is considered obvious or lacking inventive step
- The ‘post-grant’ question of whether a granted patent on an improvement on a core technology is being used in the marketplace to restrain a competitor’s activities beyond the legal scope of the actual patent right - in other words to impede a third party from making legitimate use of the unimproved core technology

This example may illustrate that in addressing current IP and public health issues, it may be important to distinguish the strictly pre-grant or patentability issues from the post-grant or market regulation issues, recognizing nonetheless that there is a considerable degree of interplay between these two domains.

Pre-grant regulatory issues	Post-grant legal and regulatory issues
<p><i>Determining whether a patent should be granted:</i></p> <ul style="list-style-type: none"> • Assessing claimed invention against scope of patentable subject matter (e.g. morality exceptions) • Assessing novelty against the full prior art • Assessing non-obviousness • Establishing utility or industrial applicability • Determining, as needed, inventorship and entitlement to apply • Assessing adequacy of disclosure of the invention as claimed and appropriate scope of claims • Implementing additional disclosure requirements (genetic resources, TK) 	<p><i>Assuming patent as granted is valid (otherwise liable for challenge and revocation):</i></p> <ul style="list-style-type: none"> • Regulation of patented technologies from point of view of safety and efficacy • Relationship between regulatory approval and patent system • Assessment of impact on competition and pro-competition interventions • Legitimate scope of assertion of patent rights, and potential abuse • Reserve legal capacity for government use • Restrictions on patent enforcement (equitable conduct, available remedies – e.g. injunctions)

II.2 Mapping the issues: across the product development pipeline

One way of analysing the innovation process, and assessing the impact and potential role of the IP system, is to consider the questions that arise at each stage of research and developing leading to a new product. This enables a focus on the specific practical and policy issues, and highlights the immediate possibilities for improvement at each step of innovation. But it also provides for an overall perspective, clarifying the implications at each stage for the ultimate goal of improved public health outcomes.

For illustrative purposes only, to set this in the context of a hypothetical project for meeting a neglected disease need, the IP issues at each stage can be identified:

Innovation planning for health outcomes

- Setting IP policies and management strategies, including questions of ownership, access and control over research outcomes
- Surveys of existing technology as research inputs and patterns of ownership (according to patent holder, and territorial effect of patents in force), to identify potential partners and possible barriers
- Assessment of freedom to operate, status of existing technology, and technology partnering, access and pooling options

Initiating research on unmet public health needs

- Incentives for investment in research and other contributions (including financial and other resources, background technology, infrastructure, scientific and technology management expertise, risk exposure, and opportunity cost)
- Negotiation of terms and conditions covering research and development, including using IP in negotiating guarantees of development and access to finished product; and negotiation or implementation of public interest safeguards ensuring adequate access to research outcomes
- Establishing and implementing publication and IP management policies for researchers

Initial IP protection

- Following initial research outcomes, the decision at an institution or firm level whether or not to seek IP protection, in what jurisdictions and according to what overall development, commercialization and diffusion strategy
- Decisions at the national and regional levels concerning the patentability of the research outcome according to patent grant criteria

Beyond the initial research: proof of concept and scaling up

- IP arrangements in negotiations on financing and conducting clinical trials, and in attracting further investment, philanthropic support or allocation of public resources
- Other incentives to push candidates into the applied development phase
- Assessment of IP implications of moving beyond a pure research phase into preliminary stages of full drug development

Clinical trials and regulatory approval

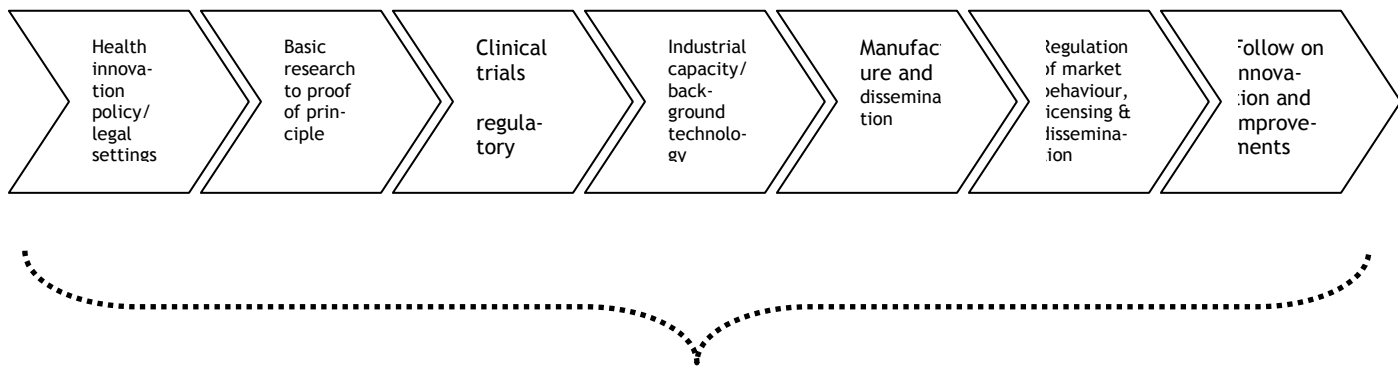
- Arrangements for generating, protecting and accessing clinical trial data, incentives for investing in this process, and the legal and policy settings that govern this; mechanisms for facilitating or reducing the cost of regulatory approval, such as push and pull incentives in ‘orphan drugs’ schemes
- IP aspects of questions such as mutual recognition of regulatory approvals, sharing of data, negotiating access to clinical trial data

Manufacture and distribution

- Access to necessary manufacturing, excipient and adjuvant, drug delivery and platform technologies
- IP management strategies for effective global outcomes (including differential ownership, different approaches to 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 to public or philanthropic funded research, etc.)

Distribution and marketing phase

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



Ideally, for such a hypothetical project, each stage of the innovation might be 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), while providing the level of innovation that is needed to meet the twin goals of innovation of the technology itself, and application of resources in the extensive development process through to a finished product.

II.3 Mapping the issues: policy and practice in perspective

In analysing the role and impact of the IP system, it can be helpful to clarify the policy and practical dimensions: distinguishing, as needed, the broader normative, policy and standard setting questions on the one hand, and, on the other hand, practical questions of how IP is practically deployed in research and development and program management to achieve new public health outcomes and to promote effective access to those outcomes.

Promoting useful innovation and the practical availability for the public benefit of the fruits of innovation are the twin goals of the patent system. How, and to what extent, these goals are achieved, involves consideration of:

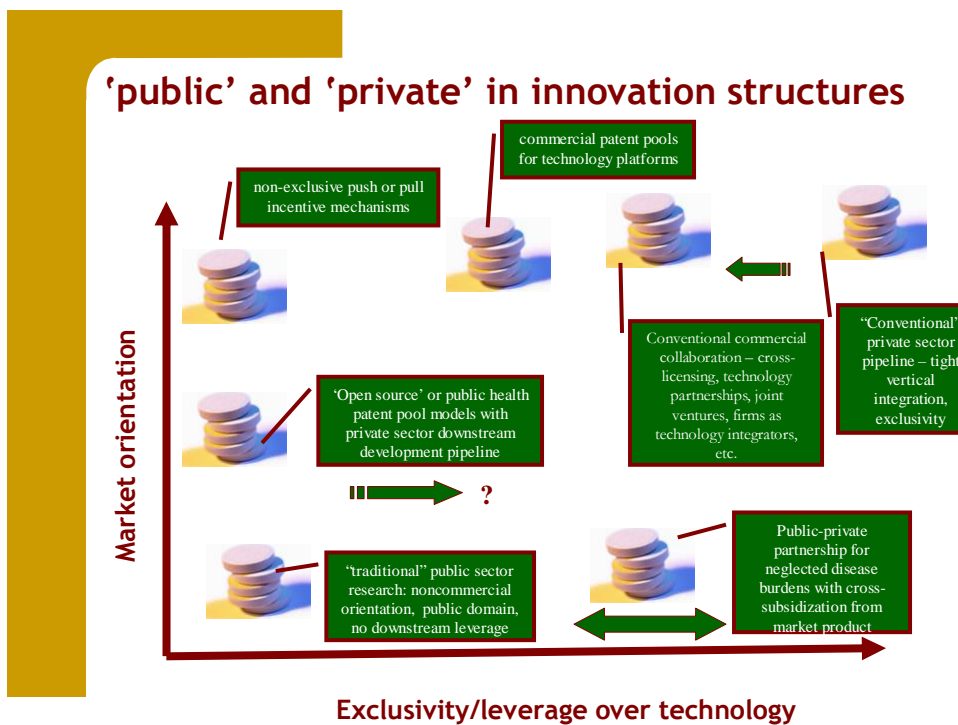
- Legislative and policy settings and the interaction between the IP system and the overall regulatory and policy environment
- and how effectively existing mechanisms are used – including the emerging understanding of the distinct requirements for IP management in the public interest by public research institutions, funding bodies and public health programs, so that IP is used to advance their public interest objectives

II.4 Mapping the issues: public and private in perspective

IP and public health issues are typically assessed across a public vs. private spectrum, with exclusive IP rights being seen as embodying private interest, and stress on the public interest in the public domain as one element of a balanced and effective IP system.

Private rights are also granted in the public interest, of course, this being the rationale of the IP system as a public policy tool. But also, in practice, the greater diversity of actual and proposed innovation structures in the life sciences domain may call for a broader approach to assessing and categorizing practical options.

For instance, public sector entities increasingly hold IP rights on key life sciences technologies, including crucial upstream technologies such as research tools. And private IP rights on life sciences technologies may be exercised in non-commercial ways, such as to leverage downstream applications and commercialization of technologies to provide for guarantees of access or tiered pricing in certain defined markets, such as in developing countries.



II.5 Mapping the issues: addressing the law and ethics dimensions

Both at the international and national levels, debate over IP and public health raises issues that span the distinction between law *as such* and ethics *as such*, while recognizing that there are important links and substantive overlaps between these two normative domains. The application of some patent law is directly affected by ethical assessments: such as the scope within many national patent laws for the exclusion of inventions the commercialization of which would be contrary to morality. In the field of health technologies, there have been claims that some forms of licensing or otherwise exercising patent rights on key technologies may be considered unethical even if strictly legal.

In the most general terms, it may be helpful to distinguish four sets of ethical questions:

- (i) Ethical aspects of a technology as such
e.g. the ethics of stem cell research
- (ii) Ethical dimension of the grant of IP rights over national authorities granting IP
e.g. morality issues weighed when a patent office grants a patent on a higher life form
- (iii) Ethical aspects of an individual seeking exclusive IP
e.g. ethical dimension considered when a publicly funded agency assesses whether to patent research
- (iv) Ethical aspects of the forms of exercising IP rights
e.g. the ethical considerations that may apply to licensing patents on key medical technologies

II.6 Mapping the issues: distinguishing levels of policy intervention

Patents are ultimately shaped, granted and exercised at the level of national law, and accordingly their impact on public health issues will ultimately be felt at the national level. Moreover, choices whether or not to seek a patent on a given technology, and how to exercise rights over a patented technology, are taken at an individual firm or institution level and the net effect of the patent system is ultimately a simple accumulation of all of those choices. International treaties clearly shape the environment in which national systems and then individual actors operate, but cannot be viewed in isolation when reviewing public health issues from a holistic point of view. Therefore it is essential to consider the patent system at these distinct but inter-related levels:

- Practical IP management and building capacity for effective negotiations with technology partners on IP issues – so that public health is promoted through specific licensing arrangements and other technology partnering deals
- At the level of institutions or specific projects and partnerships, the operational policies and strategies for IP management will determine the public health impact, such in the approach taken to selecting technology for patenting, the geographical scope of patents sought, and patent licensing policies
- National policy settings for public-funded or public interest research may determine how patents are used or licensed, or otherwise regulated
- Specific, targeted legislative initiatives aim to create incentives to meet neglected health needs, such as orphan disease program
- More general impact flows from the approach taken to national innovation policy

and legislative settings, including IP laws – what is protected and to what extent - and their interaction with other aspects of the regulatory system, such as the different choices for interplay between regulatory approval of medicines and patents on medicines

- International cooperation on policy issues, and specific international initiatives to address funding shortfalls and research and development gaps
- International norms and standard-setting through soft-law mechanisms, and the framework of multilateral and bilateral treaties

Effectively addressing IP and public health issues entails considering not merely each of these levels, but the interaction between them – for instance, the constraints on national policymaking created by international treaties, and the influence on actual patenting activity in medical research exerted by national funding policies and innovation strategies. Further, capacity-building, policy analysis and skills development may be necessary at each of these levels, ranging from essentially practical IP management within an institution, to the kind of level policy skills and awareness of policy options at the national and international levels that were called for in an earlier WIPO document: policy skills and awareness of policy options “are part of the general package of policy development and implementation, not an add on or afterthought.”²

² WIPO Patent Agenda: Options For Development of the International Patent System, WIPO document A/37/6 (August 19, 2002), at 28-34 (‘Managing Policy Tensions’).

III. ‘Reviewing current issues’

The following section provides a brief overview of some current issues, with suggesting the list is complete or establishes any priority, nor offering an assessment on the substance of the issues.

Cluster 1: Transparency and illuminating the landscape

The increasing availability of patent data and the dynamic shifts in actual patterns of use of the patent system in the public health area creates both the need and the opportunity for greatly enhanced information for health policymakers:

- What are the trends in overall use of the patent system in the public health domain?
- Who are the players – geographically, commercially, and institutionally?
- What are the needs of public health policymakers for distilled and accessible analysis of these trends?

Cluster 2: Harnessing resources for public health innovation

Tangible and intangible resources required for innovation for public health include know-how, research and product development capacity, clinical trial expertise, regulatory infrastructure, background IP, platform technologies and research tools, and the investment of public and private capital.

- How to generate necessary new resources?
- How better to apply, coordinate and focus existing resources?
- How to clarify and structure the mix of public and private resources that go into public health innovation, and the IP policy issues that ensue: much basic research is funded by the public, but few products are brought all the way to the public in finished form without some engagement of private sector players?

Cluster 3: Interaction of IP with regulation of medicines

The necessarily stringent regulation in the medical field for safety and efficacy has implications for the IP system in a range of ways, each of which has been the subject of extensive policy debate and diverse legislative initiatives, for instance:

- The creation of distinct forms of protection of clinical trial data
- ‘Bolar’ or regulatory approval exceptions to allow steps towards regulatory approval for generic producers during a patent term
- Patent term extensions implemented to compensate for effective loss of patent term due to regulatory approval processes
- The forms of ‘linkage’ present in some national laws between the patent system as such and the regulatory approval process

- New challenges for regulators, such as so-called ‘biosimilars’ or generic copies of biologic therapeutics which are more complex than small molecule pharmaceuticals, such as recombinant therapeutic proteins

Cluster 4: Management of public sector IP for public health

What are the implications for IP management of the sharp increase in patent portfolios held by public sector or philanthropic entities, and the growing number of focused, non-market mechanisms to address neglected health needs?

- Is there a distinct, emerging skill set for public interest and/or public sector IP management?
- Some suggest that 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”³
- How to capture lessons of growing practical experience in this domain, and to clarify and distil ‘best practice’ ideas?

Cluster 5: Innovation structures

What forms of innovation structures are in operation or are proposed for public health innovation?

- Vertical integration of the product development pipeline
- Cross licensing and other conventional technology partnerships
- Public private partnerships for neglected disease burdens
- ‘Open source’ and patent pooling arrangements
- Orphan disease and other distinctive incentive mechanisms
- Other non-IP mechanisms, including direct public and philanthropic funding initiatives

How is the changing technological, economic development, commercial, social and public health landscape affecting these innovation structures?

Cluster 6: Patent law and policy questions

Within the domain of patent law itself, numerous issues are the subject of debate:

- The application of core patentability criteria, and the boundaries of patentable subject matter, in the life sciences

³ Kettler & Towse, OHE, 2002

- The scope of patent claims, and the degree to which they ‘reach through’ to derivative products, such as products derived from patented research tools
- The application of exceptions and limitations, including government use authorisation, compulsory licensing, and research exceptions
- The interplay between patent law proper and the regulation of competition, such as questions relating to licensing practices
- Enforcement questions, such as the nature and impact of remedies for infringement of patent rights in different commercial and technological circumstances

WIPO and public health questions

WIPO, as a UN specialized agency, is 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.” This responsibility guides WIPO’s work on public policy issues, such as its technical input on IP related questions relevant to the public health issues. WIPO has no formal competence on public health questions: at the international level, public health matters are of course the core responsibility of the World Health Organization (WHO).

Yet the increasing salience of intellectual property (IP) questions in international policy debates on public health raises the need for greater dialogue and technical-level cooperation on IP as it affects public health outcomes. WIPO’s technical, neutral contributions on IP questions relevant to public health, such as its input to the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), is not intended to pre-empt or influence policy debate on public health issues. This document therefore briefly outlines a range of current IP and public health issues, as a brief overview for participants in the policy debate. This informal paper does not express a formal view and does not seek to advocate any particular position regarding the issues outlined.

The current WIPO Program and Budget includes a program on IP and public policy, of which the Life Sciences Program is currently the sole component. The program, as approved, aims to “to provide objective and reliable information concerning the actual functioning of IP systems, and the range of options available, so that policymakers have a richer basis from which to address current policy issues.” The program recalls that the “role of IP within life sciences is under particular scrutiny, from a range of perspectives: the ethical basis of IPRs in this field; the role of private rights in achieving public interest outcomes; the appropriate use of IP to ensure public welfare dividends from investments of public resources in research; the relationship between the application of specific patentability criteria in these emerging technologies and the broader public interest; the

possibility of supplementary innovation structures and models specific for medical technology and agricultural biotechnology; and, the need for new analytical tools and understanding of patenting trends in these specific sectors.” The program is to “encourage objective analysis and empirical information, to further support debate and informed policy choices on IP-related questions arising in the area of public policies. An enhanced base of practical information, legal analysis and documentation of policy options and strategic national approaches to use IP for enhanced public welfare outcomes will be developed in cooperation, where appropriate, with relevant international organizations. In particular, empirical studies and issues papers will be developed to assist international policymakers, government agencies and legislators in assessing policy options and formulating recommendations. The approved program activities include consultative workshops “held for a wide range of stakeholders, including the civil society and NGOs, to provide an opportunity for exchange of information in making use of the IP system in public policies, including in life sciences.”