

PRELIMINARY COMMENTS OF WIPO TO
THE WHO COMMISSION ON INTELLECTUAL PROPERTY RIGHTS,
INNOVATION AND PUBLIC HEALTH

These are preliminary and informal comments only, intended as an initial contribution to the work of the Commission. On the basis of the deliberations of the Commission at its first session, it is proposed to prepare a formal information note as an initial contribution by WIPO to the Commission's work. These preliminary comments should not be seen as an official position on behalf of WIPO or its Secretariat.

1. The World Intellectual Property Organization (WIPO) welcomes the opportunity to be involved in the work of this Commission. The Commission has a broad and challenging mandate, on a set of issues of fundamental and pressing importance: promoting the creation of new medicines and other products for diseases that mainly affect developing countries. These initial comments summarize a range of issues that may be of interest to the Commission, including areas where WIPO is able to offer further information if required. Further, more developed materials would be offered once the Commission sets its own directions for its work, including any technical input and expertise within WIPO's competence that the Commission indicates that it would find helpful or useful.

WIPO WITHIN THE UN SYSTEM

2. As a specialized agency of the United Nations, WIPO is recognized "as being responsible for taking appropriate action in accordance with its basic instrument, treaties and agreements administered by it, *inter alia*, 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..." WIPO administers treaties relating to intellectual property, provides a forum for policy dialogue and treaty negotiations between its Member States, operates an arbitration and dispute resolution facility, promotes public awareness and education in intellectual property, and provides capacity building and legal and technical advice when requested by Member States.

3. From a policy perspective, WIPO is concerned with intellectual property issues that arise in connection with the life sciences and related technologies – both the broader role of intellectual property in economic and social development, and in terms of specific issues relating to life science technologies. The need to understand and analyze the policy implications of intellectual property in these technologies is widely felt, and is of great importance to development of sound public policy. More generally, WIPO is responsive to the call for the fruits of innovation to be more widely available in developing countries, and to promote the capacity of developing countries to yield the benefits from their own domestic research and innovation. The need to translate research

outcomes into practical, widely available technology is of utmost importance in the field of public health. It is vital, both within the context of this Commission and beyond, to take up the challenge, set out in the Commission's mandate, to "focus on the creation of new medicines and other products" and to come to understand in practice analysis of "how intellectual property rights can promote innovation relevant to public health, and how funding and other incentive mechanisms, including institutional arrangements, may contribute to this end".

4. Among the opportunities before the Commission are the possibilities of
 - Identifying the key considerations required for effective public interest management of knowledge to deliver new public health outcomes, including the lessons of practical experience, an examination of legal structures and technology partnering, what ways of blending incentives and public interest safeguards, and what forms of IP management and leveraging IP interests have been effective in yielding public health outcomes. While much of the practical experience in this area could be considered to be 'work in progress,' a vital new skill set is emerging, relating to the public interest management of knowledge.
 - Enlarging the base of innovation, and broadening the drug development pipeline. This includes bolstering indigenous innovative and drug development capacity in developing countries, and empowering developing countries to extract maximum benefit from their research activities, and using their indigenous capacities to leverage access to external technology and knowhow. This would entail supporting capacity and infrastructure development and managing research activities in developing countries so that developing countries retain greater say over the use of technologies and safeguard access to technologies to which they have contributed. This broader perspective could also entail respect for and recognition of traditional medical knowledge. Traditional communities continue to develop and maintain valuable bodies of proven and effective medical knowledge. While this can be diverse in nature and may be linked to distinct social, value and belief systems, it may be a valuable form of innovation and treatment of health, and it may be appropriate to support and encourage its continuation for the benefit of the originating communities, in conjunction as appropriate with external, more resource-intensive technologies. Enhanced respect for and protection of traditional medical knowledge, and the implementation of principles of prior informed consent and equitable benefit sharing would provide a sound and equitable basis for its use as an empirically and intellectually respected and valued input into external innovation programs.

THE ROLE OF IP AND PUBLIC HEALTH INNOVATION

5. The intellectual property system is one component of a broader set of national and international policy settings that determine how public and private resources are garnered and channeled to serve public health needs. Hence it is necessary to consider how the IP system functions within the full framework of push and pull incentives, public research and development policy, public and private investment in health infrastructure, the impact and cost structure of the regulatory system for pharmaceuticals, and funding,

subsidies and market regulation in the health sector, as well as the impact of competition and international trade. In considering the specific role of IP in this matrix, it is important not to consider protection of IP as an end in itself, but as a public policy and technology management tool, with the goal of creating new technologies from which the public derive actual, tangible benefits. The role of the IP system, ideally, is to harness private interest and to channel productive investment, so as to serve the broader interests of society. Naturally, this entails a balancing of specific private interests and broader public policy objectives, a dynamic process that is conducted at various levels: by the policymaker and legislator, by the regulator or judicial authority, and by the public sector funding agency or public health program.

6. Innovation policymakers have twin responsibilities: promoting innovation in neglected areas, and ensuring the practical availability of the fruits of innovation. The challenge for IP law and policy is to find the optimal linkage between these two goals. This linkage can be portrayed as a zero-sum trade-off between public and private interests, with a view of minimizing the impact of the IP system on public interests; or it can be portrayed as a dynamic harnessing of public and private interests, an encouragement to deploy resources to serve society's needs. In this latter conception, there is a need for incentives to take risks, to support research and to invest in the full development and equitable dissemination of a finished product; and for remedies and other interventions when this model fails.

7. In analysing the specific role of the intellectual property system, it can be helpful to clarify (and distinguish, as needed) the broader normative, policy and standard setting questions on the one hand, and, on the other hand, practical questions of how intellectual property is deployed in research and development and program management to achieve new public health outcomes and to promote effective access to those outcomes. A comprehensive understanding of the role, and the untapped potential, of the overall IP system will need to embrace both its policy and practical aspects, and indeed how they interact. Promoting innovation, and the availability for the public benefit of the fruits of innovation, are the twin goals of the intellectual property system. How, and to what extent, these goals are achieved is at once a question of IP policy settings and the interaction between the IP system and the overall regulatory and policy environment; and yet a question of 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.

8. Practical IP management interacts with the policy settings which set the framework for use and governance of IP naturally interplay. The kind of structures and mechanisms the Commission will be addressing will likely cover practice and policy together. One means of clarifying the IP questions would be to consider arising at each level at which the challenge of new medicines and products is being addressed, from the individual project level to the fully international – the dimension of individual project to international level:

- Practical IP management questions, access to necessary skills and information, and capacity building for effective negotiations with technology partners on IP issues

[example: MIHR handbook, World Bank procurement guide, IP information resources],

- Institutional-level or project-level policies and strategies for IP management, for example to leverage IP arrangements in technology partnerships to ensure guaranteed levels of access to new technologies for neglected diseases or communities [example: range of public private partnership agreements for public health outcomes],
- National policy settings for public-funded or public-interest research, using various settings on ownership, control and access to IP rights to promote active take-up and practical application of public funded research, with various forms of guarantees or safeguards for public benefit [the US Bayh-Dole approach being one model, and alternative approaches in other jurisdictions],
- Specific, targetted legislative initiatives to create incentives to meet neglected health needs, such as pediatric applications and ‘orphan’ diseases [e.g. orphan drugs programs providing a menu of push and pull initiatives for drug development in the absence of sufficient incentives],
- More general national and regional innovation policy and legal settings with bearing on IP, including IP laws themselves 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 international initiatives, standard-setting and the operation and development of the international legal framework [e.g. Global Forum for Health Research, international treaties on IP and related treaties].

9. At the same time, the IP issues can be ordered along a second dimension, the innovation dimension: this would entail considering what questions arise at each stage of the whole process of innovation, from project planning and institutional or national policy settings, through the product development process and regulatory procedures, through to arrangements to ensure the practical availability of the finished product to the target groups (these are discussed below). To order the issues in this way would not mean setting aside an holistic view, but would help clarify how each distinctive layer or stage of development interacts with the whole innovation environment.

10. It is important also to consider alternative technologies and approaches to health care that may be as valid as mainstream Western medicine, and indeed may be more affordable, sustainable and appropriate for communities with a distinct heritage of medicinal knowledge. Greater respect for, recognition of and suitable protection for traditional medical knowledge may be an effective means of addressing some neglected health needs, in contrast to an exclusive reliance on mainstream medical traditions. Innovation within distinct traditions of medical knowledge continues, and is of value in itself. Traditional medical knowledge is also a valuable intellectual contribution to ongoing innovation in the medical field in general, but this requires due respect for and recognition of this contribution, and equitable sharing of benefits from its use where appropriate. Such benefits may entail, for instance, availability of the fruits of innovation.

THE CHALLENGE OF INNOVATION FOR NEGLECTED DISEASES

11. In view of its terms of reference, the Commission may focus on the shortcomings in research, development and innovation directed at the diseases that particularly affect the poor, building on the valuable studies already undertaken in this field. Shortcomings may arise at the level of basic research, in applied research aimed at creating specific treatments, in taking promising candidates through the drug development pipeline, or in the practical availability, accessibility and workability of finished products. Just as innovation is itself a diverse and complex process, the causes of failure, inadequacy or neglect in innovation are diverse and complex.

12. The Commission is likely to encounter a wide range of issues: resource allocation, systemic failures and infrastructure constraints, the respective roles of public institutions and private actors, and the impact of the regulatory system, are all of potential concern. Even to 'focus on the creation of new medicines and other products' may require consideration of the full time-line of basic, then applied research; development of potential candidates; clinical trials and regulatory approval; manufacture and dissemination, including arrangements for optimal access to the finished product. At each stage, it may be necessary to assess whether the cause of neglect is structural, a failing at the level of fundamental principles, policy settings or institutional values, or practical, a shortcoming in the way that existing tools and remedies are exercised and applied. Yet an overall perspective of the complete innovation process is also needed: at the practical project level, planning for new research to address neglected health needs may have to look well beyond the research itself, and consider how research outcomes will be taken up, developed into safe and efficacious products, manufactured, and distributed to the widest possible target group; initiatives funding even basic research for neglected diseases need to plan and negotiate intellectual property arrangements to safeguard access to the finished product, even though this may entail looking forward over a decade or more, when the research finally yields a safe, efficacious finished product ready for production and distribution.

THE STAGES OF INNOVATION: THE INTELLECTUAL PROPERTY ISSUES

13. As noted, one way of analysing the innovation process, and assessing the impact and potential role of the IP system, would be 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.

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

Project 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

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 , 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, 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 project, each stage of the innovation would 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.

THE PATENT SYSTEM IN CONTEXT

15. The range of intellectual property rights and policy tools with bearing on innovation for public health is wide, and aspects of unfair competition law, the law of trade marks, industrial designs, and the protection of test data and undisclosed information are immediately relevant. However, the chief focus of debate concerning innovation in the field of health has been the patent system, and one aspect of discussing innovation policy is to set the patent system in its broader context.

16. The search for enhanced innovation, research and development ranges over many issues; much depends on how the necessary resources can be secured and distributed, and how the necessary infrastructure can be developed. But to the extent that the public health challenge concerns the patent system, it is, in essence, an urgent and acute form of the underlying dilemma that has long defined both the development of national patent law and international cooperation on IP: how to promote the development of the new technologies that society needs, while ensuring that the fruits of this activity are effectively made available to the public. Resolving this dilemma involves striking a balance of interests, which can partly be achieved through the use of the patent system, giving practical effect to its core principles. Attaining that balance can require strategic application of the patent system as an instrument of public policy. Some technical aspects of patent law have been harmonized internationally, but key policy choices and operational matters remain in the domain of domestic law and policy. International debate has recently focussed on safeguarding the policy flexibility governments have available within the patent system; but what is the best way of using this flexibility? Should there be international cooperation to explore how best to use national policy flexibility – or is this a contradiction in terms, since flexibility is all about regulatory diversity and choices tailored to specific national interests?

17. The basic principles of the patent system may, in part, illuminate the way forward, as it concerns finding the balance between promoting innovation and ensuring that it provides benefits to society. The patent system, even when most effectively used and most precisely balanced, does not of course provide a panacea or a stand-alone solution for public health. Yet the core principles of patent law evolved over many years as a practical means of resolving tensions between public and private interests, for overall public welfare, and to project technological information and the capacity to use it into the public domain. The principles of patent law do not exist to privilege the private interest over public needs. To the contrary, the patent system was developed as a policy instrument to bridge gaps and to clear obstacles, not to create them. Its very role is to create dynamic linkages between ostensibly divergent interests – between public welfare and private interest, between basic research in the laboratory and new technological products available to the public, between new technological knowledge and the public domain.

18. The patent system also needs to interact with other regulatory mechanisms, and getting this interaction right is a key policy challenge. Patent rights do not operate in isolation from other areas of national policy and regulation. In assessing how the patent system can best serve the public interest in the health domain, it can be necessary to consider how it interacts with areas such as public research and innovation policy, competition policy, regulation of pharmaceuticals and other aspects of health regulation, regulation of restrictive practices concerning technology and other aspects of technology policy, bilateral and multilateral trade relations, regional initiatives, the scope and manner of government use of patented technologies, and constitutional law.

19. The current public health challenge is not about abstract policy issues, but about what practically can and should be done, both immediately and for the longer term. The principles of the IP system, the basic ideas that shape patent law, have been developed over time not as abstract concepts but precisely in order to produce practical benefits. Yet ongoing efforts are needed to ensure that the patent system remains true to its principles, and serves the public policy role it was created for. The patent system has played a central role in pharmaceutical innovation in general, and has an incentive role in attracting and concentrating the economic resources needed to take innovations from the stage of a research outcome to products practically available for peoples' use. Both basic research and product development are needed to provide sustained innovation, but they require different economic and technical capabilities that need to be taken into account: this is particularly so in the public health field, in which both the overwhelming public importance and the need for meticulous regulation are paramount, so that the process of trial, development, marketing and distribution is typically more risky and resource-intensive than the initial basic research.

20. Increased research activity and increased research outputs do not in themselves provide a complete solution to critical, unmet health needs. Many of the prospective products of research activity stay in the lab or go no further than early development stages. It is also necessary to bridge the gulf from technical innovations into useable products. Assessment of how the necessary resources and expertise are to be mobilized

to form this bridge must consider not merely the scientific research that develops candidate drugs, vaccines and therapies, but also the riskier and the more resource intensive drug development process where different or additional skills are required and the risk capital needed to commercialize an innovation can exceed the cost of research many times over.

21. Research grants can push a project through initial research and perhaps to the identification of a possible product but can not provide the funds needed to pull that potential product through clinical trials, manufacturing scale-up and commercial launch. It is in this area that the appropriate use and strategic management of patents can play a vital role in constructing the necessary incentive and access framework. To the extent that private companies are to assume the risk and expense of advanced clinical development (and this is in itself a public policy choice), the patent system can enhance the pull demand provided by the market for finished products, and thus help channel the necessary investment in the final stages of the drug development pipeline. But the existing array of incentives, especially those that rely on the attraction of a commercial market for the product, may – by definition – have limited effect for the diseases that mostly affect the poor. Case by case, it may be necessary to consider how existing incentive structures and access mechanisms can be better focussed and applied, and what new or supplementary mechanisms are needed. Some neglected diseases initiatives have used the pull of a potential market in the developed world to cross-subsidize low-cost availability for communities of critical need in developing countries, and intellectual property arrangements have been structured to facilitate this. Alternative approaches may be needed for those public health needs that overwhelmingly burden the developing world.

Specific areas for consideration

22. The Commission will doubtless review a wide range of potential responses that may contribute to developing or improving the incentives that would ensure sustained innovation, research and development for neglected disease burdens. Immediate practical steps as well as longer-term policy mechanisms should be reviewed. The following specific suggestions focus in particular on the final terms of reference assigned to the Commission: “5) Consider the importance and effectiveness of intellectual property regimes and other incentive and funding mechanisms in stimulating research and the creation of new medicines and other products against these diseases; 6) Analyze proposals for improvements to the current incentive and funding regimes, including intellectual property rights, designed to stimulate the creation of new medicines and other products, and facilitate access to them; and 7) Produce concrete proposals for action by national and international stakeholders.”

Public sector IP policies

23. Various policies and practices have been deployed 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. These include policies on ownership and licensing of IP on public funded research, and access arrangements or guarantees built into research or funding contracts, whether as a matter of funding policy or as a legislative requirement. For instance, research funding agreements have included guarantees that new products will be made available at reasonable prices or in a timely fashion, in certain defined markets (such as in the developing world), with the right reserved to license the technology and related material such as clinical test data to third parties in case access conditions are not met. It may be timely to take stock of these programs, to learn what practical lessons are emerging, and to assess the policy options for government and university policies to manage IP from publicly funded research in the life sciences to advance public health outcomes.

IP management for public health outcomes

24. Whether established as formal partnerships or not, there is a diverse range of public-private partnering structures and IP management strategies that are being applied to combine public and philanthropic inputs with private sector drug development and regulatory management skills to create and disseminate new medicines for neglected diseases. These arrangements may include practical dispensations of intellectual property, varying in different countries, so that the incentive gained from access to wealthy markets offsets the cost of drug development, trial and approval, and enables provision of the new product immediately to developing countries at a public sector or social marketing cost. It is unlikely that any one template is likely to emerge as a best practice model, but the choices made in such programs, and the range of options explored, should shed light on the overall dynamic interaction between IP and innovation, with a pragmatic focus on the actual delivery of finished products to service neglected disease burdens.

Practical lessons from orphan disease programs

25. Programs established to address the need for new treatments for so-called orphan diseases may provide 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. These include an array of ‘push’ and ‘pull’ incentive structures, cross-subsidization from other products, and exclusive marketing arrangements. This practical experience could shed light on the most advantageous structures for creating new incentives, and ensuring the necessary flow of resources to neglected areas.

Information on trends in research and development

26. In basing its work on up to date information, the Commission may also have recourse to data on trends in the use of the patent system in the medical domain by public sector research institutions and the private sector in developing countries. These data reveal widely varying levels of use between countries, with some experiencing rapid increases in the use of the system in health-related innovative activity, and others registering continuing low or fluctuating levels of use. While patenting activity should

not be confused with innovative activity in general, patent data may provide some insights into overall trends, including the focus of innovative activity in relation to neglected diseases, and the shifting international patterns of applied medical research. The decision to file a patent, and the accumulated data about such decisions, is in general terms a signal of an intention to carry an apparent innovation through to practical application and use. Judicious use of patent data, and whatever value-added analysis can be performed, may help set the context for the Commission's work and shed some light on patterns of applied innovation.

Legal and practical IP issues confronting researchers

27. Research may be facilitated by enhanced information about relevant IP holdings and information about specific patent law issues that arise in relation to research in the life sciences field, such as the legal implications of patent pooling, patent exceptions applicable to medical research, and the development of protocols and strategies for the use of 'research tools' and platform technologies used in biotechnology, and the impact and extent of 'reach through' claims on products developed with research tools.

International dimension of enhanced incentive structures

28. An international approach to the challenges raised by neglected disease burdens includes the possibility of incentive systems for stimulating research and development, such as "roaming" exclusivity (trading off marketing rights in one product or one jurisdiction in exchange for a commitment to service other products or markets which would otherwise be neglected), or fast track or otherwise facilitated product approvals, addressing directly a major cost deterrent to investment and later drug development. As one form of market exclusivity, intellectual property arrangements could form part of such incentive mechanisms. This could also involve a focus on cross-jurisdictional opportunities, including differential pricing arrangements, 'social marketing' and public sector pricing structures, and IP management strategies that provide for cross-subsidization of newly developed drugs in developing country markets of need. The implementation of such mechanisms could entail considering the international legal and administrative implications.