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# Making norms to tackle global challenges: The role of Intergovernmental Organisations

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ABSTRACT

This paper argues that Intergovernmental Organisations (IGOs) can play a significant role in the processes of system transformation required by Grand Challenges. The reason is their potential to influence socio-technical regimes connected to policy areas in which they have authority. Supported by mandates, moral standing and technical expertise, IGOs act in two ways: operating with high level of political support, these organisations guide priority setting and norm development through the definition of collective problems and solutions, including STI aspects, establishing a shared vision; involving public and private actors, IGOs implement and protect novel practices that reinforce the new norms, from legally binding agreements to the creation of new spaces for international collaboration. These processes are examined here in the field of global health, where outside pressure directed at the intellectual property rules in connection to access to medicines prompted the WHO to define the health challenge as a need to stimulate innovation and ensure wide access to technology at the same time. Two of the solutions implemented by IGOs to achieve both goals are analysed: the Medicines Patent Pool, designed by UNITAID to fulfil access and innovation needs in relation to HIV/AIDS drugs, and WIPO Re:Search, set up by WIPO to support collaboration and accelerate discovery and product development for Neglected Tropical Diseases, Malaria and Tuberculosis.


## 1. Introduction

There is widespread agreement that science, technology and innovation (STI) have a role in helping countries tackle social challenges such as climate change, pollution and public health. Providing comprehensive solutions for these global and interconnected problems, however, exceeds the capacity of single states or market forces alone. By definition, Grand Challenges involve "a need to cooperate worldwide to create public goods (mitigation of climate change, health), or protect the global commons (the environment, fisheries)" (OECD, 2010, p.165), calling for action that goes beyond the conventional role played by governments. For policy-makers, thus, the task is also about how to develop and align new policies and practices to address shared societal problems and enhance the impact of solutions.

The term Grand Challenges was added to the EU policy terminology in the late 2000 s (EU, 2008)[1], fuelling scholarly interest in the role of STI in strategic responses to collective problems. Part of this work aimed at defining and understanding their characteristics, with one aspect regarded as particularly important: Grand Challenges are qualitatively different from traditional STI concerns, often considered under the logic of national systems of innovation geared towards economic growth (Gassler et al., 2008; Kallerud et al., 2013). Developing technical solutions to achieve relatively uncontested goals is a far cry from the much messier business of mobilising and integrating different actors and perspectives across policy issues and geographical lines to set priorities and agree on solutions in which STI plays a role.

In other words, tackling Grand Challenges requires a broader perspective and calls for system transformation (Mowery et al., 2010), an exercise that involves not only "innovation as traditionally studied and stimulated, but also novel ways of assembling and re-assembling heterogeneous bits of work (including tradi-

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[1] €31 billion was allocated to the EU's Framework Programme for Research and Innovation 2014–2020 to address seven Grand Challenges: Health and Wellbeing; Food security; Transport; Energy; Climate Action; Society: and Security.

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tional innovation) into evolving constellations that address a Grand Challenge" (Kuhlmann and Rip, 2014, p.4). When policy-making aims solely at technology-specific change, the connections with policy arenas hosting "other types of policies, actors and discursive spheres" are missed (Weber and Rohracher, 2012). In the same way, when scholarly attention is placed mainly on the role of governments as providers of R&D and funding, complementary actors and initiatives remain under the radar.

This paper aims to contribute to this debate by making a case for Intergovernmental Organisations (IGOs) as an important actor in processes of system transformation. More specifically, it brings insights from the discipline of International Relations (IR) to reflect on IGO's contribution. The short answer is that IGOs can aid transition processes by influencing norms and practices in the policy areas where they have authority. Endowed with a rational-legal authority sustained by mandates, moral standing and technical expertise, IGOs operate with high level political support to create rules able to impact socio-technical regimes, defined here as "the semi-coherent set of rules that orient and coordinate the activities of the social groups that reproduce the various elements of socio-technical systems" (Geels, 2011; p.27). This is done in two ways: by defining the challenges and the best solutions to them, including STI aspects, creating a collective vision and direction for action; and, by involving private and public actors in novel practices that reinforce this new direction, ranging from legally binding agreements to the creation of protected spaces that support new transnational instruments.

To illustrate, I examine two interconnected processes: the development of a new vision in public health, in which the promotion of needs-driven health innovation and its equitable dissemination are considered fundamental to address the global burden of disease, making innovation and access two sides of the same coin; and the establishment of two mechanisms designed to achieve these goals. The first is the Medicines Patent Pool (MPP), set up and funded by UNITAID, part of the World Health Organisation (WHO), to accelerate the development and availability of HIV/AIDS drugs at affordable prices. The second is WIPO Re:Search, a consortium developed by the World Intellectual Property Organisation (WIPO) to facilitate sharing of intellectual property (IP) assets and know-how in relation to Neglected Tropical Diseases (NTDs), Malaria and Tuberculosis (TB).

The debate was triggered in the 1990s after a change in international rules: the creation of a standardised and global system of IP protection through the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Political pressure, driven by criticism articulated by social movements, led states to reinforce the WHO mandate to explore consequences of the treaty for public health. The initial aim of increasing access to medicines for infectious epidemics in developing countries through TRIPS flexibilities has, since the signature of the Doha Declaration, in 2001, widened to comprise STI practices and a broader range of diseases and technologies relevant for developed nations. Solutions involve different kinds of expertise and depend on interactions between health and other policy domains, including development, IP and international trade.

This article proceeds as follows: the next section reviews the literature on Grand Challenges and introduces the literature on IGOs to make a case for their role in supporting transitions. Section three describes the research design. Section four reviews the access to medicines, IP rights and innovation debate and analyses the IGO-led process of shaping the definition of the problems and solutions. Section five examines the MPP and WIPO Re:Search, and the involvement of IGOs in establishing and supporting new activities aiming to achieve innovation and access.

## 2. Global challenges and system transformation

The inclusion of Grand Challenges as an important target for STI policy at national and international levels, and the recognition of the different nature of these collective problems (JIPP, 2012; OECD, 2011), have triggered a series of studies attempting to understand and improve their governance. The need to engage heterogeneous actors and manage their interaction has brought the issue of coordination and cooperation to the fore (Edler, 2010; Prange-Gstöhl, 2010), while the governance of transnational programmes have been evaluated on their ability to support priority setting, financing, knowledge sharing, outreach and capacity-building to aid problem solving and diffusion (OECD, 2012).

Part of the academic work on the issue has focused on policy instruments and their potential for addressing Grand Challenges. A whole *Research Policy* special issue was dedicated to the scrutiny of mission R&D programmes in the health, agriculture, energy and defence sectors, including analyses of demand side instruments such as public procurement for innovation, and the use of prizes and regulation (Foray et al., 2012b). These accounts highlight the different problems involved in solving Grand Challenges in comparison to narrower missions and propose a basis for better programme design. This literature, however, has been criticised for not addressing the transformative character of Grand Challenges by confining the role of governments to R&D and funding; giving little consideration to alternative actors; and, focusing on end-goals rather than on open-ended processes (Kuhlmann and Rip, 2014).

### 2.1. The rationale for a multi-level approach

The problem partly stems from the current logic of the innovation systems approach, which aims at optimising firm-based innovation processes for economic growth (Foray et al., 2012a; Mowery et al., 2010). Weber and Rohracher (2012) argue that policies seeking to stimulate innovation at the micro-level need to be complemented by multi-level, transition-oriented policies able to deal with the more contested and non-linear political and policy processes involved in determining and supporting societal goals. Engaging with the transitions literature, the authors build on the multi-level perspective in which niches, regimes and landscapes interact and align to bring about system transformation. Their argument is that placing emphasis on regimes, defined around societal functions and needs, the multi-level approach can help "highlight the way these needs are fulfilled, the role of demand and use, and the inter-linkage of institutions, technologies and social practices", complementing the narrower focus of systems of innovation (Weber and Rohracher, 2012; 1039). The combination of the two frameworks leads to the identification of four shortcomings that can hinder system transformation: directionality (identification of problems and establishment of shared visions, including requirements outside the innovation system); demand articulation (enabling the uptake of innovations by users); policy coordination (between national, regional and sectoral actors, but also between STI and sectoral policies); and, reflexivity (ability to monitor and involve actors in self-governance).

Adopting the multi-level approach not only helps unearthing failures that can hinder system transformation, but also highlights the role of regimes, and of regime change, in transformative pathways. As "the semi-coherent set of rules that orient and coordinate the activities of the social groups that reproduce the various elements of socio-technical systems" (Geels, 2011), socio-technical regimes tend to stability and have structuring effects, functioning as inhibiting factors that resist change (Kemp et al., 2001). Because of this stickiness, the transition approach has traditionally traced transformative processes back to activities initiated at niche/micro level (Berkhout et al., 2004), where "it is possible to deviate from the

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rules in the existing regime" (Geels, 2004; p.912). New technologies and practices, therefore, can be nurtured in a protected environment and managed in ways that support regime transformation (Kemp et al., 2001, 1998).

Direct regime change prompted by top down internal and external pressures, however, are increasingly being examined. Berkhout et al. (2004) consider four types of regime transitions, including purposive transitions in which a broader set of interests, mostly located outside the regime in question, target the current regime. These processes are commonly initiated by the engagement of interest groups attempting to change landscape variables. Geels and Schot (2007) add timing and the nature of multi-level interactions to propose four different pathways in which transformation is likely to be preceded by regime-adjustment activities. In their typology, landscape pressures initiated by actors outside the regime, such as social movements or professionals, lead to an intermediate phase of adjustment and reorientation of regime rules by incumbent actors before transformation is achieved.

Change, therefore, happens when the interrelated rules that make up socio-technical regimes become misaligned (Geels, 2004; p.905), prompting regime-adjustment that aims at restoring coherence. This process precedes system transformation. International regimes studied in the discipline of IR, are part of these interrelated rules: intellectual property, trade, tax and environment agreements are just a few of the international frameworks that are linked to systems of innovation. If rules created at international level are part of this alignment, agency at this level has, accordingly, potential to trigger tensions and misalignments in socio-technical regimes and spark changes that can lead to the system transformations required by Grand Challenges. This takes us to IGOs.

### 2.2. The role of IGOs

The debate on how international institutions and regimes influence the global political economy, and the role of IGOs in these processes, has long interested IR scholars. Research has reflected a divide between two traditions: rationalists, holding a state-centric approach and focusing on the conditions by which states accept international regimes; and constructivists, considering a large number of actors and networks and the importance of normative sanctioning (Seabrooke, 2010). In a nutshell, rationalists take state engagement with regimes and IGOs to be dependent on the extent they can benefit from them (Keohane, 1989; Simmons and Elkins, 2004); constructivists, on the other hand, expose the limits of instrumentality and highlight a logic of appropriateness, in which norms and ideas are central (Finnemore and Sikkink, 1998; March and Olsen, 1998).

Insights from both traditions, as well as the development of scholarship that attempts to incorporate rationalist and constructivist views, shed light on why states create IGOs, how they operate, and processes of policy change. Rationalist lenses are particularly useful in explaining the conditions under which states establish IGOs and the conditions of their autonomy. Examining organisations across different policy areas, Abbott and Snidal (1998) single out centralisation and independence as characteristics that entice states to engage with IGOs. Centralisation, which allows collective activities to take place under one stable organisational structure, increases IGOs' ability to shape the environment in which states operate; independence entails a capacity to manage interstate disputes in a neutral manner. Member states, however, attempt to constrain IGOs' autonomy. One way this is done is through their design, with organisational features such as membership rules considered to be the result of "rational, purposive interactions among states and other international actors to solve specific problems", preferably in a way that advance states own goals (Koremenos et al., 2001; p.762).

Rationalists have also explored issues of autonomy through principal-agent (PA) theory, which considers the reasons for creating actors that, by pursuing their own interests, can hinder states from pursuing theirs. The dilemma here is that while the type of contract established between principals and agents can help reduce agency slack (independent action by the agents against principals' interests) and autonomy (action that escapes control mechanisms), it can also diminish the benefits of delegation. According to Hawkins et al. (2006), all delegation is based upon division of labour and specialisation. Rather than performing a task, be it for lack of willingness or capacity, states delegate the task to a specialised agent with expertise, time, political capacity or resources to perform it. Hawkins and his colleagues, however, identify five additional benefits that may entice states to delegate to IGOs: managing policy externalities, facilitating collective decision-making, resolving disputes, enhancing credibility and creating policy bias.

Policy externalities create a need for mutually coordinated action to facilitate agreements. In coordination dilemmas, granting authority to a neutral third part that evaluates alternatives through technical standards reduces transaction costs and improves outcomes. States also benefit from delegation in collaboration dilemmas such as provision of public goods, when IGOs may be tasked with providing the goods or collecting information about individual efforts to provide them. Decision making problems can be aided by the delegation of authority to an agenda-setting agent able to bring policy choices closer to the collective preference. Impartial and autonomous agents can also help resolve disputes between states, securing the "social benefits of cooperation". The credibility of policy commitments, on the other hand, may be enhanced by delegating authority to enforcing agents with high discretion and clear preferences to move policy in the desired direction. Lastly, delegation can be used to perpetuate particular patterns of power through the structuration of incentives in ways that protect current policy beneficiaries. In all these cases, however, the probability and extent of delegation interact with preferences and power of states (Hawkins et al., 2006, p.12–20).

PA theory, thus, recognizes that IGOs' autonomy is a precondition for their usefulness to states, but does not downplay the importance of state preferences and power. In this view, states and IGOs have a mutually dependent relationship (Reinalda and Verbeek, 2003). Rationalist scholarship, however, has less to say about how IGOs' interests are formed, how they pursue these interests, and how they change. Constructivist scholars have developed this research agenda further.

### 2.3. The creation of norms

Barnett and Finnemore (2004) argue that IGOs are better understood as bureaucracies that not only pursue the tasks delegated to them by states but develop their own views and organisational cultures to promote good policy (p.5). Their claims to authority are based on rational-legal neutrality, delegation, expertise and their position of defenders of common values of the international community (Barnett and Finnemore, 2004; p. 20–25). Central to their power is their ability to transform information into knowledge that shapes social reality and spur action, a process supported by autonomy to set the agenda, decide what data should be collected and choice of actors participating, or not, in the debate.

In this view, IGOs constitute and regulate behaviour through three mechanisms: classifying problems, actors and actions; fixing meanings by establishing how to solve it and by whom; and, articulating and diffusing norms and rules. "IGOs define problems for other actors (by classifying them as such), specify which actors have responsibility for solving those problems, and use their authority to identify the right or appropriate kind of solution for the particular problem under consideration" (Barnett and Finnemore, 2004; p.34).

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While these organisations play a central role in the so-called "norm life cycle" (Finnemore and Sikkink, 1998), they do not act alone but work with entrepreneurs based on NGOs (Betsill and Corell, 2001; Price, 1998) and transnational advocacy networks (Keck and Sikkink, 1998), including epistemic communities with recognised claims of policy relevant expertise (Haas, 1992). Mytelka and Smith (2002), for instance, show how interactions between policy makers and academics inside the OECD and European Commission led to a co-evolution of policy ideas and innovation theory. This process reconfigured the conceptualisation of innovation and suitable policy instruments, inserting RTD and innovation policy as part of wider policy objectives such as growth. In this case, these organisations functioned as protected spaces in which heterodox ideas on objectives and instruments of public policy could develop into new rules.

These interactions also support the processes of socialisation through which IGOs attempt to diffuse and enforce norms, which involve state and private actors (Clegg, 2010; Zürn and Checkel, 2005). IGOs have traditionally diffused norms via state ratification of legally binding treaties whose compliance will often be monitored by their own staff. Increasingly, however, they have expanded their governance capacity, and effectiveness, by changing and regulating behaviour of private actors (Abbott and Snidal, 2010). Abbott and Snidal call these new practices orchestration. In orchestration, IGOs also rely on the authority afforded by their mandates, moral standing and technical expertise to reach out to private actors and institutions, collaborating with them, supporting and shaping their activities. Through orchestration, IGOs decrease political frictions that usually hinder public-private and private–private collaboration; reduce transaction costs and bargaining problems through the identification of participants and enabling negotiations; decrease mistrust by acting as a neutral broker and offset power imbalances by assisting weaker participants (2010, p.337).

For rationalists and constructivists alike, being perceived as independent actors exercising a neutral, impartial, value-neutral knowledge to transform interstate relations is central to IGOs' legitimacy claims (Abbott and Snidal, 1998; Barnett and Finnemore, 2004). IGOs gain legitimacy from influencing state behaviour through the establishment and diffusion of norms, while states gain international legitimacy by adhering to them (Claude, 1966; Finnemore and Sikkink, 1998). Legitimacy is also related to being seen as serving a useful function valued by international society and key constituencies which, in turn, secures autonomy and material resources to perform the job (Barnett and Coleman, 2005).

### 2.4. IGOs and Grand Challenges

Solving Grand Challenges requires the performance of a series of collaborative and specialised tasks that individual states lack expertise, time, political capacity or resources to perform alone. There are, therefore, clear benefits from delegation to knowledgeable and neutral actors able to manage collaboration and coordination dilemmas, facilitate collective decision making, resolve disputes and enforce changes in their particular areas of remit. I suggest here that IGOs are able to use their autonomy, authority and legitimacy to tackle Grand Challenges in two ways (Fig. 1):

The first is through the re-definition of societal problems and of the solutions to them, a process that involves other IGOs, states and private actors. Their mandates secure high level of state support to bring different aspects of a problem to the agenda. Their technical expertise, neutrality and capacity to produce and borrow issue-specific knowledge, from states and non-state actors, facilitate the task of identifying needs and defining goals and ways to achieve them. These activities give directionality to action by establishing a common vision based on a shared understanding of what should be done and by whom.

The second way relates to the process of changing practices in line with the new norms, as enforcement agents. This can be done through treaties directly shaping state behaviour, or through orchestration supporting the creation of spaces for collaboration involving private actors. IGOs moral authority and neutrality enhance their appeal as independent brokers in negotiations comprising actors with different interests and levels of power, enabling new arrangements; their capacity to produce expertise, on the other hand, support the creation of knowledge necessary for the success of these solutions.

## 3. Methodology

Research for this paper was conducted 2012–2015 as part of the ERC project Professions in International Political Economies (PIPES). The project examined how professionals cooperate and compete to solve transnational problems in different policy areas. Its starting point was the analysis of more than 40 reports and documents on challenges in public health produced by expert committees and in-house experts at WHO and member states from 1994 to 2014. This established the centrality of innovation and IP issues in health, particularly for access to medicines and medical technologies. Instruments advocated by participating actors in three expert committees between 2006 and 2012 were reviewed and my choice of the two mechanisms analysed in this paper, the MPP and WIPO:Re:Search, was informed by their different levels of novelty (i.e. challenge to current practices), as well as types of states and IGOs facilitating the set up and running of their activities. A more practical consideration was timing: both initiatives were launched 2010/11, enhancing my chances of tracing the processes that led to their choice and implementation, including access to the actors involved.

Fieldwork entailed the analysis of dozens of documents from UNITAID, WHO and WIPO. This was complemented by participant observation of meetings in Geneva and Cape Town in 2012, 2013 and 2014; and, in-depth semi-structured interviews with 34 professionals working for IGOs, NGOs, foundations, industry and national governments participating in the debate on innovation and access to medicines (Appendix A). The majority of these professionals (80%) occupy senior positions, and 21 were directly involved in the setting up or management of MPP and WIPO RE:Search. Interview questions covered involvement in the debate and details about the implementation and running of the instruments, but also explored their perceptions of global challenges in health, other ways to address the connection between STI and health challenges, and role of national and international organisations in solving problems. Given this is a relatively small community and there were confidentiality concerns, information attributed to interviewees will be cited as personal communication, followed by organisational affiliation.

## 4. Results

Having proposed two ways in which IGOs may contribute to tackling Grand Challenges in Section 2, this section moves to the empirical work focusing on the process of norm development.

### 4.1. Outside pressure: linking lack of access to intellectual property

The debate on access to medicines attracted global attention in late 1990s, when developing countries and civil society groups started to question the impact of TRIPS on the cost and affordability of medicines. TRIPS required countries to translate into domestic law global IP standards and extended patent rights from 15 to 20

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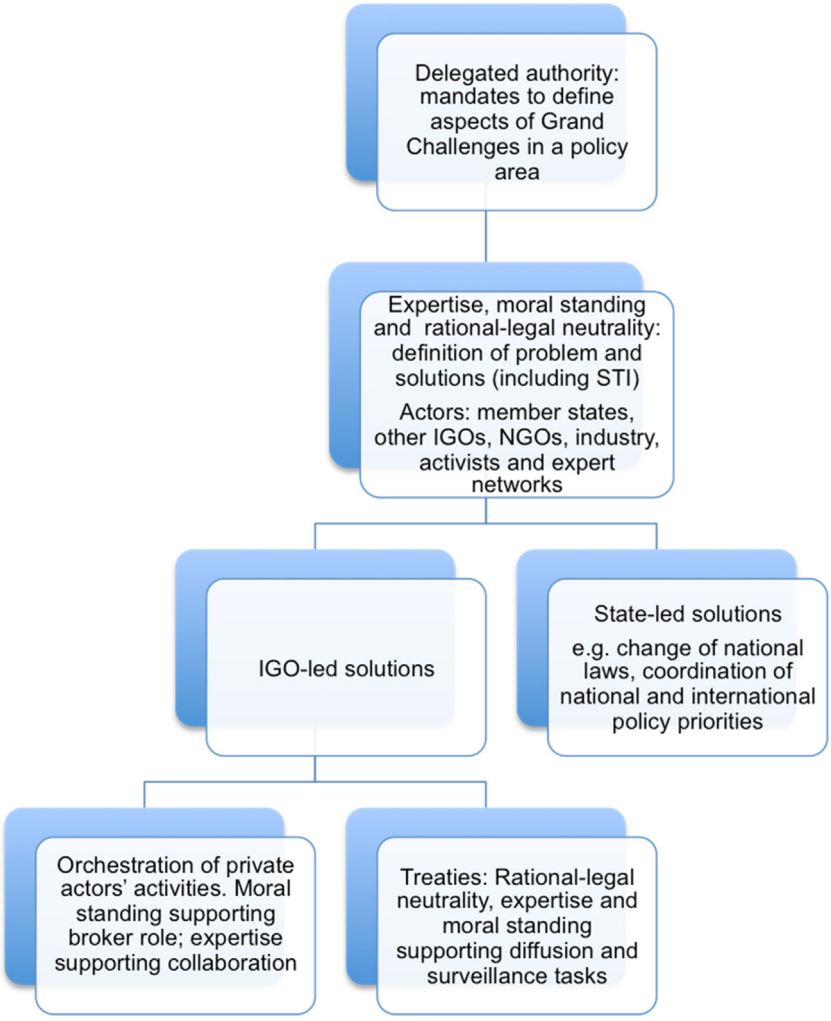


**Fig. 1.** The role of IGOs include defining problems and solutions, as well as diffusion of norms through treaties and orchestration.

years. New conditions to issue compulsory licenses were put in place, potentially restricting the freedom of states to pursue public health policies. NGOs working on health/consumer rights were the first to react, setting in motion a process that would intersect distinct expert and organisational networks (Nilsson, 2017) in an attempt to evaluate the consequences of the treaty for public health.

The NGO-led international campaign for access to medicines ('t Hoen, 2002; Sell and Prakash, 2004) made the connection between lack of access and high costs driven by IP rights. In 2000, a group led by James Love, from the NGO Consumer Project on Technology, secured a deal with CIPLA, an Indian generic pharmaceutical company, for the production of $365 a year (1$ a day) anti-retroviral drugs that were at the time charged between $10.000 and 15.000 a year by brand pharmaceutical companies. At the same time, South Africa, trying to deal with HIV/AIDS related problems by passing legislation to reduce drug costs, was facing legal action and sanction threats from developed countries and their industry (Schneider, 2002). Under intense political pressure, the WTO led negotiations on the Doha Declaration. The declaration reinstated the priority of public health over private IP rights and clarified the use of TRIPS flexibilities[2] by countries.

The establishment of the issue of access to medicines in the transnational agenda, therefore, was a reaction to an international trade regime that established global IP rules and mechanisms for enforcement. This development led experts and activists to question the effects of undifferentiated and widespread IP protection on public health, with the HIV/AIDS pandemic providing a window for activists to challenge: industry's claims of no substantial links between IP and prices; trade agreements that hinder state action to meet health and development needs and address emergencies; and business models based on drugs unaffordable to low and middle-income countries. By the time the Doha Declaration was signed, access to drugs and IP[3] were linked issues, but there was no clear definition of the problem, which actors should be brought into the debate and the possible solutions. This would be the task of a joint IGO effort led by the WHO.

### 4.2. Giving direction by defining the challenge and its solutions

By 2002, three IGOs were directly involved in the access to medicines debate: the WHO as the health authority; the WTO as the authority to interpret TRIPS' legal framework; and WIPO as the authority on IP. WHO leadership was not simply a result of its

[2] On flexibilities, see http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html.

[3] There were reports produced by WHO on the possible impact of TRIPs on health and on the ways states could make use of flexibilities published as early as 1997 but no attempt to debate the issue in relation to other variables or propose solutions that built on but went beyond the TRIPS framework.

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mission to promote health, but a response to reinforced state delegation: between 1996 and 2002, its mandate was strengthened by a series of resolutions[4] aiming at creating policies to increase access to medicines. In 2003, member states requested the set up of a time-limited working group to consider the relationship between IP, innovation and public health. Established in 2004, the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) conducted the first international exercise to identify factors impacting access to medicines. Its terms of reference included considering "the importance and effectiveness of IP regimes and other incentive and funding mechanisms in stimulating research and the creation of new medicines and products"; and analysing "proposals for improvement to the current incentives and funding regimes, including IP rights, designed to stimulate the creation of new medicines and products" (p.4)

The process, which involved experts working for UN organisations, governments, NGOs, universities and foundations, included consultations with member states, multi-stakeholder meetings, and 22 commissioned studies on the subject. With TRIPS and the Doha Declaration guiding the discussion, the CIPIH brought STI to the centre of the inquiry, including in-depth analyses of national systems of innovation in developing countries and of the multifaceted and complex innovation cycle from discovery to delivery of medicines. Recommendations pointed at possible activities that could address the problem at national and transnational levels. National instruments ranged from R&D strategies to changes in patent law frameworks, while transnational tasks were mostly related to international coordination, provision of information and technical support to member states.

The CIPIH paved the way for the establishment of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), the first forum to involve policymakers and experts from every WHO member state, as well as UN agencies, NGOs, industry and foundations. Between December 2006 and May 2008, negotiations were conducted in Geneva and in all WHO regions. A significant event half-way through the negotiation was WIPO's adoption of the Development Agenda (2007), a request from developing countries for further integration of the development dimension into policy making on IP protection. The Agenda aims to close the knowledge gap and the digital divide between wealthy and poor nations and its 45 recommendations[5] require WIPO's input on norm setting, coordination, governance and assessment activities, as well on more traditional technical assistance and capacity building activities.

### 4.3. A global vision and plan of action

Despite disagreements between developed and developing countries in relation to IP issues and the extent to which alternatives models to foment innovation in health are needed (Velásquez, 2014), member states adopted the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property in May 2008. The strategy comprises 8 elements and 108 related actions that speak to STI in health and, to some extent, addresses the failures of directionality, demand articulation, policy coordination and reflexivity identified by Weber and Rohracher (2012). With an explicit aim of promoting new thinking on innovation and access as intertwined goals, the elements cover different mechanisms to ensure needs and demand are identified with the help of relevant stakeholders and tailored to national and local particularities. There is a clear emphasis on connections between national, regional and international policy arenas, complementary actions required to achieve changes, and suggested time frames. Also in place are reflexive arrangements such as monitoring and reporting systems for the strategy as a whole and for the different instruments proposed (e.g the Global Observatory on Health R&D, now fully operational at WHO). Further support was to be developed in form of working groups focusing on the current financing and coordination of R&D, in 2010 and 2012. A trilateral cooperation between the WHO, WIPO and WTO started in 2009 and a joint report on access and innovation was released in 2012.

The IGO-led activities described above, therefore, examined the shortcomings and strengths of the current socio-technical regime in health to suggest a direction of change, in which new roles for public and private actors are necessary. As the work progressed, the definition of the challenge moved from a tight focus on IP and particular diseases affecting developing countries to include wider aspects of the health innovation system. The Global Strategy has created a common vision and established complementary mechanisms and solutions with potential to, in the medium term (15 to 20 years), transform the pharmaceutical R&D system to better align the goal of supporting needs-driven innovation in tandem with widespread access.

A significant number of instruments and mechanisms to achieve this goal depend on international leadership, coordination and technical support. Following a specific recommendation of the Global Strategy to examine upstream and downstream patent pools, the WHO and WIPO moved to establish the Medicines Patent Pool and WIPO Re:Search, targeting innovation and access in relation to HIV/AIDS, NTDs, TB and Malaria. They will be reviewed next.

## 5. Orchestrating collaboration for innovation

The Medicines Patent Pool (MPP) and WIPO Re:Search were established in 2010 and 2011, respectively (Table 1).

The MPP creates economies of scale and facilitates the production of new and affordable HIV/AIDS treatments, including formulations for children, by pooling together multiple patents and sub-licensing them to generic companies. Its work reduces transaction costs, simplifies procurement for governments, UN agencies and foundations, and creates larger markets for firms in the process. WIPO Re:Search is an open innovation consortium able to coordinate research efforts across geographical areas and types of organisations in relation to R&D and innovation for NTDs,

[4] An overview and link to all WHA resolutions can be found at the Department of Public Health, Innovation, Intellectual Property Division and Trade of the World Health Organisation http://www.who.int/phi/documents/en/index.html.
[5] http://www.wipo.int/ip-development/en/agenda/.

**Table 1**
Comparison between the MPP and WIPO Re:Search.

| | WIPO Re:Search | Medicines Patent Pool |
|---|---|---|
| Original idea | WIPO Global Challenges Division | NGOs Knowledge Ecology International and MSF |
| Problem | Market failure (TB, Malaria and NTDs) | Market failure (HIV/AIDS medicines for children); lack of access/affordability |
| Goal | Foster R&D, technology transfer and capacity building | Enhance access and development of needs/user driven innovation |
| Governance | Led by Bio Ventures for Global Health (BVGH), a non-profit biotechnology company | MPP is registered as a Swiss Charity with a governance board |
| Main Participants | Industry, universities, research centres | Industry (generic and research pharma/IP holders), NGOs |

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Malaria and TB, fostering technology transfer and skills development between developing and developed countries. Any innovative products developed through the platform are to be produced without payment of royalties in low-income countries.

Aiming at accomplishing innovation and wide access simultaneously, the two instruments match the concept of facilitative orchestration: they were created to reach out to private actors, collaborate with them and shape their activities. In both cases, the mechanisms are financially supported by the IGOs that established them but primary governance has become the responsibility of non-profit actors. WIPO contributes to the activities of the MPP, and the WHO provides support for Re:Search.

### 5.1. Creating new spaces

The MPP and WIPO Re:Search were launched less than a year apart, but their gestation time differed significantly. The NGO Medicines Sans Frontier (MSF) first proposed the MPP to the UNITAID board in 2006. Work on feasibility and implementation took three years and included a preliminary legal review (Gold et al., 2007), a multidisciplinary expert group on design of the Pool and a Task Force. Opening space for the establishment of the MPP was more complex for at least two reasons: it requires firms to share their profitable IP assets; and the idea was championed by an epistemic community pushing for changes in IP rules. In fact, the concept of a patent pool for medicines, first proposed in 2002 by the NGO Consumer Project on Technology, had been presented to the WHO before without success (personal communication, NGO). A senior officer involved in the process summarised the problem: "The WHO has a very good understanding of the issue and is aware that the current innovation system for health is not working but is unwilling to be involved in polemical issues such as IP rights. They do not wish to clash with member states like the US and Japan" (personal communication, WHO).

The approving nod towards innovative IP management mechanisms given by the CIPIH, in 2006, and the new tasks delegated to WHO in connection with the Global Strategy, opened a new window for the consideration of instruments like the MPP. The crucial development, however, was the creation of UNITAID, in 2006. UNITAID is also a response to the access to medicines problem and was designed to complement work done by the Global Fund, UNICEF and UNAIDS. Despite being a WHO agency, UNITAID was set up by Brazil, Chile, France, Norway and the United Kingdom to function as a financial mechanism influencing prices of drugs and diagnostics. The agency uses buyer-side market leverage to impact costs and quality of HIV/AIDS, Malaria and TB health products for developing countries. The MPP fits UNITAID's mission of improving access through innovative market-based instruments, including pro-public health approaches to IP. Moreover, MPP's aim of speeding the delivery of second-line and new products for procurement connects with UNITAID's tasks of anticipating needs and markets. Last, but not least, UNITAID's smaller board does not fully replicate disagreements between developed and developing countries regarding IP, at the same time that its members are important players in the field. The idea was met with cautious curiosity: "I remember the first time MSF explained the MPP. It was a strange idea and we did not know whether it was a good or bad one. The decision of the board in 2007 was positive, but we all felt strongly that the first step was to investigate how to develop it and make it work" (personal communication, UNITAID).

WIPO Re:Search, on the other hand, was a product of brainstorming processes among new experts employed by WIPO to run what would become the Global Challenges Division (personal communication, WIPO), created in 2008 to work on the intersection of IP and innovation to tackle Grand Challenges in health, climate change and food security. As an interviewee closely involved in the process explained, the platform is a direct response to recommendations 19 and 20 of the Development Agenda, which requires WIPO to facilitate access to knowledge and technology, to foster creativity and innovation, and promote norm-setting activities related to IP that support a robust public domain in member states. The more traditional design of WIPO Re:Search, which fits comfortably with current practices, and the tight connections between WIPO and the industry, facilitated the task at hand. For WIPO, creating new norms is about showing different ways of using IP for innovation: "We do not aim to modify the system but to sketch out what is unique about WIPO and to show how IP can contribute to development and innovation even when there is no market incentives. Companies are our clients after all" (personal communication, WIPO).

### 5.2. IGOs as brokers

Part of the process of moving these initiatives from ideas to functioning platforms was the capacity of these IGOs to bring actors with different interests and expertise to work together. Supported by their moral standing, IGOs were able to build trust and help create the knowledge necessary for the implementation and running of the instruments.

For the MPP, maintaining the support of the countries and donors on the UNITAID board and enticing industry to enter negotiations depended on the creation of a public health entity oriented towards innovation, not an advocacy group demanding patents (personal communications, UNITAID and MPP). The time gap between the decision to investigate the proposal and UNITAID's final decision to sponsor the Pool reflects the need to reduce mistrust by enabling negotiations involving several actors: UNITAID, WHO, countries on the board, the Bill & Melinda Gates Foundation and civil society communities. This was imperative to define the scope and mandate of the Pool and navigate divergent interests and technical difficulties, while protecting the interests of weaker partners. "All board members within UNITAID had a set of concerns regarding the MPP and sometimes the nature of their interests was not very consistent to one another. The whole process was about this delicate and negotiated language between UNITAID and the board, this very interesting situation in which the UNITAID secretary was negotiating on behalf of an organisation that did not exist yet" (personal communication, UNITAID). This process was captured in a Memorandum of Understanding agreed between the MPP and UNITAID in 2010, which includes both immediate and aspirational goals, and has been renewed in 2016 for five more years.

WIPO Re:Search is different because it focuses on less lucrative diseases (patents that are not yet profitable) and upstream collaborations, which in principle require less involvement of actors outside R&D departments. The leadership of WIPO, however, is still important in this case. In 2009, in response to the MPP proposal, GSK set up the Pool for Open Innovation, an industry-based attempt to coordinate research on NTDs. Despite making available more than 100 patents related to these diseases, no partnership was established and these patents are now part of WIPO Re:Search. WIPO, as the orchestrator, gives companies a clear signal that IP core principles will be followed and conflicts of interest arbitrated in the course of collaborations, at the same time that the interests of weaker players, such as less developed/developing countries, are taken into consideration and protected in line with the Development Agenda. Consultations were intense with industry actors, but also involved member states, academics, associations and foundations. The guiding principles and standards for licensing, for instance, were not an adaptation of industry templates but developed in partnership with the Rockefeller and Bill & Melinda Gates

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foundations, a process that has now moved on to setting priorities for product development (personal communication, WIPO).

### 5.3. Mobilising expertise

In both cases, being able to produce or access information was key to the process of facilitating and guiding the design of the instruments and the day-to-day running of their activities.

As mentioned above, the implementation of the MPP was preceded by a preliminary legal review, conducted by academics, and an advisory group. The advisory group brought experts from the WHO, WIPO and WTO to consider issues raised by the review and discuss the range of options available in relation to the design of the MPP. It had also, in the opinion of some participants, the role of enhancing trust and legitimacy."The technical advisory group has made the project seem more balanced. The proposal came from NGOs and some people were suspicious of it solely for that reason. The multi stakeholder expert group tackled this" (personal communications, NGO and member state representative). As a result of these technical meetings, the MPP went from being built on the implicit assumption that compulsory licenses would be issued if patent holders did not volunteer their IP, to a strictly voluntary license approach. They have also ruled out the initial idea of having the organisation hosted inside the WHO or UNITAID, as UN agencies cannot be involved in commercial negotiations for not being susceptible to lawsuits or prosecution (personal communication, WTO). The latter also applies for WIPO Re:Search.

Once the MPP was given the go-ahead and a budget by UNITAID, knowledge produced by the WHO and WIPO has become essential for implementation. WIPO was requested to assist the Pool in the identification of the legal status of 35 patent families (i.e. where in the world key patents are valid) and, after this first stage, to expand the list to identify relevant patents for potential new products, a so-called state of the art search. The work on a patent database containing data landscape from different countries had already started with external consultants but, without WIPO as intermediary, it would be difficult and time consuming to reach regional and local offices to retrieve information. WIPO was also particularly active in the compilation of patent status data for pharmaceutical products from over 70 countries, a database now openly available for consultation and regularly updated by the MPP, benefiting procurement agencies over the world, such as UNICEF and the Global Fund, as well as universities and firms.

The licences negotiated with patent holders and sub-licensed to generic companies by the MPP, on the other hand, are based on a priority list drawn by the WHO. The list contains existing medicines for the treatment of HIV/AIDS such as second line ARVs (Anti-Retrovirus drugs) for adults but also includes missing medicines, the ones yet to be developed. This wish list is the starting point for negotiations aiming at the development of innovative drugs, particularly for paediatric use. Every licence is negotiated individually and the geographical scope of the sub-licensing to generic companies is agreed case by case. While less developed countries are always included, middle-income countries are subjected to more restrictions and might lead to alternative arrangements, such as segmentation between private and public markets or differentiated royalties. Invitations to sub-licensees are done through an open call published in industry publications and sent to companies that belong to the WHO Pre-Qualification[6] list, but bidders have to present an Expression of Interest showing a business rationale. Different from traditional patent pools, the MPP does not sub-license to any interested party as this could disrupt the generic ARV market and hinder access efforts (personal communication, MPP).

In WIPO Re:Search, companies, universities and research facilities holding IP assets on NTDs, Malaria and TB make their IP available, from compounds, unpublished scientific data and regulatory material to patents and patent rights, to be consulted and used for innovation purposes by researchers based anywhere in the world. The platform is hosted by WIPO to provide a one-stop shop for data that is not easily found, encouraging new R&D, particularly in relation to diseases like Chagas and Dengue. Industry partners include GSK, Merck & Co., Novartis AG, Pfizer and Sanofi. Besides making this global catalogue available, the platform has a Partnership Hub and offers support for licensing activities. The Partnership Hub is led by Bio Ventures for Global Health (BVGH). BVGH's main responsibility is to identify and connect suitable partners by reviewing their research and partnering interests. Encouraging small and mid-sized companies to get involved in the global health area to focus on product development is one of the main targets of the hub (personal communication, WIPO). If companies wish to combine IP to develop products, it draws a science plan and takes part in the licensing process. Licences are royalty free for products distribution in the least developed countries.

WIPO experts were involved in the creation of the database, in the development of guiding principles and standards of licensing with the Rockefeller and Bill & Melinda Gates foundations, and continue to support the initiative. In-house knowledge of the IP framework and capacity to provide specialised patent information, such as legal status and state of the art, is a crucial complement to BVGH's job of drawing science plans and coordinating partnerships. WIPO experts have developed mediation and arbitration procedures in form of a template that can be adapted to different cases and contribute to the quality and length of the partnerships (personal communication, WIPO). Technical expertise provided by the WHO in relation to public health needs and opportunities is also available. This includes questions related to patents from neighbouring fields, for instance animal health, and their relevance for the neglected tropical diseases WIPO Re:Search is trying to bring solutions to.

The platform is also being used to diffuse knowledge to member states, with IP management seminars offered to developing country members. Distance learning modules based on the Trilateral Report can be accessed through the WIPO Academy.

### 5.4. New norms contributing to system transformation?

The MPP had, by mid-2016, negotiated licenses on 12 priority ARVs from seven different patent holders, with more than 50 product development projects in the pipeline. It has established the Paediatric HIV Treatment Initiative with UNITAID and Drugs for Neglected Diseases Initiative (DNDi) to speed development and production of missing formulations for children (MPP, 2014) and generic partners have distributed 3,5 billion doses of low cost products to 121 low and middle-income countries. WIPO Re:Search had, by May 2016, established 100 collaborations and partnerships, with activities ranging from sharing of data to hosting scientists and access to research facilities. Collaborations established so far involve, for example, an agreement between Merck & Co. and Emory University regarding a purifying membrane-protein for a new TB treatment, and a partnership between the National Institute of Immunology in New Delhi and GSK to study molecular signalling pathways of malaria parasites.

While it might be too early to give a verdict on how successful they are in delivering health innovation, it is fair to say that the MPP and WIPO Re:Search introduce new norms that contribute towards structural changes in pharmaceutical R&D. Despite their

[6] The Pre-Qualification Programme was originally intended to give UN procurement agencies, such as UNICEF, a choice of products meeting various standards certified by WHO. It has become a central service for other agencies and governments.

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differences – WIPO Re:Search is based on collaborations that fit current industry practices and the MPP is a more radical experiment, requiring stronger protection and support to function – their activities lay the foundations for a different approach to innovation in health by (1) adopting a targeted priority setting approach to align R&D efforts with public health demands and needs (2) coordinating international cooperation involving novel combinations of public and private actors, including foundations and end-users, with particular efforts to integrate partners from developing countries (3) employing and advising on IP management strategies able to leverage innovative outcomes while protecting the rights of different actors (4) ensuring broad dissemination of knowledge and information, from support on legal and technical issues to continuous provision of data that have been previously unavailable or difficult to access.

By producing knowledge and reducing information asymmetries, transaction costs and mistrust between social groups involved in the socio-technical regime, these instruments disrupt traditional patterns of power relations and pave the way for a different approach to innovation that can be replicated beyond neglected diseases that disproportionally affect developing countries. Examples of health challenges that can be tackled by similar arrangements in the near future are the urgent problem of antimicrobial resistance, as well as R&D efforts against future outbreaks of infectious diseases (e.g. Ebola or Zika).

## 6. Conclusions

This paper argues that IGOs can contribute to the system transformations required by Grand Challenges by creating norms that influence socio-technical regimes connected to these problems. The rules and practices they establish have the potential to question aspects of socio-technical regimes linked to Grand Challenges, creating tensions and misalignments able to trigger the reorientation that precede system transformation (Geels and Schot, 2007).

In the case of global health, the authority, autonomy and legitimacy to develop new rules were supported both by state delegation, in form of successive strengthening of WHO and WIPO mandates, and IGOs' capacity to create knowledge while engaging with state and non-state actors. This process, however, did not imply consensus or overlapping interests. There were considerable disagreements regarding problem and solutions, with aspects of the Global Strategy watered down by powerful states. Extended delegation, however, supported IGOs' agency as being in line with the collective will of member states. This has allowed them to create spaces for ideas that differ or even go against established interests and practices in order to provide solutions to the challenge at hand. Justifying these ideas, in turn, was connected with their capacity to produce knowledge, a process supported by of an extensive multi-stakeholder examination of the current health innovation system.

The establishment of a new direction in form of a Global Strategy was followed by orchestration activities for the implementation of the MPP and WIPO Re:Search. This process also depended on IGO's authority stemming from delegation (i.e. the Strategy itself), moral standing and expertise. Operating as impartial and knowledgeable brokers, WHO/UNITAID and WIPO engaged actors with different interests and capacity in various forms of collaboration. This was particularly important in the case of the MPP, which relies on practices that differ substantially from incumbents' preferences, but also played a role in WIPO Re:Search. Part of establishing trust involved creating knowledge: guiding principles and standards developed by WIPO established clear rules and arbitrating procedures; the list of existent and yet to be developed medicines created by the WHO for the MPP gave a medical/needs driven rationale for the negotiations of specific patents and delineated the necessary types of collaboration. Provision of technical expertise on medical/pharmaceutical and patent issues was also central for implementation and continues to support their main tasks.

The collaboration between IGOs for the development and diffusion of norms that cut across international regimes, reviewed in this paper, highlights a yet overlooked area in the literature on IGOs and international regimes. These increasingly common interactions, partly connected with the distinctive complexity of Grand Challenges, raise questions about the current understanding of international norm development as reflecting the organisational culture and expertise of particular bureaucracies, as well as the extent to which articulating and diffusing norms become a collective exercise that disrupts attempts from individual IGOs to control issues and claim authority over them. This opens up new avenues for the exploration of how the interplay between multiple bureaucratic cultures and member state interests may shape the way policy preferences and IGOs themselves change, potentially speaking to a growing scholarship focusing on norms as contingent and contested (Seabrooke, 2010; p.265).

The paper also contributes to the Grand Challenges literature by further developing our understanding of the different actors and activities that play a role in open-ended processes of systemic transformations. By focusing on IGOs, this paper shows how interventions outside the nexus government-driven R&D and funding address these shared problems while actively contributing to change by establishing directionality. Examining agency outside the traditional STI spectrum showcases the potential of different actors to influence socio-technical regimes of innovation and highlights another way in which horizontal policy coordination between STI and thematic areas can occur at transnational level. The departure point here is not innovation policy arenas that reach out to other areas, but the opposite: organisations with authority in policy areas related to Grand Challenges bring STI concerns into their sectoral debate, making the connection between them and proposing action.

The processes analysed here also speak to the transition scholarship by suggesting that IGOs have functions that mimic transition policies, centred around a specific problem area and underpinned by the development of joint societal visions and orchestration of activities that reinforce a desired direction. The empirical material shows how norms developed by IGOs can insert tensions in socio-technical regimes as a response to external pressure, and hints at ways in which both incremental/adaptive and unorthodox activities may happen simultaneously in response to the new norm. While WIPO Re:Search addresses the re-definition of innovation and access as two sides of the same coin through a platform that keep the centrality of strong IP protection for innovation in health, as in the model preferred by incumbents, the MPP moves towards novel arrangements to achieve needs-driven and affordable products.

Constrained to the case of global health, this analysis is limited. In addition, the policy area might have facilitated IGOs' agency. Firstly, the nature of the issue enhances the likelihood of outside pressure from social movements. Research suggests that some problems are more likely to be taken up by social movements at transnational level, with those involving bodily harm to vulnerable individuals being specifically relevant, especially when a short and clear causal chain and culprits can be established (Keck and Sikkink, 1999). The linking of the suffering caused by the HIV/AIDS pandemic to unaffordable prices of medicines and IP by NGOs is a key factor behind states' decision to negotiate the Doha Declaration and delegate more power to IGOs to investigate the problem. This type of political pressure is weaker in less sensitive areas, such as transport and energy. Secondly, the declining efficiency of the pharmaceutical industry in developing new drugs despite the strong reliance on IP rights, coupled with the rise of incremental innova-

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tion in form of 'me too' drugs, could mean internal tensions were already propelling change and weakening incumbent resistance to it.

Despite these limitations, the case made here for IGOs as authoritative actors able to perform tasks that are part and parcel of open-ended processes that lead to transformations required by Grand Challenges still stands. This is particularly relevant when there are growing calls for the creation of new organisations to perform similar roles.

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## Appendix A. List of interviewees.

| Organisational affiliation | Direct involvement in instruments | Date/place of interview |
|---|---|---|
| MPP | Yes | February 2012, Geneva |
| MPP | Yes | March 2012, phone |
| MPP | Yes | February 2014, phone |
| MPP | Yes | May 2013, Geneva |
| MPP | Yes | March 2013, Geneva |
| WHO | Yes | May 2013, Geneva |
| WHO | Yes | December 2013, phone |
| WHO | Yes | June 2013, phone |
| WHO | Yes | May 2013, Geneva |
| WIPO | Yes | March 2012, Geneva |
| WIPO | Yes | March 2012, Geneva |
| WIPO | Yes | March 2012, Geneva |
| WIPO | Yes | October 2013, Geneva |
| WIPO | Yes | March 2012, Geneva |
| WIPO | No | October 2013, Geneva |
| WTO | Yes | March 2012, Geneva |
| WTO | Yes | March 2012, Geneva |
| WTO | No | October 2013, Geneva |
| UNITAID | Yes | March 2012, Geneva |
| Consultant | Yes | March 2012, phone |
| Member state expert | No | January 2014, phone |
| Member state expert | No | December 2015, phone |
| Member state expert | Yes | March 2012, phone |
| NGO | Yes | March 2013, Geneva |
| NGO | No | March 2012, phone |
| NGO | No | March 2012, Geneva |
| NGO | No | October 2013, Geneva |
| NGO | No | October 2013, Geneva |
| NGO | No | December 2013, Cape Town |
| NGO | No | December 2013, Cape Town |
| Academic | Yes | August 2013, Copenhagen |
| Academic | No | December 2013, Cape Town |
| Industry representative | No | November 2014, phone |
| Foundation | No | August 2013, phone |

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