

Intellectual Property, Public Health, and the Influence of Experts

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February 2022 (latest version)

*****Note to the readers from the GSIPE Workshops:** This paper is still at a very early stage. It is the first draft “paper” coming out of my master’s thesis, which is still in writing (in French). In this regard, please excuse the style and language (French) of my references, as they are taken straight from my thesis. For this workshop, my focus is more the content and less on the structure/wording. I am looking forward to any comment you may have, but more particularly on the theoretical framework. Thank you for your time.*

Abstract

The global governance interface between public health and intellectual property (IP) is particularly complex as rights overlap: the right to health and the right to IP. Equipped with flexibilities, the global patent regime was conceived in a way that should have allowed it to evolve and respond to public health concerns. However, a quarter of a century later, the COVID-19 pandemic has thrust into the spotlight a hesitant global governance relying on a substantially unchanged multilateral framework. If international law partly explains the regulatory complexity of this interface, international political economy offers explanation for its remarkable continuity. Adopting a broader conceptualization of epistemic communities, this research shows that this interface fosters an epistemic competition where networks of experts, by providing their expertise and circulating ideas, influence the normative framing of the issue. A social network analysis based on the events of the WHO, WIPO, WTO Trilateral Cooperation on public health, IP and commerce provides centrality indicators for each epistemic community. Interviews with key experts then allow for a more comprehensive understanding of the epistemic competition mechanisms at play. Presenting its preliminary results, this research contributes to the understanding and democratization of this global governance interface.

Introduction

Shaking the world since 2020, the COVID-19 pandemic has abruptly thrust into the spotlight a hesitant global governance. The array of intellectual property (IP) sharing measures that have been deployed to respond to the pandemic¹ and the raising questions on the efficiency of the global patent regime bring us back to the recurring criticisms leveled at the regime after each epidemic since its implementation. Why has the regime not evolved before in reaction to these criticisms?

The regime is typically questioned for its role in the interface with public health. By protecting innovation, the patent regime ensures returns on investment, which cover the risks and costs of research and development (R&D). This pharmaceutical innovation system is understood as an essential incentive to R&D, but also entails pressure on availability and accessibility of medicines². These effects were felt very early on: as the Agreement on Trade-Related Aspects of Intellectual Property Rights³ (TRIPS) was signed, in 1994, the world was facing a devastating HIV/AIDS crisis, during which the costs of treatments were revealed to be kept excessively high by pharmaceutical firms. Led by Médecins sans Frontières (MSF) 's *Access Campaign*, the civil society organized itself around a non-governmental organizations (NGO) network to put pressure on the international community. As a result, the regime was granted flexibilities in the Doha Declaration on the TRIPS Agreement and Public Health⁴ (Doha Declaration), in 2001, which were further defined in the Amendment of the TRIPS Agreement in 2005. It is fair to say that, originally, the regime showed responsiveness.

However, several epidemics followed and systematically attracted similar criticism, but the regime did not react further. The 2009 H1N1 influenza virus pandemic prompted the World Health Organization (WHO) to develop the Pandemic Influenza Preparedness Framework, in 2011, targeting IP rights management as an issue-area in pandemic prevention and response. This did not result in changes in the global patent regime. Later, the 2014-2015 Ebola outbreak showed that, still, “new models were needed for coordinating and financing R&D for preventing and treating pathogens of epidemic potential”⁵. The WHO developed its R&D Blueprint for Action to Prevent Epidemics as a direct response. The global patent regime

¹ OMC, OMS, & OMPI, *Promouvoir l'accès aux technologies médicales et l'innovation - Intersections entre la santé publique, la propriété intellectuelle et le commerce*, 2e édition, 2e éd, Suisse, 2020 ch An integrated health, trade and IP approach to respond to the COVID-19 pandemic.

² OMC, OMS, & OMPI, *supra* note 1.

³ *Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce*, 1994.

⁴ *Déclaration sur l'accord sur les ADPIC et la santé publique*, WT/MIN(01)/DEC/2 2001.

⁵ OMC, OMS, & OMPI, *supra* note 1 à la p 154.

remained unchanged. It is then of no surprise that the unchanged regime faced similar criticism when the world was plunged into the historic COVID-19 pandemic, during which an advance market commitment had to be guaranteed⁶ to incentivize treatment development and distribution, and a global TRIPS waiver was even proposed⁷. This paper investigates why, despite its initial responsiveness and recurring criticisms, the global patent regime did not keep evolving in its interface with public health.

Building on the concept of epistemic community, this paper argues that the interface between IP and public health is plunged into an epistemic competition, where defendants of the established and the emerging views struggle with one another. If the idea of epistemic competition is far from new to the epistemic community literature, it has remained widely understudied. This paper argues that exploring epistemic competition processes holds significant explanatory potential and shows that doing so may bridge important knowledge gaps.

This paper also answers the calls of the literature on the interface between IP and public health to push further our understanding of competing networks using systematic methodological tools and mixed methods. First, social network analyses (SNA) were done, mapping out the interactions between epistemic communities. Then, semi-directed interviews were conducted with several community members to provide a more in-dept understanding of the mechanisms at play.

The first section of this paper provides a brief literature review. The second section then presents the theoretical approach of this research. The third section elaborates on the mixed methods. The results are then discussed in the following section and the last section concludes.

Literature Review

The regime was conceived in a way⁸ and in an institutional context⁹ that should have allowed it to keep adapting. In that sense, literature explaining the evolutive capacity of the

⁶ « La garantie de marché COVAX de Gavi expliquée », en ligne:

<<https://www.gavi.org/fr/vaccineswork/garantie-marche-covax-gavi-expliquee>>.

⁷ *Déroptions à certaines dispositions de l'accord sur les ADPIC pour la prévention, l'endiguement et le traitement de la COVID-19*, IP/C/W/669 2020.

⁸ See TRIPS Agreement, article 27, paragraph 3 b), which includes a review provision for patentability.

⁹ The TRIPS Agreement is hosted by the World Trade Organization (WTO), which aims to be a forum of discussion and negotiation. Moreover, a TRIPS Committee is specifically devoted to facilitating exchange between Members on key issues and to monitoring the impacts of the Agreement on society.

regime abounds¹⁰. Ironically, the initial reactivity of the global patent regime has even been quoted as an example of how, when successfully linked to other issues, such as public health, IP law can evolve¹¹. There has been great work unveiling resistance from developed countries: in an analysis for the South Center, Velásquez¹² reveals continuous efforts from industrialized countries to counter multilateral initiatives aiming to delink R&D costs and prices of medicines. The use of regional trade agreements by the United States of America to limit the use of TRIPS flexibilities has also been extensively documented¹³. However, States are not the only players in this governance interface.

The idea that a shift in the understanding of the role of the global patent regime in the pharmaceutical innovation system is the result of a struggle between networks of actors defending the established paradigm and the new paradigm is fairly consensual in the literature¹⁴. Sell and Prakash¹⁵ provided a great analysis of what is often referred to as the “paradigm shift” of this interface. The authors first trace back how IP rights have initially been pushed into the global political agenda by pharmaceutical industry players, linking IP rights with innovation and economic growth. These efforts are credited to have led to the TRIPS Agreement, and to have established the “traditional” paradigm, according to which strong IP protection is essential to sustain innovation. The authors then show how, as described in the introduction of this paper, civil society has organized in response to the HIV/AIDS crisis. By publicly revealing the profit margins pharmaceutical firms were making from the treatments, the movement managed to disseminate the idea that the global patent regime needed to be made more flexible to enable it to respond to sanitary crisis. This network is credited for the

¹⁰ Laurence R Helfer, « Regime Shifting in the International Intellectual Property System » (2009) 7:1 *Perspect Polit* 39-44; Valbona Muzaka, « Linkages, contests and overlaps in the global intellectual property rights regime » (2011) 17:4 *Eur J Int Relat* 755-776; Leonhard Dobusch & Sigrid Quack, « Framing standards, mobilizing users: Copyright versus fair use in transnational regulation » (2013) 20:1 *Rev Int Polit Econ* 52-88.

¹¹ Valbona Muzaka, « Trade Rules and Intellectual Property Protection for Pharmaceuticals » dans *Handb Glob Health Policy*, John Wiley & Sons, 2014 409.

¹² *Le rôle de l'OMS dans l'analyse des questions liées à l'accès aux médicaments et à la propriété intellectuelle*, by Germán Velásquez, Zotero, Genève, Centre Sud, 2013.

¹³ Peter Drahos, « Four Lessons for Developing Countries from the Trade Negotiations Over Access to Medicines » (2007) 28:1 *Liverp Law Rev* 11-39 à la p 13; Jean-Frédéric Morin, « Multilateralizing TRIPs-Plus Agreements: Is the US Strategy a Failure? » (2009) 12:3 *J World Intellect Prop* 175-197.

¹⁴ Susan K Sell & Aseem Prakash, « Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights » (2004) 48 *Int Stud Q* 143-175; Jean-Frédéric Morin, « Paradigm shift in the global IP regime: The agency of academics » (2014) 21:2 *Rev Int Polit Econ* 275-309; Andrew Harmer, « Understanding change in global health policy: Ideas, discourse and networks » (2011) 6:7 *Glob Public Health* 703-718; Steven Ney, « Making Sense of the Global Health Crisis: Policy Narratives, Conflict, and Global Health Governance » (2012) 37:2 *J Health Polit Policy Law* 253-295; Michael Stevenson & Jeremy Youde, « Public-private partnering as a modus operandi: Explaining the Gates Foundation's approach to global health governance » (2021) 16:3 *Glob Public Health* 401-414; Drahos, *supra* note 13; Helfer, *supra* note 10.

¹⁵ Sell & Prakash, *supra* note 14.

emergence of this “new” paradigm. Morin¹⁶ adds on to their analysis, showing the supporting role played by academics in the paradigm shift efforts. Partnering with NGOs and think tanks, he argues that academics added legitimacy and visibility to the network’s claims.

The paradigm shift described in the literature seems to have reached the international community; the past twenty years have witnessed a proliferation of programs and fora to discuss and monitor the interface between IP and public health¹⁷. Most notoriously, in 2010, the World Trade Organization (WTO), the WHO and the World Intellectual Property Organization (WIPO) intensified and formalized their joint activities on the topic by forming the Trilateral cooperation on IP, trade and public health (Trilateral Cooperation).

By enlightening how the discourse has shifted, the literature’s optimism contrasts significantly with the decades-long immutability that characterized the global patent regime after its initial responsiveness, even when faced with repeated criticism.

Theoretical Approach

The concept of epistemic communities has been revisited and applied by an increasing number of disciplines, but its application in International Relations by Emmanuel Adler and Peter Haas¹⁸ remains central. Haas defines them as “a network of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge with that domain or issue-area”¹⁹. He identifies them through four key characteristics: “a shared set of normative and principled beliefs”; “shared causal beliefs”; “shared notion of validity”; and “a common policy enterprise”²⁰.

This definition remains key today, but more recent literature has called for a broader conceptualization of epistemic communities; too rigid and constraining approach to them does

¹⁶ Morin, « Paradigm shift in the global IP regime », *supra* note 14.

¹⁷ OMC, OMS, & OMPI, *supra* note 1 à la p 32; World Trade Organization & World Health Organization, *Les accords de l’ OMC et la santé publique : étude conjointe de l’ OMS et du secrétariat de l’ OMC*, Genève: Organisation mondiale de la Santé, 2002; OMS, « Élaboration d’une feuille de route sur l’accès aux médicaments et aux vaccins 2019-2023 », en ligne: OMS <http://www.who.int/medicines/access_use/road-map-medicines-vaccines/fr/>; OMC, OMS, & OMPI, *Promouvoir l’accès aux technologies médicales et l’innovation - Intersections entre la santé publique, la propriété intellectuelle et le commerce*, Suisse, 2013.

¹⁸ Morgan Meyer & Susan Molyneux-Hodgson, « « Communautés épistémiques » : une notion utile pour théoriser les collectifs en sciences ? » (2011) 18:1 *Terrains Trav* 141-154 à la p 142 , Bibliographie_ available: 1Cairndomain: www.cairn.info/CitePar_available:1publisher:ENS-Paris-Saclay.

¹⁹ Peter M Haas, « Introduction: Epistemic Communities and International Policy Coordination » (1992) 46:1, *Int Organ* 1-35 à la p 3.

²⁰ *Ibid.*

not account for the entirety of the empirical, cognitive, and normative reality of the international political context.

To start with, many authors note that boundaries of epistemic communities should be understood in a looser way to better reflect the dynamism of the communities' cognitive processes and members' composition. Meyer and Molyneux-Hodgson²¹ suggest one should not strictly focus on what they share and what holds them together, but should rather explore the different organizing modes and dynamics that leads them to assemble. In the same idea, Cross insists²² on the importance of internal dynamics such as persuasive and relational processes that define epistemic communities. Akrich²³ adds to that, arguing that their dynamism also extends beyond their borders. The author underlines that the linkages between concepts and issues are not rigid nor mutually exclusive; they can belong to more than one community, and this also applies to their members. The fact that they are part of an epistemic community does not prevent experts from being members of or coming from other communities or transnational networks, such as advocacy networks²⁴. On that note, it is relevant to clarify that, if epistemic communities are not the same as professional networks, professions can potentially play an important role in shaping common beliefs and building relations. In that sense, professions can help foster epistemic communities, possibly several²⁵. Acknowledging the complexity of the socio-political environment where they exist, the distinction between epistemic communities and other types of networks must be perceived in a more interactive way.

Rather than criticizing it, later literature quite aligns with Adler and Haas' take on the normative functions of epistemic communities. Roth and Bourguine²⁶ center the concept around a "common concern", which links the members of an epistemic community by a shared understanding of the issue; its causes, its possible impacts, and the normative solutions that ensue from this understanding. As indicated by Adler and Haas, "epistemic communities bound the range of collective discourse on policy, as well as guide decision makers in the choice of appropriate norms and appropriate institutions within which to resolve or manage problems"

²¹ Meyer & Molyneux-Hodgson, « « Communautés épistémiques » », *supra* note 18 à la p 150.

²² Mai'A K Davis Cross, « Rethinking epistemic communities twenty years later » (2013) 39:1 Rev Int Stud 137-160 aux pp 12-13.

²³ Madeleine Akrich, « From Communities of Practice to Epistemic Communities: Health Mobilizations on the Internet » (2010) 15:2 Sociol Res Online 116-132 à la p 282.

²⁴ *Ibid* au para 7.4, 11.2-11.4; Morin, « Paradigm shift in the global IP regime », *supra* note 14 à la p 282; Cross, *supra* note 22 à la p 18.

²⁵ Morin, « Paradigm shift in the global IP regime », *supra* note 14 à la p 281; Cross, *supra* note 22 à la p 148.

²⁶ Camille Roth & Paul Bourguine, « Epistemic Communities: Description and Hierarchic Categorization » (2005) 12:2 Math Popul Stud 107-130 à la p 2.

²⁷. Furthermore, the interactivity of epistemic communities with networks outside their borders, explained earlier, provides them with the ability to “shed light on the nature of complex interlinkages between issues” ²⁸. On the basis of having such relevant expertise and a shared understanding of the causal mechanisms linked to the issue, its consequences and its appropriate normative solutions, epistemic communities believe they have a risk assessment capacity and function²⁹, and it is in that respect that they get involved with policymakers. In this regard, in this paper, the activity of epistemic communities is not understood as a political enterprise formally organized, but rather as the product of the beliefs and activities of their members³⁰.

In addition to their risk assessment function, the expertise epistemic community members hold gives them the responsibility of translating technical information about highly complex issues to policymakers, which gives considerable significance and weight to the way they frame the information they provide³¹. This places them in a position to influence how the issue itself is framed, how it is prioritized in the political agenda and how critically it is perceived by the public³². More precisely, by interacting with one another and with policymakers, epistemic communities diffuse their ideas and their normative framework, contributing to shape a perception of reality³³. Establishing their epistemic authority consequently heavily relies on the control they have on the circulation of information in social interactions³⁴. In the context of their functions and interactions, members of epistemic communities can end up creating an information bridge between organizations, entertaining multiple relations, developing particularly influential connexions, etc. This connectivity provides them with a strategic position in the socio-political environment surrounding policymakers, which then translates into increased ability to diffuse their normative

²⁷ Emanuel Adler & Peter M Haas, « Conclusion: Epistemic Communities, World Order, and the Creation of a Reflective Research Program » (1992) 46:1, *Int Organ* 367-390 à la p 375.

²⁸ Haas, *supra* note 19 aux pp 15-16.

²⁹ Jessica Templeton, « Framing Elite Policy Discourse: Epistemic Communities and the Stockholm Convention on Persistent Organic Pollutants » 36 aux pp 5-6.

³⁰ *Ibid* à la p 11.

³¹ *Ibid* à la p 4.

³² Lasse Folke Henriksen & Leonard Seabrooke, « Transnational organizing: Issue professionals in environmental sustainability networks » (2016) 23:5 *Organization* 722-741; Cornel Ban, Leonard Seabrooke & Sarah Freitas, « Grey matter in shadow banking: international organizations and expert strategies in global financial governance » (2016) 23:6 *Rev Int Polit Econ* 1001-1033; Andreas Antoniadis, « Epistemic Communities, Epistemes and the Construction of (World) Politics » (2003) 17:1 *Glob Soc* 21-38 à la p 33.

³³ Antoniadis, *supra* note 32 à la p 29.

³⁴ *Ibid* à la p 30.

frameworks³⁵. That is precisely where epistemic community members come into play: “ideas would be sterile without carriers, who function more or less as cognitive baggage handlers as well as gatekeepers governing the entry of new ideas into institutions”³⁶. In other words, to assess adequately the impact of epistemic communities in the normative environment, they can not be conceived separately from the members that constitute them; at the cognitive and practical levels, the agency of their members is key in shaping and diffusing the normative framework³⁷.

Considering the elements mentioned above, this research adopts a broader conceptualization of epistemic communities. They are defined as communities of which members form networks of knowledge and share a similar comprehension of a highly technical issue. More precisely, their shared causal understanding of the issue leads them to similarly perceive the risks it entails and the solutions that are appropriate; they share a common concern. It is in that respect that they aim to provide policymakers with their risk assessment competency. This broadened conceptualization also calls for a looser delimitation of epistemic communities.

Applying the concept of epistemic communities to the competing groups identified in the interface by Sell and Prakash is actually not too far off the way the authors themselves have characterized those groups:

“The consensus-building process drew upon expertise (identifying the problem, providing information and loss estimates), framing skills (translating arcane intellectual property issues into new instruments of trade policy), and the normative appeal of the solutions advocated.”³⁸

To be sure, the networks they identified provide significant guidance in the identification of the epistemic communities in the interface between IP and public health. As explained in the literature review, their analysis did not account for all actors involved and did not explain the immutability of the regime that followed. However, it undoubtedly uncovered key components of the same mechanisms we are exploring. Thus, applying the concept of

³⁵ Henriksen & Seabrooke, « Transnational organizing », *supra* note 32; Emilie M Hafner-Burton, Miles Kahler & Alexander H Montgomery, « Network Analysis for International Relations » (2009) 63:3 Int Organ 559-592; Amandine Orsini et al, « Complex Systems and International Governance » (2019) Int Stud Rev 30.

³⁶ Haas, *supra* note 19 à la p 27.

³⁷ Antoniades, *supra* note 32 aux pp 28-29.

³⁸ Sell & Prakash, *supra* note 14 à la p 159.

epistemic communities to both groups is consistent with their work, but also allows for further and broader analysis of the mechanisms at play.

Another important criticism aimed at Adler and Haas' approach to epistemic communities relates to their conditions of existence: their emergence is not linear, and they are rarely on their own in a given issue-area. As knowledge is the product of social interactions, multiple perceptions of reality can exist; knowledge is continuously contested³⁹. If epistemic communities can constitute themselves in response to a new issue or to an issue newly added to the political agenda, they can also emerge when there is a change in how an issue is approached and understood⁴⁰. A new paradigm is built, aiming to bridge the gaps of the established paradigm or to respond to the problems raised by the latter⁴¹. Typically, this process is understood as an evolution, a replacement of the established view by the new one, a "paradigm shift".

Applied that way to the interface between IP and public health, the literature would imply that the new paradigm promoting increased flexibility has established itself, a shift seen as embodied by the Doha Declaration. The immutability of the regime that followed when criticized, then, seems odd. The hesitation of the international community to fully use the TRIPS flexibilities and to adopt a temporary waiver, even while plunged into the historical COVID-19 pandemic, contrasts even further with the apparent "establishment" of the new paradigm.

If the literature largely recognizes that through the continuous challenging of knowledge there is epistemic competition, the concept remains little studied and rarely applied in the field of International Relations. The epistemic competition theory suggests that going from A to B when understanding the emergence of an epistemic community misses out on important processes. First, the development of a new paradigm prompts the constitution of a new epistemic community. Meanwhile, the previously established community resists, which looks at epistemic communities through a novel lens; and then, both communities enter a phase of epistemic competition. Conceiving epistemic competition as a phase in itself allows for the

³⁹ Antoniades, *supra* note 32 aux pp 35-36; Morin, « Paradigm shift in the global IP regime », *supra* note 14 à la p 280.

⁴⁰ Antoniades, *supra* note 32 à la p 33; Adler & Haas, *supra* note 27 à la p 384.

⁴¹ Fridolin Gross, Nina Kranke & Robert Meunier, « Pluralization through epistemic competition: scientific change in times of data-intensive biology » (2019) 41:1 Hist Philos Life Sci 1 aux pp 23-24.

study and unveiling of the mechanisms at play when a governance interface enters – and, possibly, stagnates – into such a competition phase.

Gross, Kranke and Meuniergros⁴² suggest that epistemic competition prompts increased interactivity between the competing communities, which, instead of leading to a permanent divide or to the victory of one, rather fosters a new community, bridging both epistemic approaches⁴³. For this paper, the main interest of the epistemic competition theory is that it allows to shed light on mechanisms otherwise omitted. Its predictability function will hence be left aside for now. However, the authors' comprehension points to interesting processes. Initially, as the emerging and the established communities have different epistemic approaches, risk assessments and causal understanding on the same issue, they perceive each other as competing. They then enter a stage of debate, where the communities co-exist, diffuse their normative framework, and question the validity of each other's beliefs. This context encourages increased interactions, which, according to the authors, progressively leads the communities to perceive each other less in competition and more in complementarity, leaning towards mutual acceptance⁴⁴.

In contrast, the literature on polarization (section to be developed) provides important hints to understand how this interactivity can lead to, on the contrary, increased antagonism. In turn, this will likely translate into the proliferation of contradictory actions, depending on where each epistemic community holds the most influence. Also, in a context of multilateral policymaking where decisions are consensus-based, this perspective provides credible explanations as to why, when a highly complex normative issue is subject to an epistemic competition, it may appear to “stagnate”. Looking at such apparent stagnation through the lens of the epistemic competition process allows us to reveal instead a dynamic arena where multiple mechanisms are at play.

Epistemic competition is a dynamic where epistemic communities struggle with one another to defend their understanding of the reality, and the causal and normative beliefs it entails⁴⁵. In that sense, epistemic competition must be distinguished from scientific controverse: it is not a narrowly delimited and empirically solvable contestation⁴⁶. Then, again,

⁴² Gross, Kranke & Meunier, « Pluralization through epistemic competition », *supra* note 41.

⁴³ *Ibid* à la p 4.

⁴⁴ *Ibid* aux pp 24-15.

⁴⁵ Antoniadès, *supra* note 32 à la p 36; Claire Dunlop, « Epistemic Communities: A Reply to Toke » (2000) 20:3 Politics 137-144 à la p 11; Morin, « Paradigm shift in the global IP regime », *supra* note 14 à la p 280.

⁴⁶ Gross, Kranke & Meunier, « Pluralization through epistemic competition », *supra* note 41 à la p 24.

the idea of a “struggle” does not refer to a formal and structured action, but rather to a dynamic inherent to epistemic competition.

The interface between IP and public health

First and foremost, the concept of epistemic communities is well-known for the empirical difficulties it entails. Claiming exhaustiveness and exactness when identifying the epistemic communities’ members would bring us dangerously close to caricaturizing the international normative environment. This paper uses the concept of epistemic community mainly as a heuristic tool, allowing us to apprehend reality without ever pretending to perfectly reflect it. Indeed, if knowledge is continuously contested, nuances and changes in views promise variations in the degree and nature of experts’ membership to an epistemic community.

The initially established epistemic community will be referred to as “pro-status quo”. Built around the “traditional” paradigm, its members believe IP protection to be an essential incentive to pharmaceutical R&D. Consequently, they are concerned by infringements to IP rights, which they believe will jeopardize the sustainability of the pharmaceutical innovation system. Members of this community are expected to be coming from the pharmaceutical industry, developed States, commercial and private law and some intergovernmental organizations (IGO) (WIPO, WTO)⁴⁷.

The community that emerged with the “new” paradigm will be referred to as “pro-reform”. The members of this community are concerned that IP rights limit the availability and affordability of medicines. Built around the “new” paradigm, they believe that the global patent regime must show flexibility to respond to public health issues. Members of this community are expected to be coming from NGOs, the academic sector, developing States, human and public health law, think tanks, some IGOs (World Bank, WHO) and other civil society organizations. Fabricants of generics, through their promotion of generic competition, are seen as contributors to this network⁴⁸.

As epistemic communities are described as influencing the political agenda, it may seem counterintuitive that experts from the Trilateral Cooperation’s IGOs, which are key in the governance of this interface, are included. The literature on epistemic communities calls for relativity when distinguishing between them and policymakers. Knowledge is the product of

⁴⁷ Sell & Prakash, *supra* note 14; Jean-Frédéric Morin, « The Two-Level Game of Transnational Networks: The Case of the Access to Medicines Campaign » (2010) 36:4 Int Interact 309-334.

⁴⁸ Sell & Prakash, *supra* note 14; Morin, « Paradigm shift in the global IP regime », *supra* note 14.

social interactions. Consequently, and particularly true in the international normative context, the inputs they add must be included to get a comprehensive understanding of the dynamics within this epistemic competition. As Antoniades puts it: “through this framework there can be no successful attempt to draw meaningful boundaries between the political and the epistemic; between ‘power’ and ‘knowledge’.”⁴⁹.

As stated earlier, applying the concept of epistemic communities entails empirical challenges and limits. In addition, civil society organizations have noted that some actors of this interface have a “pro-reform” discourse, but rather “pro-status quo” actions. Investigating their exact epistemic membership would undoubtedly be relevant, but considerably challenging. In the context of this paper, these actors will be assigned to a “grey zone”.

Without going into too much detail, it is relevant at this point to briefly explore the sprawling particularity of one organization: the Bill and Melinda Gates Foundation (BMGF). Since its creation in 2000, the Foundation has massively invested in health to promote innovation in a global access prospective⁵⁰. The global patent regime is at the core of its strategy. By multiplying partnerships with pharmaceutical firms and academic institutions, the Foundation invests in R&D for neglected diseases, all while ensuring that its partners own the IP rights that come out of it. From the medicines sold to rich countries, the Foundation and its partners obtain a return on investment, which is then reinvested in R&D. Meanwhile, least developed countries can get these medicines at the lowest costs and without regards for IP⁵¹. Through these voluntary initiatives and a monopolistic IP management, the BMGF insists that, to protect R&D incentives, the global patent regime should not be infringed⁵². The Foundation’s “philantro-capitalist” position is critical. Indeed, the Foundation is behind the creation and the funding of several key organizations in this interface (e.g., UNITAID, the GAVI Alliance (GAVI), The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), the Coalition for Epidemic Preparedness Innovations (CEPI), the Access to Medicine Foundation, etc.). This paper does not imply that this relation automatically translates into an influence from the BMGF in the governance of these organizations. UNITAID, for instance,

⁴⁹ Antoniades, *supra* note 32 à la p 37.

⁵⁰ Catherine Jewell, « IP and Philanthropy: the Gates Foundation’s approach », (août 2013), en ligne: *WIPO* <https://www.wipo.int/wipo_magazine/en/2013/04/article_0006.html>.

⁵¹ William New & Catherine Saez, « Bill Gates Calls For “Vaccine Decade;” Explains How Patent System Drives Public Health Aid », (17 mai 2011), en ligne: *Intellect Prop Watch* <<https://www.ip-watch.org/2011/05/17/bill-gates-calls-for-vaccine-decade-explains-how-patent-system-drives-public-health-aid/>>; Jewell, *supra* note 50.

⁵² Jewell, *supra* note 50.

firmly promotes the use of TRIPS flexibilities to respond to public health concerns⁵³ and has most recently supported South Africa and India's proposal for a temporary TRIPS waiver⁵⁴. In the same line, in its famous yearly reports, the Access to Medicine Foundation measures the industry's support for the use of TRIPS flexibilities as an indicator to grade their performance in the promotion of access to medicines and vaccines. The position of GAVI and of the Global Fund, however, is harder to track. Initially, and in its official statements, the Global Fund supports the use of the TRIPS flexibilities⁵⁵. Nevertheless, UNITAID and Médecins sans Frontières (MSF) have noted that the organization's recent strategy in relation to grant and support for developing States portends reinforcement of IP rights, which in turn may hinder generic competition and access to medicines⁵⁶. Furthermore, the Global Fund's initiative to develop a global framework for tiered-pricing raised major concerns within civil society on the impacts this could have on access to medicine; more than 200 civil society organizations co-signed an open letter asking the executive director in place at that time to abandon the project⁵⁷. Notably, GAVI supported the project and promoted it⁵⁸. More recently, GAVI and CEPI came under intense scrutiny as they are key players in the COVAX initiative, heavily funded and promoted by the BMGF. Created to respond to the COVID-19 pandemic, the COVAX initiative has not reached its production and distribution targets, which prompted suspicion on the motives of the organizations behind the initiative:

“Two of COVAX's three leaders, CEPI and Gavi, are backed by the foundation, and some question whether Gates' involvement might have led COVAX to take a less radical approach to vaccine distribution —

⁵³ Jorge Bermudez & Ellen 't Hoen, « The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good » (2010) 4 Open AIDS J 37-40; « Unitaids's Contradictory Approach to IP Rights Risks Progress », (27 novembre 2019), en ligne: *IPWatchdog.com Pat Pat Law* <<https://www.ipwatchdog.com/2019/11/27/unitaids-contradictory-approach-ip-rights-risks-progress/id=116451/>>.

⁵⁴ « Unitaids supports call for intellectual property waivers and action for access to COVID-19 products », en ligne: *Unitaid* <<https://unitaid.org/news-blog/unitaid-supports-call-for-intellectual-property-waivers-and-action-for-access-to-covid-19-products/>>.

⁵⁵ « Global Fund strategy aims to help shape market and ensure sustainability of AIDS treatment », en ligne: <<https://www.theglobalfund.org/en/news/2011-05-26-global-fund-strategy-aims-to-help-shape-market-and-ensure-sustainability-of-aids-treatment/>>.

⁵⁶ « MSF open letter to the Global Fund to Fight AIDS, TB and Malaria », en ligne: *Médecins Front Access Campaign* <<https://msfaccess.org/msf-open-letter-global-fund-fight-aids-tb-and-malaria>>; « The Global Fund has been backing away from efforts to promote generic competition », en ligne: <<https://aidspace.org/fr/c/article/3696>>.

⁵⁷ « Open letter to Mark Dybul: Abandon the “Blue Ribbon Task Force to Develop a Global Framework on Tiered-Pricing” | Global Fund Advocates Network », en ligne: <<https://www.globalfundadvocatesnetwork.org/resource/open-letter-to-mark-dybul-abandon-the-blue-ribbon-task-force-to-develop-a-global-framework-on-tiered-pricing/>>.

⁵⁸ Gorik Ooms et al, « Could international compulsory licensing reconcile tiered pricing of pharmaceuticals with the right to health? » (2014) 14:1 BMC Int Health Hum Rights 37.

particularly regarding COVAX's stance on intellectual property (IP) laws.”⁵⁹

It is noteworthy to mention that both CEPI and GAVI have not publicly supported the temporary TRIPS waiver proposal by South Africa and India. If the BMFG has announced its support for the proposal, it is only after Bill Gates drew outrage online for having stated that IP rights were not holding things back in the case the COVID-19⁶⁰. In other words, in the context of this research and of the current pandemic, discerning the epistemic beliefs of these actors proves to be difficult.

This paper argues that, following the emergence of the “pro-reform” epistemic community, the established “pro-status quo” community has resisted, which has plunged the interface between IP and public health into an ongoing epistemic competition.

The next sections of this paper have not been drafted yet. More details on the mixed methods will be presented at the workshop. Preliminary results will also be shown and discussed.

⁵⁹ « ‘Naively ambitious’: How COVAX failed on its promise to vaccinate the world », (8 octobre 2021), en ligne: *STAT* <<https://www.statnews.com/2021/10/08/how-covax-failed-on-its-promise-to-vaccinate-the-world/>>.

⁶⁰ « Bill Gates’ Comments On COVID-19 Vaccine Patent Draw Outrage », (28 avril 2021), en ligne: *Observer* <<https://observer.com/2021/04/bill-gates-oppose-lifting-covid-vaccine-patent-interview/>>; « COVID-19: Bill Gates hopeful world “completely back to normal” by end of 2022 - and vaccine sharing to ramp up », en ligne: *Sky News* <<https://news.sky.com/story/covid-19-bill-gates-hopeful-world-completely-back-to-normal-by-end-of-2022-and-vaccine-sharing-to-ramp-up-12285840>>.

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