TOWARDS A GLOBAL SYSTEM FOR ACCESS AND BENEFIT SHARING OF PATHOGEN MATERIALS

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ABSTRACT

A global debate has flourished on the interface between patent protection and access to biomedical technologies. Recent research suggests that an expansive trend in patent law might impede access to basic research; restrict access to medicines for low-income countries and also threaten the equitable exploitation of genetic resources by their countries of origin. The interface between access to patents and materials is particularly complex in the biomedical area, since many biotechnologies can be used either as research tools for biomedical research or as end-products; and also since the economic effects of patents are difficult to determine empirically, are spread over a long time span and are often unevenly distributed among countries. This paper looks at the problem of access and sharing of genetic resources (including those regulated by the Convention on Biological Diversity) and specifically examines the case of access and sharing of pathogen materials exemplified by the controversy on access to influenza viruses samples, which originated in Indonesia during the H5N1 influenza in 2007.

The paper focuses on the global governance of pathogens access/sharing as a case that creates important concerns for global health. The paper examines global rules and institutions, which are regulating the issue in parallel, in particular the IPR system as embedded in the TRIPS Agreement, the access and benefit sharing system established in the CBD and the recently agreed Pandemic Influenza Preparedness (PIP) framework of the WHO, aiming to address access to virus samples and sharing of vaccines and other benefits.

Among the conclusions of the paper are that a comprehensive system to guarantee access/sharing of biological materials should include all pathogens rather than being confined to Influenza viruses and should explicitly address the issue of IPR. In particular, as regards policy proposals, an important distinction is made between those proposals compatible with the current IPR system (as embedded in the TRIPS agreement); and those that would require a reform of the current regime. While the meaning and scope of "access" remains difficult to define, and while some proposals (as the expansion of the "microbial commons") still need time to be fully developed, in some cases effective implementation is also hampered by problems of institutional design: one paramount example is the PIP framework, which did not established clear-cut rules to govern IPR issues. Moreover, some of the current proposals seem to overly rely on market-based mechanisms, while initiatives as the "scientific commons" are normally confined to low-value resources. One suggestion that emerges from the paper is that most proposals are valuable, but only if complemented by a thorough revision of current patent law and policy.

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1 INTRODUCTION

> *"No matter what one believes about the response to the 2009 pandemic by WHO and other authorities, all must be grateful that relatively few people died. Influenza viruses are notoriously unpredictable. We were lucky this time, but as the report concludes, the world is ill-prepared for a severe pandemic or for any similarly global, sustained and threatening public- health emergency."*
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> Harvey V. Fineberg Chair, Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009

The enactment of the TRIPS Agreement has generated a worldwide debate on patents and access to medical-related technologies, which poses an important challenge for Global Health Governance (hereinafter GHG). There is a surmounting although controversial claim that the current expansive trend in patent protection is obstructing access to knowledge. In particular, patent protection could impede access to basic research that was traditionally placed in the public domain in the biological and biomedical areas. Were these arguments truth, the expansion of proprietary rights over essential biomedical technologies and especially over research tools might contradict the central aim of patent law, which grants temporary exclusive rights in order to provide incentives to foster investment in R&D activity.

This debate on how to achieve a balance between fostering biomedical R&D and granting access to biomedical patented technologies has been raised in the context of three different cases. The first case, which has received most attention so far, is that of access to medicines for developing and least-developed countries in the context of increased patent protection, that is, a case of access to finalized products. The second case focuses on access to previous research for further development of biomedical innovations, that is, access to research tools (which could also or not be final products).

This paper concentrates on a third case of access to patents on technologies and products developed in the area of pathogens. This particular case of tension between patent protection and access to knowledge became evident during the potential pandemic influenza outbreak that captured the public attention in 2006[1]. In the middle of this

[1] A pandemic is difficult to define exactly, although it has been largely considered as an infectious disease outbreak, which reaches a vast geographical space. For a throughout discussion on the definition and description of a pandemic see Doshi, Peter, *The elusive definition of pandemic influenza*, available at http://www.who.int/bulletin/volumes/89/7/11-086173/en/index.html, who discusses among other things, how the WHO changed its definition of pandemic influenza from one that requie "several simultaneous epidemics worldwide with enormous numbers of deaths and illness" to a more flexible definition which would arise whenever "a new influenza virus appears against which the human population has no immunity." Importantly, pandemics can be more easily distinguished from annual epidemics of seasonal influenza as the former are rather infrequent. For a detailed account see http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf, describing the three influenza pandemics recognized in the 20th century which occurred during 1918–19, 1957 and 1968. Pandemics, by definition, can affect human populations throughout the world but the characteristics of each one of them, including

outbreak, the refusal to share viruses samples by the Indonesian government was seen as a possible threat to global health, especially as the virus threatened to mutate into a form allowing human-to-human transmission that could have potentially imposed a huge death toll. The Indonesian government argued that the international regulations at place did not oblige a country to share virus samples; that such materials could be used by pharmaceutical industries with the commercial purposes of developing vaccines whereas the government did not have any guarantee that Indonesia would have access to those vaccines at reasonable prices. The impasse was eventually resolved through negotiations at the WHO which lead to the adoption of a Pandemic Influenza Preparedness (hereinafter PIP) Framework, providing for alternatives to regulate the sharing of samples and issues of IP ownership through standard Material Transfer Agreements (MTA's).

This case involves multiple GHG concerns such as access to biomedical patented technologies, access to genetic resources and samples of virus strains, which are crucial to global trade and global health goals, including the attainment of socially productive R&D, sustainable development goals and the management of global pandemics. To be sure, access is a complex issue and has been addressed from multiple perspectives. Many policy proposals to improve access to biological materials and patents have been variegated, due to the multiple international forums and stakeholders involved. Purported solutions have included complements as well as substitutes to patent protection and have often put together mechanisms addressing innovation incentives and access, sometimes offering confusing policy suggestions to address the access problem.

So far, none proposal seems to have alleviated the problem of access to health-related patented technologies and materials. This could be due to the fact that some proposals need more time to bring about any improvement but some deficiencies of the proposals could also be related to the institutional design, including the multiplication of efforts sometimes in a duplicative way as well as the solutions being borrowed from different contexts of "the access problem". Just to mention a few, clearinghouses and patent pools, which have been used in domestic law to aggregate rights and reduce transaction costs have been suggested as a possible answer to the problems of global access to medicines and it is still debatable whether they have effectively contributed to this area. Open access, meaning a system borrowing from the "open source movement" has also been advanced as a possible solution for access to biomedical innovations and to foster research on neglected diseases. Whereas such mechanisms address the problem of access to patented technologies by follow-on innovators, they seem only indirectly aiming to improve access for consumers. Moreover, duplicative efforts are likely to be expensive and run counter to a more stable solution at the global level.

Problems related to the access to patents in the biomedical field have been indeed widely studied within different contexts. Nonetheless, the exact meaning of "access" remains difficult to define. Whereas economic and legal research has produced interesting conclusions, it is especially difficult to transform such conclusions into prescriptive guidance for policy makers, and this applies even more critically to discussions at the global level. The paper examines the mechanisms already in place to share virus samples and microbes and seeks to identify the challenges ahead for a robust global system especially on how a fair and equitable system for guaranteeing access to pathogens and benefit sharing from such materials could be developed and its implications for GHG. By using a definition of global health governance as the set of formal and informal institutions

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countries and segments of population mostly affected, their severity and the speed by which they are disseminated largely vary.

and processes, including the design, implementation and enforcement of policies that affect multiple stakeholders worldwide, I examine the issue of access to patents and biological materials from the perspective of the challenges for GHG. The paper is structured as follows. The first part introduces the case, the second part describes the problem of access to patents and materials and provides a law and economics framework for addressing this issue. The third part places the issue of access to pathogen materials into the current global health governance context. The fourth part describes the current global system. The fifth part examines whether the current system is capable of facilitating or is in fact hindering access to pathogen materials. The sixth part concludes by examining some alternative policy options to address this problem.

2 THE PATENTS AND "ACCESS" DEBATE

The patent system is largely justified as a mechanism to provide incentives for private actors to invest in research and development (R&D) activity. By granting exclusive rights to innovators, patent protection imposes a trade-off between fostering innovation incentives in R&D and providing access to new technologies. This economic rationale is especially defended in the pharmaceutical sector, where the development of a new drug is a particularly costly process, which includes not only the identification of new molecules but also the examination of their effectiveness and safety, through a highly regulated process that eventually culminates in the approval for commercial exploitation[2].

During the past decades, a trend towards increasingly protective IPR standards has been described as a "second enclosure" movement, a label given after the first enclosure movement which took place with the took place in England beginning in the fifteenth century and lasted through the nineteenth century constituting a long process by which common land was fenced into private property. The historic enclosure of common land is similar to the new process of privatization of knowledge by means of IPR protection and the subsequent shrinking of the space known as public domain[3]. During the last decades, a surmounting debate has given raise to a social movement named access to knowledge (A2K) that has extended its action over different areas:

"A2K is an emerging mobilization that includes software programmers who took to the streets to defeat software patents in Europe, AIDS activists who forced multinational pharmaceutical companies to permit copies of their medicines to be sold in South Africa, and college students who have created a new "free culture" movement to "defend the digital commons"—to select just a few. A2K can also be seen as an emerging set of theoretical commitments that both respond to and reject the key justifications for "intellectual property" law and that seek to develop an alternative account of the operation and importance of information and knowledge, creativity and innovation in the contemporary world"[4].

When it comes to biomedical patented technologies, the debate on patent protection and access to technologies is particularly complex due to several reasons. Firstly, the debate

[2] See information on clinical data trials; US Food and Drug Administration (FDA) and the European Medicines Agency EMEA.
[3] See James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 J.L. & CONTEMP. PROBS. 33, 45–46 (2003).
[4] Gaëlle Krikorian and Amy Kapczynsky (eds.), *Access to Knowledge in the Age of Intellectual Property*, Zone Books, New York, 2010.

reflects the complex nature of biotechnologies, which often possess a dual nature: most biotechnologies are tools for further biological research (creating a need of access by other researchers) and at the same time also finalized products (creating a need of access by consumers)[5]. Secondly, biomedical technologies are often surrounded by important ethical debates that have sometimes captured most of the attention of policy-makers in detriment of issues of access[6]. Thirdly, the economic effect of patents and the real impact of the trade-off between innovation incentives and access to innovation is theoretically straightforward but difficult to determine empirically. Hence the costs and benefits of patent protection are mostly a guess that extends over a fairly long period of time and is unevenly distributed among countries or between producers and consumers in a domestic market.

To sum up, access to patented technologies in the biomedical field has repercussions at multiple levels and affects diverse stakeholders and has gained more importance as new medicines are increasingly based upon biological research and materials[7]. At the global level, the issue has been mainly placed within the context of access to medicines. Lack or insufficient access to medicines is a problem that disproportionally affects poor countries while the purported benefits of patent protection for poor countries might be insignificant for two inter-related reasons. Firstly, patent protection cannot provide enough incentives for R&D activity in neglected diseases (i.e. tropical diseases or diseases affecting poor countries), because of the small market size and/or limited willingness to pay of potential consumers of such products. Secondly, research has growingly underscored, especially after the signing of the TRIPS Agreement, that poor countries might not gain much out of the patent protection trade-off in terms of building technical capabilities and providing incentives for their own industries to develop[8]. On the contrary, at the cost-side, patent protection leads almost certainly to higher prices for patented medicines. These issues have led to increasing opposition against negotiations for more protective commitments called TRIPS-plus and included in free trade and bilateral investment agreements[9].

At the domestic level, a similar debate has focused on whether patent protection foster or hinders further development of biomedical innovations. Several scholars have warned about the possibility that the increasing number of patents granted during the last decades could end up creating a "tragedy of the anti-commons", hence impeding scientific progress[10]. While some empirical studies have evidenced that more than patent protection,

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[5] See Dreyfuss, Rochelle, *The Patentability of Genetic Diagnostics in U.S. Law and Policy* (September 16, 2010). Pharmaceutical Innovation, Competition and Patent Law - A Trilateral Perspective, Josef Drexl and Nari Lee eds., Edward Elgar Publishing; NYU School of Law, Public Law Research Paper No. 10-68; NYU Law and Economics Research Paper No. 10-44. Available at: http://ssrn.com/abstract=1678123

[6] Such debates, which were especially present during the long discussion preceding the adoption of a Biotechnology Directive in the EU, include the patentability of human genes, patentability and experimentation with transgenic animals and plants, the field of stem cells research (especially when it comes to experimentation on the basis of embryonic stem cells) and the development of genetic diagnostic tools that allow prenatal control, among other fields.

[7] For instance, the emerging field of pharmacogenomics aims at matching specific therapeutic drugs to the genome of the patient and is obviously based upon genetic information that might often be patented. See Rebecca Eisenberg, *Will pharmacogenomics alter the role of patents in drug development?* 2002.

[8] Clearly a distinction should be made between developing countries with industrial capabilities and those lacking sufficient capabilities to develop their industry, especially least developed countries.

[9] See in particular, the TPP currently under negotiation as well as other FTA's with the EU and the U.S.

[10] For the general theory of anti commons see Michael Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets* (1998), Harvard Law Rev, N. 3, 111, 621– 688; for an application to the biomedical sector and patenting see Michael Heller and Rebecca Eisenberg, *Can Patents Deter Innovation? The anticommons in Biomedical Research*. Science 280, 5364 (1 May 1998).

it is restrictions on the use of biological materials that might be obstructing biomedical research[11], other studies have underscored the effect that patents have on the negotiation of material transfer agreements, which suggests that access to patents in effect interacts with access to biological materials and the interface between the two issues is indeed a more complex issue than it seems at first sight[12].

Finally, the debate on access to "genetic resources" illustrates another important conflict regarding patent protection and access to knowledge. The use of resources originating in biologically diverse countries has been controversially regulated by the Convention on Biodiversity, among other rules through a system of "access and benefit sharing" (ABS) [13] and has been the object of hectic negotiations at the WIPO and WTO on the clash between IPR protection and the principle of sovereignty of national biological resources. The use of genetic resources and traditional knowledge, the creation of ABS mechanism and the purported cases of bio-piracy are all issues placed at the intersection of the controversy between patent protection and access to biomedical technologies and materials. Moreover, the negotiation of treaties, especially at the bilateral and regional levels has often confronted developed and developing countries with controversial demands on public health safeguards of patent protection and biodiversity related provisions.

A particular conflict between patent protection and the sovereignty over national resources arose during the 2007 avian influenza A (H5N1) outbreak when Indonesia announced that it will not continue to share biological samples of avian with the World Health Organization (WHO). Such decision was motivated by the perception that the WHO sharing system was unfair to Indonesia since this country provided samples of the strains appearing in its territory. The samples were latter shared with pharmaceutical companies developing influenza vaccines and seeking patents on such vaccines in order to commercialize them at high prices, making the final products inaccessible for countries such as Indonesia. The issue confronted two important goals of global public health. The first is that of developing effective strategies to fight a potential pandemic. The second is a purportedly inequitable system in which developing countries share biological materials and samples that are latter on protected by expanding patent rules without any equitable sharing of the benefits.

These three cases illustrate how the term access is used in several contexts within the global arena. It can refer to access to the raw ingredients for research, including genetic resources from biodiversity-rich countries and traditional medicine. It can also be used as access to knowledge as in the debate over the protection of basic and applied research. Finally, it is used to refer to access to the final product as in the patent protection and access to medicines debate. Throughout this paper, access and sharing are used in the same form as they have been used by the Institutional forums involved in this issue, that is sharing of influenza viruses and access to vaccines and other benefits. It is noticeable that the word access emphasizes a one-way process whereas the word sharing suggests a reciprocal exchange.

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[11] See Rebecca Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1063-75 (2008).

[12] See Lisa Larrimore Ouellette, *Access to Bio-Knowledge: From Gene Patents to Biomedical Materials*, 2010 STAN. TECH. L. REV. N 1. 5 A solution is still under international negotiations, including within the context of the recently held "Ninth meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing", Nagoya, Japan, 13-15 October 2010 on the "Revised draft COP-10 decision on Access and benefit-sharing", available at: https://www.cbd.int/doc/?meeting=ABSWG-09-3RD

[13] See Lori Andrews and Laura Shackelton, *Influenza genetic sequence patents: where intellectual property clashes with public health needs*, Future Virol. (2008), 3(3), 235-241.

With regard to the terminology used throughout this paper an additional foreword is needed. Although the issue of patenting and having access to biological materials, including pathogens has been increasingly the object of analysis, there is not unitary definition of what constitutes biological materials. Nonetheless, important Agreements in the patent field have defined the terms that we mention throughout this paper. The European Patent Convention defines biological material as "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system"[14]. The CBD also gives a definition for the following terms: biological resources "includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity"; genetic material "means any material of plant, animal, microbial or other origin containing functional units of heredity"; and genetic resources "means genetic material of actual or potential value"[15]. The importance of a comprehensive definition of biological and genetic materials, is that, as we will discuss below, a global system for access and benefit sharing of pathogen materials should probably be broad enough to include all living forms, and not only influenza viruses, as well as to accommodate and possibly to anticipate new techniques in order to be more coherent and forward-looking.

2.1 Access to biomedical patents & materials: public and private goods

The ambiguity that surrounds the patents and access discussion suggests that in addition to a prelude over the terminology used, it is also important to provide a foreword on the theoretical framework to be applied. In order to structure the discussion that follows, this section uses economic analysis as one out of the multiple frameworks that could shed some light in the analysis of the different cases of access to patented technologies and materials.

An important concept in law and economics is that of public and private goods and intermediate categories in-between. Public goods in the economic literature have two characteristics. Firstly they are non-rival, which means that their use by one agent does not diminish the potential utility that other users could have. Secondly, public goods are non-excludable, which means that it is impossible to appropriate them and hence to exclude other users. Typical examples of public goods are natural goods such as the air or the sunlight and public services such as national defence, which are provided by States precisely because a person or group of persons could be hardly excluded from benefiting from the effects of defence and the enjoyment by some people would not impose any decline in utility on other users. On the other side of the spectrum we find private goods, which are rival and excludable by nature, the typical example being that of consumption goods, including food and other goods that can hardly be shared and for which users can be easily excluded. Public knowledge is a paradigmatic example because once an invention,

[14] Rule 26 (3) of the European Patent Convention. Rule 31 provides for a mechanism to ensure the deposit of biological material for which a written description would not otherwise enable an expert in the field to carry out the invention. See also the definition contained in the U.S. MPEP 2403, 37 CFR 1.801 defines "Biological material" as including "material that is capable of self-replication either directly or indirectly. Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds. Viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material". Such definition is however only intended to address procedural matters arising from the deposit of such biological materials for the purposes of patenting an invention and satisfying the requirements of enablement, written disclosure and best mode and does not refer to any substantial consideration with regard to the patentability of such materials.

[15] See the Convention on Biological Diversity, available at: http://www.cbd.int/convention/text/

a theory, or an type of information is made public, no one can (in the absence of IPR) exclude other users from benefiting and profiting from such knowledge. On the other hand, information is non-rival and the more it is used, the more it will probably generate more utility to other users as it is by definition the raw material to advance more and deeper knowledge.

In fact, the economic rationale for creating a system of IPR is precisely that in the absence of exclusive rights, any person would be able to use knowledge produced by others, something that in the short run might yield a higher social benefit but in the long run might threaten to destroy *ex ante* incentives to invest in R&D activity. Hence, the IPR system transforms a pure public good into an excludable good. The issue is far more complex, especially regarding basic science, as most scientists and researchers are moved by incentives other than economic profits, including reputation and other prizes given for publication of new knowledge. Incentives created by IPR systems are targeted to provide incentives for the private sector, which invests in R&D activity as a profit maximizing strategy. With time, legislation extending the possibility to patent for universities and public research centres have also been charged with changing the science ethos in the sense of substituting non-economic with economic driven incentives[16].

Between these two extreme categories we also find at least other two types of goods, called common resources (pools) and club goods. Common resources are those non-excludable but rival in use, with the typical example of fisheries and other natural resources that with time can be finished by users. Club goods are those, which are easy to exclude but that, at least up to a certain point, could be enjoyed by more users.

Table 1: public and private goods

Goods	Non-rival	Rival
Non-excludable	Public good	Common resource
Excludable	Club good	Private good

The study of common good resources has lead to a particularly fruitful literature starting from the seminal study by Hardin, which firstly described the "Tragedy of the commons"[17] when a group of individuals share a resource in common. In these cases, each individual could use the resource in a manner that maximizes her own utility but this might lead to an over-use of the resource and its eventual extinction. Typical examples of common good resources are fish and other natural resources subjected to the uncontrolled consumption by a group of individuals. The economics literature has described this case in the context of a more general behaviour named as "free riding", by which the individual takes advantage of the work done by others. In the case of a good held in common, this could be exemplified by the over-use of resources but in the specific case of knowledge, free-riding usually refers to the appropriation of other's effort without contributing or with a small contribution. In the long run, free-riding could diminish *ex ante* incentives to innovate and share knowledge if, hence giving raise to the typical rationale for IPR protection.

In the context of the present discussion, it is important to define and differentiate two different types of goods: biological knowledge and biological materials. Knowledge embedded in patented technologies is a typical example of a public good, which has been

[16] See for instance, James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 Law & Contemp. Probs. 33, 45–46 (2003), arguing that there are important non-economic motivations behind knowledge production, creativity and innovation activities.
[17] See Garret Hardin, *The Tragedy of the Commons*, Science 162, 1243 (1968), available at: www.sciencemag.org/sciext/sotp/pdfs/162–3859–1243.pdf.

made excludable by means of IPR. More specifically, in the biological field, the target of innovations has increasingly switched from living materials and organisms to information encoded by living organisms and their biological molecules in the form of sequences of nucleotides contained in DNA or RNA, polypeptides and other molecules. The patent system creates also an important distinction between information which is not-patented and hence pertains to the public domain and information which is subject to patent protection. In addition to patent protection, it is also important to consider that an important amount of information for biological research might increasingly be covered by data protection (as it is the case with the database Directive in the EU).

Biological materials are slightly more difficult to categorize. On the one hand, samples of biological material are a rival and excludable good. On the other hand, and as mentioned above, biological research has allowed scientists to decipher in great part the messages carried by information molecules such as DNA and RNA. Such information is now available in the form of sequences of nucleotides and other biological molecules, making it possible to say that up to a certain extent, biological materials are now also information, a *quasi* public good.

In addition, samples of pathogen materials can consist either on a single strain or a collection of strains. Previous studies have found that while informal exchanges of single strains among researchers take place without problems, requests for collections are usually complicated due to the fact that the same researcher might be needing the material in the future for continuing her own research[18]. It could be then argued that samples of single strains are near to the point of the spectrum occupied by public goods whereas collections of strains are at the other point of the spectrum, near to private goods where use is rival in nature and users can be easily excluded from access.

Summing up, in the context of pathogen materials, which includes but is not limited to influenza viruses[19], we find information (genomic) or knowledge, which can either be protected or not by IPR; and biological materials or samples, which tend to be more excludable and rival in their use than information. With the development of such new fields of research as genomics and synthetic biology, goods that were previously considered as traditional private goods might be moving along the spectrum and becoming pieces of information that might be shared potentially in a limitless manner, save for the protection of IPR.

2.2 Sharing influenza samples and Access to vaccines and other benefits

In May 2007, the Indonesian government refused to send influenza samples originating from patients in Indonesia to the network managed by the WHO, which was in charge of monitoring Influenza outbreaks and guaranteeing access for specialized laboratories to virus samples. This controversial move by the Indonesian government came in the middle of a potential H5N1 pandemic and triggered a global debate on the efficiency and fairness

[18] See Dedeurwaerdere, T., 2010. *Global microbial commons: institutional challenges for the global exchange and distribution of microorganisms in the life sciences*, in Research in Microbiology 161 (6): 414-421.

[19] In this paper we focus on the case of influenza samples, which has been the center of a recent discussion towards building an international framework to guarantee a balance in the sharing of samples and the access to benefits deriving from the samples, such as vaccines, antiviral drugs and diagnostic tools. Nonetheless, most of the problems arising in this context can be applied more generally to other microbes and also to other types of biological materials.

of a system that guaranteed access to virus samples but did not provide any rule favouring access to vaccines or a share in the economic benefits deriving from the use of those virus samples.

Following Indonesia's refusal, WHO member states started negotiations on a Framework to regulate the sharing of virus materials and access to vaccines and other benefits as well as to strengthen influenza surveillance and responses (PIP Framework). The main purpose of the PIP Framework is to give incentives for countries to share Influenza samples, especially by including some (loose) rules on access to vaccines and other benefits deriving from the samples. Nonetheless, preparedness for a potential pandemic influenza (and a similar reasoning could be applied to any other virus-transmitted pandemic), also requires rapid and comprehensive access to any available vaccine or treatment[20].

In preventing and controlling a potential pandemic it is fundamental to guarantee the sharing all available strains of a virus, which are the rough resources that might be used for the purposes of surveillance and management, as well as for the development of related vaccines, treatments and diagnostic tests. In addition to these concerns, developing countries claimed an equitable share of the benefits arising from and more access to, vaccines, drugs and tests developed by the users of virus samples circulated under the WHO framework. Hence, the issue was initially presented as a rather limited case: that of sharing influenza virus samples between countries of origin of such materials and countries that might eventually use such samples to develop vaccines and other therapeutic responses. Nonetheless the topic raises a host of broader questions.

To start with, influenza virus are just a type of multiple pathogens that might be used for developing drugs or vaccines[21]. One could only hypothesize the reasons why influenza virus has been the core of such sharing mechanism. Influenza viruses are used to develop a seasonal influenza vaccine, which is updated yearly with samples of viruses circulating around the world. This seasonal vaccine is mostly commercialized in developed countries, and constitutes a business growing at an impressive rate[22]. In addition to the seasonal vaccine, there is also an important public health and commercial interest in developing vaccines for specific strains as it was the case with the H5N1 outbreak or the H1N1 pandemic. In fact, the subsequent 2009 H1N1 pandemic was surrounded by allegations of

[20] For instance, although anti-retrovirals such as Oseltamivir (better known by its brand name "Tamiflu") does not prevent or cure the influenza, it could diminish its symptoms while helping to contain a possible pandemic outbreak.

[21] As Professor Abbott argues: "Influenza viruses are the subject of particular attention because of the rapid transmission and onset of disease symptoms. Yet, throughout human history outbreaks of plague, smallpox, polio and other pathogen-caused pandemics or epidemics show that influenza viruses are not the only type of pathogen for which new drugs and vaccines are urgently required. Special risks are presented by pathogens that cause diseases with very high mortality rates in humans, such as the Ebola virus".

[22] See *Influenza Vaccine Market Opportunities and Challenges: Worldwide Forecast,* Renub Research January 5, 2012, available at: http://www.marketresearch.com/Renub-Research-v3619/Influenza-Vaccine-Opportunities-Challenges-Worldwide-6743344/, referring that: "Last few years have seen renewed interest in the vaccines market, overcoming the prevailing view that vaccines are a low-margin business with high barriers to entry. The flu vaccines market has been at the forefront of this trend, partially fuelled by the fear of an impending pandemic. As a result global influenza vaccine market has experienced phenomenal growth in recent years at a compound annual growth rate of more than 65% between 2008 and 2010. This growth was mainly driven by the global spread of H1N1 influenza. But in the year 2011 H1N1 pandemic flu vaccine market declined due to waning threat of swine flu disease. However seasonal influenza vaccine market is predicted to grow year on year and cross US$ 4 Billion by 2015"

commercial objectives and conflict of interest behind the recommendations of the WHO on the wide use of vaccines[23].

A second important extension of the problem goes beyond the "North-South" label that it initially had. A framework for sharing influenza samples is not only about developing countries threatening to withhold resources and developed countries trying to assert IP rights over such resources on the other. Indeed, pathogens could originate anywhere in the world and also cross frontiers within a fairly limited period of time. As a result, the issue might confront the interests of different developed countries as well[24].

Finally, by analysing this specific case in the context of the A2K debate, the potential effects of strengthening patent protection and the increasing substitution of non-economic motivations with economic incentives in scientific research are emphasized.

2.3 Ownership and proprietary rights over biological materials and pathogens

Following the above distinction between patents and materials, two different types of proprietary issues arise in the context of pathogens. The first question arises with regard to the sources of origin of the materials and their subsequent economic exploitation, including by IPR protection. When biological materials originate for instance from human tissues, there have been debates over the conditions through which such materials should be obtained, including whether prior informed consent of donors and the sharing of economic benefits deriving from patentable innovations based on said biological materials should be required.

Several decisions have addressed these questions in slightly different contexts[25]. One of the first cases on this matter, decided by a U.S. Court, confronted the claims of researchers from the University of California with a donor of tissues that were fundamental for the development of a special line of cells[26]. In this and subsequent cases, different U.S. courts rejected claims of donors that participated to similar types of research to any proprietary right over the biological materials they had donated. Some courts based their decisions on public policy reasons warning against granting control to participants of research over their biological samples[27]. However in some cases, courts suggested that the doctrine of unjust enrichment could be applied to the use of biological material when the use of said material had generated economic profit, hence allowing donors to obtain a monetary compensation[28].

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[23] See Dr. Margaret Chan, Open Letter to the Editors of the British Medical Journal (BMJ), 8 June 2010, responding to allegations of conflict of interest.

[24] See Abbott, op. cit. "Exclusive control over biological samples by a single developed country may prevent other developed countries from pursuing alternative avenues of research, of from developing and manufacturing drugs and vaccines for their own (or foreign) populations. It may be short-sighted to view the creation of a pathogen material-sharing mechanism through the lens of a North-South dialogue".

[25] Greenberg et al. v. Miami Childrens Hospital Research Institute, 264 F. Supp. 2d 1064,SD. Fla. 2003; Washington University v. Catalona, 437 F. Supp. 2nd 985, E.D. Mo. 2006, http://www.circare.org/lex/03cv01065_ opinion.pdf.

[26] Moore v. The Regents of the University of California 51 Cal. 3d. 120, 793 P.2d. 479, 271 Cal. Rptr. 146, CA. 1990).

[27] See Washington University v. Catalona.

[28] See Greenberg et al. v. Miami Childrens Hospital Research Institute, op. cit.

The second important proprietary aspect in this field refers more directly to the patentability of biological technologies. The history of modern biotechnologies is usually associated with early patents granted during the 70's to methods, such as the technique of recombinant DNA, which allowed further development of this area[29]. In 1980, the U.S. Supreme Court decided on a land marking case on the patentability of living matter, in particular a bacterium derived from the *Pseudomonas genus*, which was capable of disintegrating crude oil, and hence potentially useful for treating oil spills[30]. This decision as well as follow-up developments led to the possibility of patenting biological materials, including gene sequences and other related materials.

Nonetheless, there has been an incessant controversy surrounding the issuance of such patents, especially but not limited to patents on human genes. Most of the controversy has emerged not only because of broad ethical concerns but also because of the use of particularly restrictive practices and licensing agreements that might encumber further R&D activity. In fact, a recent controversial decision in the field was taken on the case of patents covering a diagnostic genetic test for BRCA1 and BRCA2 genes associated with the susceptibility to breast and ovary cancer by a company accused of adopting restrictive licensing practices[31].

The controversy has not been limited to the U.S. and Europe[32]. For instance, a recent Bill proposing an amendment on the Australian Patent Law, sought to ban the patentability of all biological materials as unpatentable matter. The Bill generated considerable debate, including on the broadness of the proposed definition of biological materials[33]:

"biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature"

Likewise, the debate on the protection of genetic resources and biological resources in the context of the CBD has focused on the sovereignty rights of the country of origin of such

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[29] In addition to recombinant DNA, other techniques such as polymerase chain reaction (PCR) also allowed researchers to carry on research on living organisms at a genomic level.

[30] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[31] See Association for Molecular Pathology et al. v. United States Patent and Trademark Office, et al. (USDC SDNY 09 Civ. 4515, 2010), holding that isolated DNA is not patentable in the U.S. and that method claims relevant to testing for *BRCA1* and *BRCA2* genes were invalid. The decision of the district court was based upon the reasoning that isolated DNA and cDNA are not sufficiently different from DNA as it occurs within their host cells to be considered an invention. While the Court of Appeals partially retreated from the decision by the district court, a decision by the U.S. Supreme Court.

[32] In Europe, ethical concerns were largely the reasons why the Biotechnology Directive took long time to be adopted and implemented. In addition, the European Patent Office revoked and then reissued in part the patent on a method for genetic diagnosis of breast and ovary cancer owned by Myriad Genetics, mainly motivated by public health concerns. The decision followed a procedure initiated by several medical institutions for research and simultaneously, the opposition process triggered a legal reform to expand compulsory licenses to *in vitro* diagnostic methods for public health purposes in Belgium, France and the Netherlands. In Canada, the patent was refused and a reform to Canadian Law was also suggested to allow opposition of patents and to restrict broad patents.

[33] See Australian Law Reform Commission. ALRC 96, *Essentially Yours: The Protection of Human Genetic Information in Australia* (Sydney, Australia, 2003), available at: http://www.austlii.edu.au/au/other/alrc/publications/reports/96/. For a discussion on the proposed Bill see Vaughan Barlow, *Mumbo jumbo: The patentability of biological materials in Australia*, arguing that such Bill would jeopardize the development of the biotechnology industry and that it also might be in contradiction with the obligations arising from the TRIPS Agreement article 27, as the limitations there embedded are supposedly narrower than the proposed ban of the Australian Bill.

resources and their possible clash with patent rights over technologies based upon such resources. Hence, the ownership debate is not only limited to two different contexts such as sources of origin and patentability of biological materials and resources but also to the ownership either by countries or by individuals of these materials and patents with options that have only increased with time. In fact, ownership rights consist on a bundle of different rights that might be held together or might be sold, assigned or licensed. Hence, when analyzing proprietary rights over patents and materials, it might be countries, individuals or even networks of research or collections that hold some of these rights included in the bundle called property, such as the right to access, to contribute or participate to a research, to exclude others from the use or to sell the rights totally or in part[34].

3 ACCESS TO PATHOGEN MATERIALS IN A GLOBAL PERSPECTIVE

Global governance has been the object surmounting interest during the last decades. In effect, the process of globalization has accelerated and public health has not escaped this trend[35]. Globalization has also been accompanied by an increasing involvement of different actors in setting up the rules and institutions that manage many of today's regulatory challenges with the consequential focus of attention switching from government to governance[36]. In spite of its widely increasing use, there is not univocal definition for the term "global governance". For the purposes of this paper, a broad definition of global governance including all global rules and institutions, which aim at tackling some collective problems in the pursuit of common goals at the global level is followed, hence following a definition broader than international law or global law.

3.1 From International Health to Global Health Governance

Public health has not been isolated from the process of globalization which has shaped most international institutional settings. Traditionally, health has been a domain for national, regional and local authorities. Nonetheless, early forms of international health governance arose much earlier than the current wave of globalization. Early initiatives to tackle hygiene and disease control were developed during the nineteenth century, precisely with the emergence of European Institutions aiming at the promotion of peace and

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[34] See Charlotte Hess and Elinor Ostrom, *A framework for analyzing the microbiological commons*, analyzing only digital material shared in the global microbiological commons (not biological material) and arguing that a bundle of rights can be held by different actors: "as a commons or a common-pool resource, different parts of the MC (Microbial Commons) may be owned by national, regional or local governments; by communal groups ; by private individuals or corporations; or used as OA (Open Access) resources by whomever can gain access.

[35] Globalization is now a pervasive concept in almost every social science discipline although there is not consensus on its definition. For the purposes of this paper, it is sufficient to point globalization as a dynamic process that associated with the increasing easiness of exchange across national frontiers that has pervaded every historic period but has been accelerated by technological and institutional changes occurring during the last few decades, including the abolition of trade barriers, harmonization of rules and standards and lower costs of movement of goods and persons. For a thorough analysis of the concept of globalization and global governance in the IP field see Oguamanam Chidi, *Intellectual Property in Global Governance, A Development Question,* Routledge Research in Intellectual Property Series, London 2012.

[36] Richard Dogson, Kelley Lee and Nick Drager, *Global Health Governance, A Conceptual Review,* Discussion Paper N° 1, February 2002.

industrial development[37]. From the mid-nineteenth century, there was also an increasing involvement of institutions, rules and mechanisms to protect health, apparently as a consequence of the increased globalization of health during that period but also due to the expansion of international trade and the cross-border spread of infectious diseases. Since this early period, however, it was emphasized that actions at the level of IHG would principally consist on cooperation to facilitate the task of national governments:

"As such, the institutions adopted were envisioned as an extension of participating governments' responsibilities in the health field to the international (intergovernmental) level"[38].

At the same time, there was an enhanced interest in sharing knowledge between an emerging scientific community. It is probably not a coincidence that this historical period witnessed scientific advances in the understanding of the causes of diseases, specially those caused by microbes. An important number of international conferences on health took place during these years and the establishment of the Health Organization of the League of Nations in 1920 marked a first step towards building a network of global health institutions. Also by that period, the private sector started to actively contribute to the health debate. At that time, the scope of IHG was mainly conceived in humanitarian terms[39] and the emerging vision of social medicine throughout the scientific community increasingly adopted a criterion of universality, understood as the involvement of as many countries as possible in the setting up of institutions and rules, as the guiding principle.

After the war period, the most important trend on IHG was probably the expansion of the involved institutions. The World Health Organization was created in 1948 as a specialized UN Agency focusing on health. However, other related institutions under the UN umbrella were also involved in health issues. The 1948 Constitution of the WHO states that its goal is "the attainment by all peoples of the highest possible level of health". Health is at the same time understood in the WHO Constitution as "a state of complete physical mental and social well being and not merely the absence of disease", a clear move from a state-centered to a person-centered vision in International Health, at least at the level of settled goals[40]. Nonetheless, the means to achieve such "universal" right to health still was heavily entrenched on the involvement of governmental institutions:

"universality in this sense, is measured by number of member states. Where a large number of countries participate, such as the World Health Assembly (WHA), it is assumed that the health needs of all peoples are represented. The role of WHO, in turn, is designed as supporting the efforts of governments to promote and protect the health of their populations"[41]

An important step in the transition from IHG to GHG was represented by the increasing participation of NGOs and other International Organizations within the scope of the WHO. By 1998, at least 188 NGOs were registered in official relations with the WHO, including NGOs with such diverse scope as health, science, law, humanitarian health and industrial organizations. Such participation however, still remains more important at the theoretical

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[37] Dodgson, Lee and Drager, *Global Health Governance, A Conceptual Review*, Discussion Paper N° 1, February 2002, at p. 9.
[38] Ibid at p. 9.
[39] Ibid at p. 10.
[40] The universalism of the WHO's commitment has been also clear in the 1970s declaration of Health For All strategy and the 1990s Renewing Health for All Strategy, Ibid at p. 11.
[41] Ibid at p. 11.

than at the practical level with NGOs acting mainly as observers of the WHA or meetings of the regional committees and having limited access to meetings dealing with more specific scopes and operational nature.

In addition to the increasing importance of the role of non-state actors, other international organizations outside of the health field have increased their participation in the governance of health. Institutions pertain to such divergent areas such as the World Bank in the field of financial resources, institutions from the UN system as the UNICEF, UNDP, UNFPA, and also the OECD and the WTO, which have also engaged into policy recommendations and actions directly affecting public health. Hence, we can argue that while the defining characteristic of IHG was the importance given to state actors in spite of the increasing co-involvement of non-state actors, the subsequent wave of globalization accentuated the need to move from a state-centric towards a multi-layered system of GHG.

In addition to the multiplication of actors at the global level, the move from "international" to "global" health governance may be characterized by the incorporation of a broader set of issues, which cross the interfaces between international trade, human rights and health, among other traditional non-health issues. Such incorporation means in many cases to move from an individual to a collective perspective with regard to the determinants of health. In a nutshell, if the issue of preventing infectious diseases was earlier approached through a series of preventive measures centered on the individuals subject to risk factors, in a global health perspective we would also wonder what is the role of international trade and other cross-border exchanges in the transmission of infectious diseases:

"the distinction between global health and international health therefore is that the former entails a broadening of our understanding of, and policy responses to, the basic determinants of health to include forces that transcend the territorial boundaries of states. Global health requires a rethinking of how we prioritise and address the basic determinants of health, and engagement with the broad range of sectors that shape those underlying determinants"[42].

3.2 Access to scientific materials in a globalized health system

Whereas broadening the scope of action as well as the actors involved in GHG certainly contributed to the understanding of most public health issues, at the same time, however, it also complicated the institutional landscape. As a consequence, global action is needed to regulate some public health issues, especially those at the interface between international trade and public health[43] but such complicated landscape is nowadays in need of a coherent framework. A special concern at the intersection of trade and health regards precisely the issue of access to health-related technologies and how patent protection and the TRIPS Agreement can interact with global health objectives. The inclusion of health concerns within trade negotiations was initially rejected as a non-trade issue and also due to the fact that many countries gave priority to trade-related negotiations over public health and other global concerns. However, during the past few years and especially after the Doha Declaration, there has been a flourishing global discussion on the intersection between IP protection and public health.

[42] Ibid at p. 13.

[43] Areas of common work have been identified for instance at the Council of the WTO where the WHO holds official observer status and within the WTO committees relating to the Agreements on Sanitary and Phitosanitary measures (SPS) and Technical Barriers to Trade (TBT).

In spite of this evolution, the GHG system still lacks a coherent framework to regulate most of the challenges of increased globalization, including the tension between trade-related rules and the protection of public health. Some of the problems faced by GHG include institutional problems such as leadership and accountability, transparency, monitoring and enforcement of the involved institutions, of collaboration and coordination of multiple players, of guarantying basic needs and closing the gap in health and the funding of GHG problems as well as the incentives necessary to involve private funds and public-private partnerships to harness creativity, energy and resources for GHG[44]. In sum, while the current GHG is rich in rules and institutions, it still lacks a "coherent framework"[45] Focusing on the case of devising a system to facilitate access and sharing of pathogen materials, it can be argued that such framework is needed in order to balance the multiple interests involved and the variety of rules and institutions in place:

"What may be at least somewhat unique about the present situation surrounding pathogen materials is the concurrent negotiation of complex agreements on the subject in several international institutions, with modest attention paid so far to how the resulting agreements would interoperate" [46].

The following sections examine the role of global rules and institutions, which are relevant to the problem of reconciling patent protection with access to health-related technologies, specifically in the case of pathogen materials.

4 GLOBAL RULES AND INSTITUTIONS REGULATING THE ACCESS AND SHARING OF PATHOGEN MATERIALS

Even in the absence of a coherent legal framework, multiple rules and institutions are currently contributing to govern the issue of access and sharing of pathogen materials. This section examines the particular set of rules that deal with this case, namely, the Pandemic Influenza Preparedness (PIP) Framework developed in 2011 under the auspices of the WHO that seeks to incentivize the sharing of influenza viruses through a network of laboratories and research centres.

4.1 The WHO network: from Influenza surveillance to vaccine access

The WHO set a network already in 1952 known as the Global Influenza Surveillance Network (GISN), which was in charge of monitoring the changes in influenza virus in the human population and ensuring the effectiveness of vaccines[47]. Following the adoption of the PIP Framework in May 2011, the Network is know named Global Influenza Surveillance and Response System (GISRS). Similarly to its predecessor, the GISRS is in charge of monitoring the evolution of influenza viruses and issuing recommendations with regard to laboratory diagnostics, vaccines, antiviral susceptibility and risk assessment as well as managing a global alert mechanism for the emergence of influenza viruses with

[44] U.S. Report, p. 207.
[45] Ibid, suggesting that there is not lack of institutions but on the contrary, a wild proliferation of initiatives that however are not solving the "global health crisis".
[46] Frederick M. Abbott, *An International Legal Framework for the Sharing of Pathogens: Issues and Challenges*, ICTSD, Issue Paper N° 30.
[47] http://www.who.int/influenza/gisrs_laboratory/en/

pandemic potential. The current network comprises six WHO Collaborating Centres, four WHO Essential Regulatory Laboratories and 138 institutions in 108 WHO Member States, which are recognized by WHO as National Influenza Centres, in addition to *ad hoc* groups established to address specific emerging issues.

The GISN functioned as an effective mechanism to ensure that samples of virus from infected patients could be sent to specialized laboratories. In this way the system allowed diagnostic and risk assessment activities as well the development of vaccines for the seasonal Influenza[48]. Although the system was not mandatory, it continued to work during the following decades. Nonetheless, the legal status of the obligations under the GISN are actually a contentious matter. Some scholars have argued that the sharing of virus samples constituted an uniform and consistent practice[49], which had not been contested before the Indonesian episode. This position would also be sustained by a particular interpretation of the International Health Regulations 2005[50], which established the obligation to contribute with the surveillance of public health emergencies as comprising a duty to share relevant biological samples[51]

Other scholars have sustained that the preceding WHO network was neither organized as a treaty law nor as customary law[52]. This view is supported by a different interpretation of the IHR 2005 that considers that contributing to surveillance and providing public health information is a different duty from granting biological samples of relevant material and also by the application of the principle of sovereignty over natural resources as developed by the Convention on Biological Diversity[53].

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[48] See International Federation of Pharmaceutical Manufacturers & Association, Influenza Vaccine Supply, See also Vezzani Simone.

[49] See Vezzani, op. cit, p. 677 and footnote 4, arguing that " it is worth noting that, for decades, no state unequivocally manifested a refusal to accept the unwritten rule establishing a duty to share influenza viruses with WHO".

[50] World Health Organization. Revision of the International Health Regulations, WHA58.3. 2005. Available at: http://www.who.int/gb/ ebwha/pdf_files/wha58/wha58_3-en.pdf

[51] See Sedyaningsih, E. R., et al., *Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Influenza case of Indonesia*, Annals of Medicine, 37 (6), 482-8, available at: http://www.annals.edu.sg/pdf/37VolNo6Jun2008/V37N6p482.pdf, arguing that: "The first interpretation was that IHR 2005 requires a country to share relevant biological samples as part of the duty to provide WHO with accurate and detailed public health information about all events that might constitute a public health emergency of international concern (PHEIC). Although IHR 2005 does not literally or specifically express the requirement for sharing of biological samples, this school of thought believes that surveillance for aetiological agents that may cause a PHEIC can only be conducted if countries share samples in a "timely and consistent" manner, without "preconditions". This interpretation was supported by World Health Assembly (WHA) resolution adopted in May 2006 and May 2007".

[52] Fidler, David, *Influenza Virus Samples, International Law and Global Health Diplomacy*, Emerging Infectious Diseases, 14 (1), 88-94, available at http://wwwnc.cdc.gov/eid/article/14/1/07-0700.htm, arguing that: "whether sharing obligations arose under customary international law is also doubtful. To rise to the level of customary law, evidence must exist that states generally and consistently follow a practice out of a sense of legal obligation. GISN has, however, functioned without much, if any, reference to international law, making it difficult to establish that countries shared samples with WHO because they felt legally obligated to do so".

[53] See Sedyaningsih, E. R., et al., op. cit, arguing that in this view: "Public health information and biological substances are 2 independent concepts and were actually negotiated separately; public health information strictly means knowledge and facts. This school of thought argues that even the WHA resolutions of 2006 and 2007 distinguished these 2 terminologies, i.e., information and relevant biological materials. Moreover, this interpretation strongly believes that countries have sovereign control over biological resources found within their territories, as stated in the Convention on Biological Diversity (CBD). Hence, countries have the right and authority to decide whether to share their specimens with the WHO system or not, depending on their own judgment".

In spite of its legal nature, the WHO system provided a valid system to ensure the sharing of influenza samples but it lacked any mechanism to ensure access to vaccines from developing countries including the same countries that sent the samples to the network. This deficiency was evidenced by the claims raised by Indonesia precisely during the 2006 Influenza crisis. During the H5N1 outbreak, Indonesia had been particularly affected by the most virulent cases so that access to samples originating in its territory was of critical importance for risk assessment and risk management purposes.[54]

The Indonesian government reacted in particular to the development of a vaccine by an Australian company which had obtained samples from the WHO network, a vaccine that the same Indonesian government would not have been able to buy for its citizens. In addition, the WHO conceded that some modified versions of influenza samples shared through the WHO system were subject to patent protection, without any consent being asked from the countries that had contributed with the samples[55].

The decision to withhold virus samples during the influenza outbreak was harshly criticized by the international community. At the same time of the refusal, the Indonesian government started negotiations with pharmaceutical company Baxter in order to agree on the production of a vaccine, hence apparently advancing only its own claims of access and benefit sharing. In practice, however, Indonesia "took advantage" of being critically affected by the particular H5N1 strains in circulation in order to pose the issue of fair and equitable access to the fruits of research done with the help of samples shared within the WHO system.

The existing GISN network was accused of encouraging an unfair and inequitable system, in which all countries, including developing countries contributed with access to relevant samples while industrialized countries had free access to the samples and the eventual concession of patents to products developed from the samples encumbered access to vaccines, diagnostic and therapeutic products, of essential need during pandemics. In particular, the following problems were identified. Firstly, the legal conditions governing the sharing of virus samples were not clearly defined and as a result, derivations from such virus samples could be latter subject to patent and other IP rights. Although this matter was supposedly the object of single MTA's, the fact that the system did not provide any guidance could have impacted the uneven bargaining position of the parties. Secondly, the system did not provide for any type of benefit sharing or facilitated access to the end-products of research based upon the virus samples exchanged through the system. As a consequence, developing countries providing samples to the network could be later on in the position of not having access to the products developed with the help of the samples provided under the system.

4.1.1 Negotiations for a Framework for sharing/access of Influenza samples

[54] See Sedyaningsih, op. cit, reporting that: "Since July 2005 to December 2007, Indonesia has reported the highest number of influenza A (H5N1) human cases in the world, i.e., 116 cases with an extremely high fatality proportion of 81%".

[55] See Vezzani referring that: "it is not unusual for both GISN laboratories and third entities to make intellectual property rights (IPR) claims over products (genes and gene sequences, vaccines, etc.) or medical technologies based on pathogen samples shared through the network", and providing examples of some of these patents.

After the Influenza crisis, the WHO set up an Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits (IGM-PIP). However, no solution was achieved until 2011, probably due to the complexity of the issue and the different interests at stake, in particular on the protection of IP rights. Negotiations were still ongoing during 2009 when another virus, the H1N1 threatened to cause a highly virulent pandemic and also gave raise to a political debate over the management of the crisis by the WHO[56]. The 2009 influenza A(H1N1) pandemic also played a role in worsening the worries by developing-countries since influenza vaccines were not equitably shared. Nonetheless, in this latter case, there were no problems with the sharing of virus samples, partly because the countries involved, Mexico, Canada and the US were cooperatively working and exchanging samples[57].

Finally, in April 2011, a WHO Pandemic Influenza Preparedness (PIP) framework for the sharing of influenza viruses and access to vaccines and other benefits was proposed, and the World Health Assembly approved it in May 2011[58]. For the time being, the impact of the PIP framework has been assessed during the World Health Assembly 2012, based upon a report of the Advisory Group, which contained recommendations on how to allocate partnership contributions. At that occasion, members agreed to allocate 70 percent of resources for preparedness and 30 percent for response, although the exact allocation of resources is subject to the discretion of the Director General in the case of a pandemic. But probably the most controversial issued discussed was the virus sharing mechanism. With regard to this aspect, several NGO's expressed their disappointment on the functioning of the lack of use of benefit sharing agreements, which was actually one of the most important expectations for developing countries from the agreement[59].

4.1.2 The PIP Framework in International Law context

The PIP Framework was adopted under article 23 of the WHO Constitution, which establishes that the World Health Assembly "shall have the authority to make recommendations to Members with respect to any matter within the competence of the Organization". WHO Recommendations to its Member States constitute what is known in Public International Law as soft law as opposed to hard law[60]. Although soft law is not

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[56] Deborah Cohen and Philip Carter, *WHO and the Pandemic Flu "conspiracies", BMJ* 2010;340:c2912.

[57] See Abbott, op. cit. at p. 2.

[58] Gostin and Fidler, WHO's *Pandemic Influenza Preparedness Framework: A Milestone in Global Governance for Health,* 306 JAMA 200-201 (2011), available at: http://scholarship.law.georgetown.edu/facpub/68

[59] See, available at: http://ictsd.org/i/news/bridgesweekly/134023/ Health Action International, Berne Declaration, the Third World Network, and the People's Health Movement said that it is disappointing that benefit-sharing agreements have not been signed, even though WHO has been exchanging biological materials with entities outside the PIP's network.

[60] See Andorno, Roberto, *The Invaluable Role of Soft Law in the Development of Universal Norms in Bioethics*, paper at a Workshop jointly organized by the German Ministry of Foreign Affairs and the German UNESCO Commission, Berlin, 15 February 2007. Available at: http://www.unesco.de/1507.html, defining soft law was "*(…)*a third source of international law that has rapidly developed in recent decades, especially to deal with sensitive matters such as human rights, the protection of the environment and bioethical issues. The category of soft law includes a great variety of instruments: declarations, recommendations, charters, resolutions, etc", and arguing the characterization of soft law as "non-binding instruments: "is not entirely wrong but may be misleading because although soft law does not have *per se* binding effect, it is *conceived to have such effect in the long term*. This means that while treaties are *actually* binding (after ratification by states), soft law instruments are only *potentially* binding. Soft law is indeed conceived as the *beginning of a gradual process* in which further steps are needed to make of such agreements binding rules for states".

binding from a legal point of view, it is also acknowledged as an important source for interpretation as well as a politically significant step towards achieving an international agreement on contentious issues. In addition, the PIP Framework would likely have a direct impact in the negotiation of MTAs[61].

During the negotiations for the PIP Framework, the alternative options to a recommendation were either to adopt it in the form of an international treaty pursuant to article 19 of the WHO Constitution or as a regulation binding all member states pursuant to article 21 (a) of the same Treaty. The first option would have faced the controversy between member states with regard to the issues of access and benefit sharing and the management of IP rights so that the framework could have been the object of long negotiations as it happened in the case of the ITPGRFA[62]

4.1.3 Relevant provisions in the PIP Framework

The objectives of the PIP Framework are "to improve pandemic influenza preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system ("WHO GISRS"), with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing": (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and(ii) access to vaccines and sharing of other benefits.

With regard to the management of IPR and technology transfer in the PIP Framework , article 6.13.4 of the Framework establishes that:

"Influenza vaccine manufacturers who receive PIP biological materials may grant, subject to any existing licensing restrictions, on mutually agreed terms, a non-exclusive, royalty-free licence to any influenza vaccine manufacturer from a developing country, to use its intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of influenza vaccine development and production, in particular for pre-pandemic and pandemic vaccines for use in agreed developing countries".

Standard Material Transfer 1 (SMTA 1), which deals with Transfers within the WHO global influenza surveillance and response system (GISRS) establishes in article 6 that "neither the Provider nor the Recipient should seek to obtain any intellectual property rights (IPR) on the Materials". Standard Material Transfer 2 (SMTA 2) deals with transfers outside WHO GISRS, in which recipients of PIP Biological Materials are manufacturers of

[61] See Vezzani, op. cit, p. 684-685, arguing with regard to the proposed PIP Framework that: "the adoption of the framework by the Health Assembly, in the form of a recommendation, would produce legal effects at the level of domestic legal orders. It cannot pass unnoticed that MTAs with vaccine manufacturers would contain provisions that affect the enjoyment of IPR by vaccine manufacturers and, eventually, pricing policy and the possibility of allocating all the vaccines produced to the domestic market of a single state".

[62] See Vezzani, op. cit. at p. 686 referring that: "Although it has been taken as a source of inspiration for many elements of the framework, the FAO model has not been followed by the intergovernmental meeting as far as the choice of the legal instrument to implement the framework is concerned –as the adoption of a treaty subject to ratification has been clearly excluded-. On the contrary, the FAO precedent has reinforced the opinions favoring a more flexible system, to be adopted as quickly as possible and avoiding lengthy discussions on sensitive issues. It is worth recalling that the FAO ITPGRFA was opened for signature in 2001 after 7 years of intense debate and that it entered into force in June 2004, almost 10 years after negotiations commenced". In addition, the SMTA was only adopted in June 2006.

influenza vaccines, diagnostic and pharmaceuticals as well as biotechnology firms, research institutions and academic institutions.

Table 2: Standard Material Transfer Agreements in the PIP Framework

	SMTA 1	SMTA 2
Providers	Influenza laboratories recognized by the WHO	WHO
Recipients	WHO or other authorized laboratories	Any commercial or non-commercial entity, including manufacturers and research centers
Obligations and rights of providers	• Agree with onwards transfer and use of materials to all members of WHO GISRS or to entities outside the network (using SMTA2) • Inform the WHO of transfers of materials within and outside the WHO GISRS network	• To be agreed by the parties
Obligations and rights of recipients	• Inform WHO of transfers of materials within and outside the WHO GISRS network • In the event of further transfers within the network, abide by SMTA 1 • Actively seek the participation of scientists, especially from developing countries in research projects and publications related to the materials • Acknowledge contribution of collaborators, laboratories and countries providing materials	At least two of the following: • Donate or reserve at affordable prices to WHO, at least 10% of real time pandemic vaccine • Donate or reserve at affordable prices at least X treatment courses of needed antiviral medicine for the pandemic • Grant manufacturers in developing countries fair and reasonable licenses (with affordable royalties), for the production of influenza vaccines, adjuvants, antivirals or diagnostics. • Grant royalty-free licenses to manufacturers in developing countries or to the WHO for the production of influenza vaccines, adjuvants, antivirals or diagnostics.

IPR provisions	• Neither the provider nor the recipient should seek to obtain IPR on the materials • Providers and recipients acknowledge IPR over materials obtained prior to the adoption of the PIP framework	To be defined by negotiations by the parties

Beyond the PIP framework, other initiatives within the WHO have also addressed the issue of access to vaccines. Among these initiatives, it is relevant to mention the WHO Global pandemic influenza action plan to increase vaccine supply (GAP)[63] with the goal of reducing the gap between potential vaccine demand and supply during an influenza pandemic, by expanding the global capacity to produce influenza vaccine, including in developing countries.

5 INSTITUTIONS AS OBSTACLES? THE INTERFACE BETWEEN SHARING/ACCESS OF PATHOGENS AND IPR

At the same time that an exponential development of the life sciences is producing such promising lines of research such as pharmacogenomics and synthetic biology, there seems to be a trend of increasing privatization of biological and genetic materials that might encumber activities such as the sharing of pathogen samples[64]. The expansion of IPR, which aims at fostering incentives for innovation has probably contributed also to create incentives towards the propertization of technologies. Nonetheless, in the case of biological materials, the trend seems to be also linked to sovereignty claims over natural resources, mainly advanced by developing countries. The use of genetic resources and biological materials might be hence affected by ownership claims both before and after their development into innovations protected through an IPR.

Hence, whereas the previous section analysed the recently agreed framework to govern the sharing and access to influenza vaccines, this section looks at the role of other international rules and institutions in governing the intersection between this issue, IPR protection and access and benefit sharing of genetic and biological resources in general. The first part discusses the TRIPS Agreement within the framework of the WTO, and the second part focuses on the Convention on Biological Diversity (CBD), adopted in 1992, in order to promote the preservation of biological resources found in nature. The analysis focuses on the incentives created both by IPR and by the Access and Benefit Sharing mechanism of the CBD and asks whether these mechanisms have facilitated or hindered

[63] Document WHO/CDS/EPR/GIP/2006.1.

[64] As Dedeurwaerdere 2010, p. 2, highlights, "in the twentieth century, there was a tremendous increase both in the quantities of microbial and genetic resources exchanged and in the global interdependencies of these exchanges. This movement is related to several scientific developments, among which the introduction of improved techniques for the handling and long-term maintenance of living microbiological samples (e.g. freezing, freeze-drying), and thus easier and safer shipping of samples, has had a major impact. Similarly, the development of innovative methods for the isolation and cultivation of new microbial strains, the genomics revolution, and the broader impact of globalization of research in the life sciences in general have enhanced interest and cooperation in microbial research".

the effective use of innovations and materials in the biomedical and biotechnological fields with a special attention to pathogen materials.

5.1 IPR: the TRIPS Agreement, the WTO and other Institutions

The Agreement on Trade Related Intellectual Property Rights (TRIPS), which was enacted in 1995 within the framework of the World Trade Organization, established a minimum level of harmonization among countries. Although member states can adopt more or less protective standards, many of the flexibilities of the TRIPS have remained unused while political pressure and lobbying have led to a protective interpretation within national jurisdictions[65]. Among other commitments, the TRIPS established that countries should provide patent protection for any technology, explicitly including microorganisms and potentially including other living organisms at the discretion of member states[66]. From the perspective of International Law, it is important to notice that the TRIPS Agreement is a sophisticated agreement as it is included under a well-developed system of dispute resolution that links different areas of international trade. Hence, a member state arguing that another country is not complying with the TRIPS Agreement would have recourse to an adjudicatory system that could eventually allow trade measures to be imposed on the non-complying country.

After the entry into force of the TRIPS Agreement, it was clear that IPR had entered into the international trade framework. A global debate also emerged soon with regard to the interface between IPR and public health and specially on the patentability of pharmaceuticals and biomedical technologies. This debate not only involved the WTO but also the WIPO, which had traditionally been the Institution in charge of administering International IP standards. In addition, an increasing number of other UN agencies, including the WHO became also concerned with the public health and IPR debate.

The challenge of implementing TRIPS standards in a sensitive way to public health was highlighted during the AIDS epidemics in Africa. In 1997, South Africa amended its patent law entitling the government to issue compulsory licenses and allowing parallel imports in order to face the health crisis related with the spread of AIDS and the high cost of patented drugs used for the treatment of this disease. On February 1998, a group of 39 pharmaceutical companies initiated a lawsuit against the government of South Africa challenging its "Medicines and Related Substances Act", which in its Amendment 15(c) allowed for such compulsory licensing and parallel import provisions to be applied to pharmaceuticals[67]. However, in 2001, following an intense international campaign on the issue of patents and public health, the pharmaceuticals companies abandoned their cases. The surmounting pressure generated by this case created a momentum for advancing the claims of developing and least developed countries, leading to a Declaration during the Doha Ministerial Conference, which addressed the issue of public health and IP regulation[68].

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[65] See Drahos 2002.

[66] Paragraph 3 of article 27 of the TRIPS Agreement establishes that members may exclude from patentability "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

[67] Such mechanism is allowed by the TRIPS Agreement under the requirements established by article 31, *inter alia*, for cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, cases in which the mechanism is facilitated by waivering the requirement of prior efforts to obtain authorization under reasonable commercial terms.

[68] See the Doha Declaration, Declaration on the TRIPS agreement and public health, adopted on 14 November 2001, available at:

The debate about IPR and public health within the WTO also called for the involvement of other International Organizations working outside IP issues and more directly within the health field. The Fifty-ninth World Health Assembly adopted resolution WHA 59.241 on "Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action", which requested the Director-General of WHO to establish an inter-governmental working group open to all interested Member States to develop a global strategy and plan of action.

In May 2008, the World Health Assembly adopted resolution WHA61.21, "the global strategy and the agreed parts of the plan of action on public health, innovation and intellectual property". The global strategy proposes that WHO should play a strategic and central role in the relationship between public health and innovation and intellectual property within its mandate. The plan of action was approved except for a small number of actions, which remained open until the adoption of Resolution 62.16 in May 2009.

In addition, resolutions WHA60.28 and WHA61.21 have recognized that "intellectual property rights do not and should not prevent Member States from taking measures to protect public health" and "that intellectual property rights are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain".

5.2 IPR as facilitators or obstacles to innovation?

The increasing expansion of IPR protection, followed by an escalating patenting trend that includes inventions pertaining to basic research, has presumably led to an over-fragmentation of rights. The economics literature has described a mirror image of the "tragedy of the commons" in the "tragedy of the anti-commons", which arises when many agents hold a right to exclude but none has a privilege to use and as a result. In these cases the excessive proliferation of rights might lead to underuse of the resource and over-investment in obtaining private rights to exclude, a result that suggests there are potential detrimental effects of granting too many veto or exclusive rights. This theory found a special ground of application in the patent biotechnology field[69]. When technologies are complementary to each other, meaning that they yield a higher value when used together or when many complementary inputs are necessary to develop a product -as it is precisely the case with many biotechnologies- the emergence of an anti-commons can threaten to block socially useful innovations. The anti-commons literature has also described the problem of royalty stacking, which arises when each right holder of a piece needed to develop a complex technology asks for a payment (royalty) and the aggregated royalty is higher than it would have been if only one monopolist would have owned all the needed technologies. Likewise, the power to holdout during a negotiation allows the owner of a piece of technology to ask for a price, higher than the real value of that technology, given that the user of the technology has already made investments to develop a follow-up

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http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm and the Cancun Declaration, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of the General Council of 30 August 2003, available at: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

[69] See Heller and Eisenberg, op. cit. 10, explaining how the tragedy of anti commons results in resources being prone to underuse because multiple owners on upstream technologies have a right to exclude use by others and none has a privilege to use the resources.

innovation. In the end, royalty stacking as well as holdouts might preclude efficient use of technologies because it would not be profitable to pay such an amount to use all the required technologies to develop a new one. A consequence of these trends, is that in effect, patent law could be encumbering rather than facilitating follow-on research.

Nonetheless, the empirical evidence on the emergence of an anti-commons is controversial to say the least. Some studies suggest that there is a potential and growing risk, especially in fields such as genetic testing while others suggest that research is flourishing because the scientific community manages to use patented technologies either by infringing or ignoring patents, that is "in spite of patent protection"[70].

In fact, several institutions worldwide have undertaken efforts to study and tackle this issue[71]. A 2010 report of the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) concluded that there is no convincing evidence that patents either facilitate or accelerate the development and accessibility of genetic diagnostic tests, founding that on the contrary, there was some limited evidence that patents had a negative effect on clinical research and on the accessibility of genetic tests by patients[72]. An additional source of concern was that most gene patents relevant to diagnostic tests were held by universities, which received public funds for basic research and hence, the Committee advised that Universities should be more careful in devising their patenting and licensing practices.

In particular, empirical studies have addressed the question of whether the increasing trend of patenting upstream technologies by Universities after the enactment of the Bayh-Dole-Act in the U.S has lead to impediments for follow-on research. Along with the incentives created by this piece of legislation, the case of the U.S. is critical also because while the strength of patent protection has been expanding, the scope of exceptions such as the experimental exception has been shrinking due to decisions such as *Madey v. Duke*[73]. As a possible countermeasure, the US National Institutes for Health as well as the US National Research Council have issued guidelines suggesting open approaches and best

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[70] Compare Scott Stern and Fiona Murray, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis*, NBER Working Paper Series, Vol. W11465, 2005, available at: http://ssrn.com/abstract=755701, finding an anti-commons effect in citation rates after a patent is granted, with Walsh, Arora and Cohen, *Working Through the Patent Problem*, Science*:* VOL. 299. NO. 5609, (14 February 2003)*,* at p. 1021, which performed a survey among researchers and found that the IP system does not preclude sequential innovation as most researchers interpreted the research exemption in a broad way or just infringed necessary patents. But see Paul David, *A tragedy of the Public Knowledge 'Commons'?* in Global Science, Intellectual Property and the Digital Technology Boomerang, available at: http://siepr.stanford.edu/papers/pdf/00–02.pdf, criticizing the methodological grounds of the Walsh study, among other reasons because of the ways in which the questions are posed that do not allow much room for researchers to express results otherwise. Furthermore, the Walsh study highlights severe problems related to patentability of research tools while distinguishing them from the anti-commons concept whereas Heller and Eisenberg refer to both problems under an anti-commons label.

[71] See among others, Bioethics NCo. *The Ethics of Patenting DNA*. 2002., http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf; National Research Council CoIPRiGaPRaI. *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (2005); and Ontario Report to the Provinces and Territories. *Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare* (Toronto, January 2002). Available at: http://www.health.gov.on.ca/french/publicf/pubf/ministry_reportsf/geneticsrep02f/report_e.pdf (accessed February 20, 2010).

[72] Secretary's Advisory Committee on Genetics H, and Society; National Institutes of Health. Report on Gene *Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (2010). For a general discussion on the impact of gene patents see Carbone et al. *DNA patents and diagnostics: not a pretty picture*, Nat Biotechnol. 2010 August ; 28(8): 784–791.

[73] *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

practices with regard to licensing patent technologies[74]. The OECD has also issued guidelines on licensing of genetic technologies and in Europe.

Even if patent rights are not hindering research, most of these empirical studies have showed that Material Transfer Agreements establishing restrictive terms are in fact encumbering the process of sharing biological samples[75]. Two important conclusions emerge from the confrontation between the predictions of the anti-commons theory and the empirical evidence found so far. The first is that patents might have a larger blocking impact on downstream development than in upstream research. The second is that restrictions on access to materials and data seem to be more problematic than patents. As argued by Professor Eisenberg, these findings might indicate that "the burden of inertia matters in determining the practical impact of transaction costs associated with property rights"[76]. This means that the "burden of inertia" falls on patentees in the sense that these have to identify and enforce patents. As a consequence, a difference will emerge between high-value and low-value users. In the case of low-value users, high transaction costs will give them an advantage since the patentees will not find beneficial to incur in such high costs in order to stop infringement. But the situation is quite different with regard to materials as they are easily excludable and some of them might be high-valued as wel:

"by contrast, with material transfer agreements and database access agreements, the burden of inertia is on the user to obtain access to a restricted resource". Hence, high transaction costs would increase the risk of anticommons by posing a higher burden on low-value users, especially on researchers"

Moreover, it is important to highlight that MTA's include such restrictive terms precisely because strict patent protection is in place. That is, an MTA is a contract negotiated by the parties in the shadow of a certain legislation, in this case, a patent legislation that privileges the exclusive ownership of technologies above the sharing and access to previous research.

In the case under discussion, there seems to be an increasing patent activity involving influenza viruses. A WHO report on the patent landscape of influenza A H5N1 highlighted the increasing patenting activity in the area of influenza viruses, especially on the H5N1 strain during the recent years. Although the level of patent activity is a signal of the increasing involvement of private research in this area of public health, it is also worryingly creating potential constraints to future research and access to essential products[77].

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[74] See OECD, *Guidelines For The Licensing Of Genetic Inventions* (2006), available at: http://www.oecd.org/dataoecd/39/38/36198812.pdf, referring that in a 2002 workshop the conclusion was that the IP system applied to genetic inventions did not have a systematic breakdown in licensing, although specific concerns were made, especially regarding access to diagnostic tests. See also the Guidelines by the U.S. National Institutes of Health (NIH) and the National Research Council, (similarly acknowledging these problems and recommending non-exclusive licensing, trusting however in market-based solutions).

[75] See Rebecca Eisenberg, *Bargaining over the Transfer of Proprietary Research Tools: Is this Market Failing or Emerging?* In Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society 223, 225 (Rochelle Cooper Dreyfuss et al. eds., 2001).

[76] Rebecca Eisenberg, *Patents and Data-Sharing in Public Science*, 15 Indus. & Corp. Change 1013, 1019 (2006).

[77] See WIPO, Life Sciences Program, *Patent Issues related to influenza viruses and their genes*, Working Paper commissioned by the WHO from WIPO pursuant to WHA Resolution 60.28, available at: www.wipo.int/patentscope/en/lifesciences/pdf/influenza.pdf, noticing that: "Even so, this same level of activity has given rise to concerns that key technologies and their fruits – diagnostics, vaccines and treatments – may not be accessible equitably, including in the light of genetic material. Without accessible analysis of the emerging patent landscape, the sheer complexity of the evolving patent coverage of H5N1-

5.3 Protection of genetic resources

Any possible framework to regulate the sharing of pathogens materials must also take into consideration the regulation of ownership of genetic resources and hence the interface between the CBD and the TRIPS Agreement. In 1993, the Convention on Biological Diversity (CBD) set up a global framework for the protection of natural, biological and genetic resources, providing for the principle of national sovereignty over all resources held by member states. However, the actual implementation of the CBD has proven a complex task which can encumber the process of sharing biological and genetic resources in practice. This have lead some scientists to express concerns about potential restrictions on access to scientific materials. In particular, it has been argued that the implementation of the access and benefit sharing mechanism (ABS), could be threatening to curtail effective access to genetic materials[78]. In general, any system that includes restrictive terms in licenses for the distribution of genetic or biological materials could obstacle the process of sharing and having access to materials by the scientific community, as it has apparently been the case with the sharing of microbes[79].

5.3.1 The Convention on Biological Diversity and the ABS Protocol

The CBD established the principle of sovereignty of countries over their natural resources. The Convention aimed at creating incentives for the conservation of resources by biodiversity-rich countries and to prevent bio-piracy cases. In a typical case of bio-piracy, a pharmaceutical company would investigate on the potential applications of biological resources, sometimes also making use of traditional knowledge developed by indigenous communities. Then the company would develop a technology and seek patent protection without any share in the benefits from such protection with the communities holding the traditional knowledge or with the country of origin of the biological resource[80]. Hence, this

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related technology may create obstacles in itself for those seeking to clarify their freedom to operate in vaccine development and production".

[78] Tom Dedeurwaerdere, *Self-governance and international regulation of the global microbial commons: introduction to the special issue on the microbial commons*, International Journal of the Commons Vol. 4, no 1 February 2010, pp. 390–403.

[79] Ibid at p.

[80] An example from the 1980s is the rosy periwinkle (Catharanthus roseus) from which Eli Lilly developed two widely used medicines; vinblastine and vincristine, used to treat Hodgkin's disease and childhood leukemia. These drugs form a market of approximately $100 million dollars annually, but the countries of origin, Madagascar and other tropical countries, have never received any compensation; other examples include the *Neem tree* and *Turmeric herb* from India and the *Ayahuasca* from the Amazon basin However, the issue of how to regulate bio-prospecting and biodiversity protection and its interface with IP protection is complex and controversial and a full review would be out of the scope of this paper. For the purposes of this paper it is sufficient to discuss the current regulatory framework for the interface between the protection of IP and biodiversity including ABS regimes. See for instance, Chen, Jim, *Biodiversity and Biotechnology: A Misunderstood Relation*. Michigan State Law Review, Vol. 51, 2005; Minnesota Legal Studies Research Paper No. 05-24. Available at: http://ssrn.com/abstract=782184, arguing that whereas IP should be reserved for innovations which indeed foster technical advancement, traditional knowledge would be already part of the public domain and hence not susceptible of patent protection. Compare with Ullrich, Hanns, *Traditional Knowledge, Biodiversity, Benefit-Sharing and the Patent System: Romantics v. Economics?* (May 2005). EUI Working Paper LAW No. 2005/07. Available at: http://ssrn.com/abstract=838107, questioning the possibility of applying compatible rules for incentives-based regulation such as patent protection with legislation aiming at the protection of non-market driven values as biodiversity and traditional knowledge. Gervais, Daniel J., *Traditional Knowledge & Intellectual Property: A TRIPS-Compatible Approach*. Michigan State Law Review, p. 137, Spring 2005. Available at: http://ssrn.com/abstract=507302, analyses the potential regulatory options to deal with the compatibility between the TRIPS Agreement and the CBD.

case was presented in the context of the CBD as a claim from developing and least-developed countries, which are rich in biodiversity and aspired to obtain a fair and equitable share in the profits generated from the use of such resources by other countries, especially through the protection of IPR.

As described above, there are fears that the CBD framework might obstacle the process of sharing biological materials, including pathogens. In fact, the claims by Indonesia during the 2007 Influenza crisis were based upon the principle of sovereignty of states over their own biological resources established by the CBD. In order to guarantee such principle, the CBD establishes two important obligations, firstly, that there should be prior informed consent of host countries as a condition to access genetic resources and secondly, that there should be equitable sharing of the benefits arising form the utilization of such resources.

There is disagreement however, on whether the CBD framework is or not applicable to the case of access to pathogen materials. Among the definitions included in the CBD are "biological resources", a term that includes "genetic resources, organisms or parts thereof …with actual or potential use or value for humanity". It is clear that a virus or a pathogen is different from a natural resource that should be protected, monitored and conserved from a biodiversity point of view[81]. However, pathogens are indeed potentially useful for humanity, insofar as they provide the necessary material to research and develop treatments and vaccines and might even have uses which the scientific community might not be aware at the moment. As such, they are indeed part of the "biological diversity", understood by the CBD as "the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems". Indeed, viruses are among the most variable "living" species[82], with high rates of variation (DNA or RNA mutation)[83], which might cause pandemics in the case of influenza viruses but which might also constitute a precious material for scientific research. Of course, their harmful potential also raises important bio-safety concerns.

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[81] These are the requirements of articles 1, 6, 7, 8 and 9 of the CBD.

[82] Viruses could however be considered taxonomically as non-living organisms, as dependent of a host, this is debated issue among biologists. See Wikipedia entry, available at: http://en.wikipedia.org/wiki/Virus#cite_ref-55: "Opinions differ on whether viruses are a form of life, or organic structures that interact with living organisms. They have been described as "organisms at the edge of life", since they resemble organisms in that they possess genes and evolve by natural selection, and reproduce by creating multiple copies of themselves through self-assembly. Although they have genes, they do not have a cellular structure, which is often seen as the basic unit of life. Viruses do not have their own metabolism, and require a host cell to make new products. They therefore cannot naturally reproduce outside a host cell– although bacterial species such as *Rickettsia* and *Chlamydia* are considered living organisms despite the same limitation. Accepted forms of life use cell division to reproduce, whereas viruses spontaneously assemble within cells. They differ from autonomous growth of crystals as they inherit genetic mutations while being subject to natural selection. Virus self-assembly within host cells has implications for the study of the origin of life, as it lends further credence to the hypothesis that life could have started as self-assembling organic molecules" (footnotes omitted). See among others, Rybicki, EP. *The classification of organisms at the edge of life, or problems with virus systematics*. S Afr J Sci. 1990;86:182–186; Holmes EC. *Viral evolution in the genomic age*. PLoS Biol. 2007;5(10):e278; and Wimmer E, Mueller S, Tumpey TM, Taubenberger JK. *Synthetic viruses: a new opportunity to understand and prevent viral disease*. Nature Biotechnology. 2009;27(12):1163–72.

[83] Viruses undergo genetic change by several mechanisms, including genetic mutations of DNA or RNA mutate to other bases. Some of these mutations can give evolutionary advantages to viruses, including resistance to antiviral drugs. Antigenic shift occurs when there is a major change in the genome of the virus and can be a result of recombination or reassortment, processes that might result in influenza viruses developing a pandemic.

Nonetheless, article 15 of the CBD, which affirms the state sovereignty over natural resources, establishes also that the "authority to determine access to genetic resources rests with the national governments and is subject to national legislation". It is easier to argue that viruses and in general, pathogens, are genetic resources, which at the same time are included in the definition of genetic material of article 2 of the CBD as "any material of plant, animal, microbial **or other origin** containing functional units of heredity" (emphasis added). Viruses do contain units of heredity, either in the form of RNA or DNA (RNA or DNA viruses), which are in fact, the same functional units of heredity of all living organisms. The same article 2 of the CBD states that genetic resources "means genetic material of actual or potential value". Hence, viruses comply with both requirements, that of being genetic material as they have essentially three parts: the RNA or DNA, a protein coat protecting the genetic material and sometimes a lipid envelope protecting the whole structure; and secondly, that of having actual or potential value, especially for scientific research[84].

As Professor Abbott has argued, pathogen materials are probably covered by the CBD also because: "pathogen materials, including virus materials, have a value in so far as they may be used to develop drugs or vaccines for human or animal use, and they have monetary value"[85]. Professor Abbott argues that the fact that the CBD covers the issue of access and sharing pathogen materials does not directly imply that it is the best policy option to address the issue but rather that it is the current "default legal situation".

From a policy perspective it is actually difficult to exclude pathogens materials from the scope of the CBD once the policy objectives are taking into account, that is the interest of developing countries in preserving a possible share in the benefits from ownership, preservation and sustainable use of biodiversity. In fact, even though the CBD and the ABS mechanisms have been considered as potential obstacles to the "free" circulation of pathogens that would impede scientific research and ultimately threaten global public health, a similar argument could be made of pricing and availability of pharmaceuticals which might also obstacle access to medicines for an important part of the global population[86].

Of course, in the case of a global emergency such as a "declared" pandemic, such arguments such as the human right to health could be used, just in the same way they are used within the context of the access to medicines and patent protection discussion for the cases of public health emergencies. Hence, it can also be argued that countries have an ethical beyond a legal obligation to provide access to pathogen materials, which are fundamental to control or combat threats to public health.

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[84] Intimately linked is the fact that the CBD seems to exclude human genetic resources from its scope, something that is not clear from the CBD text but that was stated by the Conference of the Parties (COP), a governing body established by the CBD and also by the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization adopted by the COP in 2002, which exclude human genetic resources from the Guidelines but not from the CBD itself. See Abbott, op. cit. p. 12, arguing that the COP does not have the authority to interpret the Treaty but also that "the matter of whether human genetic resources are covered by the CBD and the ABS regime is not considered resolved". Nonetheless, human genetic resources should not encompass pathogens in general.

[85] Nonetheless, Abbott also presents the potential contrary argument that "the primary interest of science and public health is to eradicate dangerous pathogens, not preserve them, notwithstanding that they represent a form of biodiversity", op. cit. at p. 14.

[86] Ibid at p. 14

5.3.2 The ABS mechanism and current negotiations

The CBD establishes an international system of obligations for the Member States[87] but one of its most important consequences relies precisely on the implementation of an Access and Benefit Sharing mechanism, which is still under negotiation. Drafts of the ABS Protocol are still subject to discussion as it regards the inclusion of "human pathogens" and especially as to the interface between IP protection and ABS requirements[88].

The ABS Draft Protocol as it currently stands, establishes a clear reference to the case of pathogens in the form of a default rule in the absence of an agreed system under the WHO, which now exists under the PIP Framework. Nonetheless, an eventual agreement might also fill the gap between the WHO mechanism which covers only Influenza viruses and other pathogen materials.

6 POLICY OPTIONS TO BUILD A GLOBAL SYSTEM FOR SHARING/ACCESS TO PATHOGEN MATERIALS

At the present time, the global landscape is complicated but also enriched by the influence of many rules and institutions governing the issue. The most important challenge is how to reconcile an IPR system that provides strong incentives to privatize knowledge and to protect biological materials with a loose system that affirms the sovereignty of states over their resources and claims a share on the benefits arising from such resources. The answer is probably that the PIP framework, which addresses the limited case of sharing Influenza viruses and access to vaccines and other benefits provided a first step but did not solve all the remaining issues at the intersection of this complex case. This section analyses some further options that might go beyond the PIP framework in promoting a system for access and benefit sharing of pathogen materials. The options are classified according to whether it is or not necessary to reform the IPR system, which is currently the component of this debate, which has a better developed system of governance.

6.1 Working within the current IPR system

Even if the current IPR system is maintained as it is, there are mechanisms that might facilitate access and sharing of materials, including pathogens, that have been examined and proposed. Hence, a first option to deal with the issue is to adopt some facilitating mechanism for access and benefit sharing that is compatible with the current IPR global system.

[87] Interestingly, one of the main limitations of the CBD and ABS negotiations is the fact that the US has not ratified the Convention, and hence, one of the most important users of materials and developers of patentable technologies is actually not committed to the CBD system.

[88] See Abbott op. cit, p. 15, arguing that nonetheless: "despite the great public attention given to intellectual property within the framework of the CBD, the draft ABS Protocol addresses rights and obligations with respect to IPR mainly through requirements related to certificates of compliance with national legislation and monitoring of such compliance by patent offices, rather than by attempting to define substantive rights and obligations".

6.1.1 Expanding the public domain and enhancing open access

A system of public domain, which was basically in place before the CBD, means that pathogen materials could be freely used by all. Hence, resources, genetic and biological could be used by any country or industry. This is a regime that applies to resources mainly located outside of the frontiers of countries, especially with regard to "high seas", to which no state has a right to exercise its sovereignty. A similar regime is established by the ITPGR, which "recognizes the sovereign right of states to control genetic resources located within their territories", however established that parties to the ITPGR are committed to "providing facilitated access to plant genetic materials under their control"[89]. Nonetheless, the ITPGR actually provides for the use of a Standard Material Transfer Agreement which may permit the acquisition of IP rights of derivative materials, at the condition that some royalties are put in a fund that would be used for the benefit of developing country agriculture, improving technology transfer and plant genetic resources for agriculture.

In fact this mechanism does not put resources directly into the public domain; otherwise patenting would not be possible, nonetheless: "users may not seek IPR protection for the original form of the genetic resources, but they may seek such protection for derivative products, contingent on the payment of a royalty to the Multilateral System"[90].

Such a system for the sharing of pathogen materials would have the advantage of avoiding the problems of states claiming sovereignty over such materials while at the same time making them available in the public domain and allowing a limited use of IP rights over derivative inventions. Nonetheless, the problem with viruses and other pathogens are precisely linked to patents on derivative products, namely vaccines and drugs. It is seldom the case that the genetic component of the virus itself would be patented[91]. Differences between agricultural genetic resources and pathogens are also important, especially since the former are stable compared to pathogens and especially viruses which evolve so rapidly that any sharing system must require a "continuous contributions of new materials" into the public domain resource pool.

Finally, a problem with the public domain approach is precisely that developing countries might not benefit form this system given the lack of financial resources to benefit from available products such as vaccines and cures developed by others and the lack of technical capacities to develop derivative products and benefit from eventual IP protection of patentable inventions based on the shared pathogens:

"Although developing countries may enjoy some benefit from the availability of vaccines and treatments, the utility is limited by lack of financial resources. For that reason, developing countries may have little incentive to support a pure public domain option. A limited public domain option modeled along the lines of the ITPGR Multilateral System might be appealing, but this depends on the terms of the negotiated arrangement, bearing in mind the circumstances of pathogen materials and plan genetic resources are substantially different"[92].

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[89] See Abbott, op. cit. p. 5.
[90] Ibid at p. 6.
[91] Nonetheless see the HCV case on the patenting of sequences of the virus causing Hepatitis C by Chiron for the purposes of a diagnostic test. The patent(s) by Chiron are presumably responsible of having blocked further research and development of more accurate diagnostic tests, cures and a vaccine (still not available).
[92] See Abbott, op. cit, p. 6.

A slightly different option is that of joint ownership analyzed by Professor Abbott, under the framework of resources which constitute a "common heritage of mankind". Such resources are subject to collective ownership and under this option, pathogens would form a pool to which all countries would contribute. None country would have the right to sovereign claims to pathogens or the authority to block the use of such resources, hence, it would probably diminish incentives for countries to strategically withhold resources[93]. Nonetheless such system would necessitate an agreement about the use and access to resources under the "pool". Countries might view the system as a potential threat to their ownership claims (if they expect to be countries of origin) or as a cumbersome mechanism (if they expect to be net users of the materials). At the end, the system might have to be based on Material Transfer Agreements or some type of rules that guarantee access to and sharing of benefits and which at the end would not be so different from a system such as the "limited public domain" of the ITPGR or the negotiated ABS system that starts from sovereign rights but ends up in contractually agreed terms. Of course, the difference is the default rule which would change the bargaining position of countries involved.

6.1.2 Rebuilding the commons

Biological materials could be considered as a sort of "research resource commons" or "semi-commons"[94]. Some advocates of an expansion of the commons have proposed it as a measure to contend the over-expansion of IP rights in such varied areas such as global health, biodiversity and food security. Commons are described in the context of scientific research resources and information goods as: "any resource that is shared by a discrete group of people at any level, whether local or global or somewhere in between"[95].

The case of "microbial commons" has been proposed as a positive example of enhanced collaboration between the scientific community that might overcome the problems caused by the expansion of IP protection and market incentives. For instance, recent research proposes that: "networking pools of genetic resources in a global commons potentially is a workable alternative to market-based solutions, which have been shown to be unable to generate sufficient investment in the vast quantities of genetic resources that are neglected because of their **unknown and/or unlikely commercial value**"[96] (emphasis added).

However, some critics regard the limitation of the use of a commons approach, including that such initiatives remain more important precisely in the context of low-value or unknown value technologies, which is not the case of pathogen materials, and especially of influenza viruses[97]. Another possible problem with the commons is precisely the nature of

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[93] Ibid at p. 7.

[94] See Paul David, *Breaking anti-commons constraints on Global Scientific Research, Some "new moves" on Legal Jujitsu*, Designing the Microbial Research Commons: Proceedings of an International Workshop (2011) Board on Research Data and Information (BRDI).

[95] See Tom Dedeurwaerdere, op. cit. at p.

[96] Ibid at p.

[97] Jonathan Barnett, *The Illusion of the Commons*, 1756, Berkeley Technology Law Journal, Vol. 25:1751. As a conclusion, Barnett proposes that commons are complements and no substitutes to IP protection and necessitate some proprietary regime to develop and the following limitations with regard to a "commons regime" in general: "At least in innovation settings that demand substantial capital investments, it is of greater practical interest to adopt the following intermediate proposition: (1) sharing regimes confer substantial collective gains in the form of reduced transaction-cost burdens, but (2) outside of limited settings, are unlikely to persist unless supplemented by state-provided property rights or some other exclusionary mechanism of functional equivalence. This nuanced thesis explains both why (1) "stand alone" sharing regimes tend to be confined to low capital-intensity activities that tend to stand at the margins of

a "closed" group or network of sharing, which creates a community that has access to materials but excludes non-members from access.

6.2 Reforming the current patent system

Another option to ameliorate the problems arising with regard to the sharing and access to pathogen materials is through the creation of "mandatory" flexibilities within the IP system, which would necessitate a reform of the TRIPS Agreement. Although the TRIPS Agreement leaves scope for flexible options of implementation, it does not include "mandatory" exceptions and allows each country to implement more protective standards for IP rights. Some proposals have recently raised the necessity of including exceptions in the TRIPS Agreement that guarantee the same objectives that are otherwise stated in the same agreement but that lack any operational rule[98] but any such reform is likely to meet great resistance from member states[99].

In addition, discussions on the interface of the TRIPS Agreement and the CBD, are currently undergoing but no agreement has been reached yet. The TRIPS Agreement initially required a review of Article 27.3(b), which regards the patentability of plant and animal inventions, and the protection of plant varieties but latter on, paragraph 19 of the 2001 Doha Declaration stated that the TRIPS Council should also look at the relationship between the TRIPS Agreement and the CBD as well as the protection of traditional knowledge and folklore and that such work should be guided by the objectives (Article 7) and principles (Article 8) of the Agreement and should also incorporate development concerns.

On the one hand, governing the issue of access and sharing of pathogen materials within the WTO-TRIPS Forum would guarantee a system backed up by a well-developed mechanism of dispute settlement. Nonetheless, a negotiated solution would be very difficult to achieve and it is doubtful, at least at the current stage, that it would be one taking into account global health and international trade concerns in a balanced way. Nonetheless, any solution negotiated under the WTO-TRIPS at this moment is more likely to involve multiple stakeholders, including International Organizations such as the WHO, the WIPO and other UN Agencies which currently cooperate in issues at the intersection of public health, human rights and international trade.

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economic activity, but (2) sharing practices and other nominal-cost exchange arrangements persist in embedded form in broad portions of the high-technology industries that operate at the heart of the current information-based economy".

[98] For instance, article 7 states as objective of the Agreement that: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations", whereas article 8 states in the principles of the Agreement that: "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement".

[99] See Annette Kur & Henning Grosse Ruse-Khan, *Enough is enough: the notion of binding ceilings in international intellectual property protection*, (Max Planck Inst. for Intellectual Property Competition and Tax Law Series N° 09-01, 2009); Henning Grosse Ruse-Khan, *Time for a Paradigm Shift? Exploring Maximum Standards in International Intellectual Property Protection*, 1 Trade L. & Dev. 56, 69 (2009).

7 CONCLUDING REMARKS: SOME IMPLICATIONS FOR GLOBAL GOVERNANCE

Building a global system for access and benefit sharing of pathogen materials
A global system to facilitate and govern the access and benefit sharing of all required materials for research in the life science, or at least for all pathogen materials, would be more coherent than the creation of a special mechanism covering only Influenza viruses such as the PIP Framework of the WHO. Nonetheless it would be important to consider whether a dissimilar system for Influenza viruses is needed precisely because of their high potential and actual commercial value (in terms of their potential use for the development of drugs and vaccines).

In particular, it would be important to consider that any solution trying to address the issue without reforming the IPR system is likely to include low-value materials and leave aside high-value materials as Influenza viruses. Likewise, the fact that the PIP framework established a loose set of rules in the two MTA's, especially as it regards MTA 2, which regulates the access and sharing of influenza viruses with potentially commercial purposes and left the issue of IPR to be governed by the parties.

Conversely, an IPR reform could include such mandatory provisions ensuring that enough space is left for follow-on research, e.g., an experimental exception provision, compulsory licensing for the use of important patented technologies and possibly the incorporation of exceptions to the patentability of some technologies, which are likely to be "essential facilities" for the development of further research, i.e., genetic information on viruses, other microbes or human genes with multiple potential applications.

Towards the multiplication or fragmentation of GHG?
The case under study highlights different health, trade, human rights and environmental concerns increasingly overlapping and being discussed together or at least increasingly pushing global institutions to address them in a coherent way. As we have discussed above, multiple International Organizations have been gradually more involved in discussing the interface between international trade, IP protection and public health. Just to mention a few, apart from the WHO and the WTO, the WIPO, UNCTAD and UNICEF have also released statements and studies regarding the potential effects of international trade in public health. This has been an important step towards conceiving IPR as an important yet limited mechanism for the creation of innovation incentives, for instance as it regards incentives to invest in the development of drugs for diseases affecting a very low segment of the population or low-income countries (so-called neglected diseases). Hence, even if global institutions might at times look as stagnated or as not responsive to the needs of stakeholders, the multiplication of forums where issues are discussed from multi-facet perspectives is not necessarily a useless endeavour.

Nonetheless, during the last few years, many trade negotiations have taken place outside of the WTO, by means of regional or bilateral trade agreements. Such trend is by no means new, as bilateralism and regionalism have been present in the international trade area for many years. However, the assumed stagnation of further international trade negotiations within the Doha Round of the WTO, has further pushed the emergence of a recent wave of such agreements. As many of these agreements include chapters on IP protection and investment protection, at least some of them might affect attempts to build a balanced

system between IP protection and access to pathogens and patented technologies in general.

Bio-security and bio-safety concerns

The controversy addressed in this paper has been recently re-opened and complicated by the presence of bio-security concerns. At the end of 2011, some scientists were complaining about experiments creating mutant forms of the H5N1 avian influenza virus that allowed for a human-to-human infection. The US government solicited the opinion of the US National Science Advisory Board for Biosecurity (NSABB), a body created in the context of post 9/11 concerns over dual-use research, that is, those lines of research with potentially beneficial uses but that might be also misused with devastating effects, including bio-terrorism. In December 2012, under the advice of the NSABB, the US government asked two of the most prestigious scientific journals worldwide to limit the publication of two studies on this mutation of flu viruses without revealing the details that could enable other scientists to replicate such experiments. After a moratorium, one of the articles was published in its complete version while the other was partially published. However, an important debate has followed this decision since the possibility of withholding part of the results of scientific experiments is in contradiction with the scientific ethos of publication and dissemination of results.

Moreover, publication and dissemination of scientific results is also one of the cornerstones of the patent system. While the US government and the WHO are currently trying to put together a mechanism for the international oversight of dual-use research of concern, the moratorium on the publication and the incomplete dissemination of scientific papers might paradoxically move away from what developed countries and especially the U.S. was demanding from other countries of the world, that is, to provide wide patent protection for innovations (as patents are based upon the disclosure of complete information). Such move is also in contradiction with what countries were previously demanding from Indonesia, that is, to make all Influenza samples available; and from the WHO, that is, to explicitly include this obligation in the PIP framework.