Intellectual Property and Sustainable Development Series



An International Legal Framework for the Sharing of Pathogens:

Issues and Challenges

By **Frederick M. Abbott**
Florida State University College of Law

ICTSD
International Centre for Trade and Sustainable Development

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ICTSD welcomes feedback and comments on this document. These can be forwarded to Ahmed Abdel Latif (aabdellatif@ictsd.ch).

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LIST OF ABBREVIATIONS AND ACRONYMS

ABS	Access and benefit-sharing
ABS Working Group	Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing
BCH	Biosafety Clearing-House
CBD	United Nations Convention on Biological Diversity
COP	Conference of the Parties
EBS	Equitable benefit sharing
FAO	Food and Agriculture Organization
IHR	International Health Regulations
IP	Intellectual property
IPRs	Intellectual property rights
ITPGR	International Treaty on Plant Genetic Resources for Food and Agriculture
PIC	Prior informed consent
PIIPA	Public Interest Intellectual Property Advisors
SMTA	Standard Material Transfer Agreement
TRIPS	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNCLOS	United Nations Convention on the Law of the Sea
US	United States
WHA	World Health Assembly
WHO	World Health Organization
IGM-PIP	WHO Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

FOREWORD

Sharing access to influenza viruses and vaccines and other benefits has become a pressing issue on the global health agenda. Its importance has dramatically increased in light of pandemic outbreaks in recent years. Discussions at the World Health Organization (WHO) on this issue have faced many challenges in balancing a number of different considerations and interests, including development of drugs and vaccines and affordable access to them for developing countries. As in other global discussions, intellectual property has emerged as a particularly contentious issue.

Against this background, *An International Legal Framework for the Sharing of Pathogens: Issues and Challenges*, which is a recent contribution by the ICTSD Programme on Intellectual Property Rights and Sustainable Development, aims to achieve a better understanding of the issues raised in these discussions. The author, Professor Frederick Abbott, is well known for his work at the intersection of global trade, intellectual property and public health.

The paper examines in an in-depth manner the different elements of an international legal framework for the sharing of biological materials with human pathogenic potential. It looks at options for the ownership and control of pathogen materials under international law. It shows that while states have sovereign rights of ownership and control over access to genetic resources located within their territories, public international law does not define the relevant terms and conditions of access, which remain to be negotiated by states. Denial of access to pathogen materials under extreme circumstances may entail international legal responsibility. By the same reasoning, states have an international legal responsibility as a matter of human rights law to prevent or mitigate serious harm to the life and health of individuals in other states, such as by supporting affordable access to vaccines and treatments, particularly under extreme conditions.

The paper also examines relevant international norms and processes that matter for ownership and control over pathogen materials. These include the Convention on Biological Diversity (CBD), the WHO Constitution and the International Health Regulations, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and international human rights norms. Supplemental norms are under negotiation at the WHO (in the Intergovernmental Meeting on Pandemic Influenza Preparedness) under the CBD (in the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing) and at the World Trade Organization (WTO) as part of the Doha Round.

In this regard, the paper provides groundbreaking analysis on the interface between the CBD negotiations on access and benefit-sharing, the WHO discussions and the WTO negotiations. While new rules related to pathogen materials sharing should most appropriately be negotiated at the WHO because of the specific public health aspects involved, there is a real risk that the result will be a two-tiered system of access to pathogen materials: one addressing certain influenza viruses under the auspices of the WHO and another addressing pathogen materials more generally under the auspices of the ABS Protocol and/or the CBD.

There might be at least some appearance of potential conflict between the CBD-ABS negotiations and the WTO negotiations insofar as the ABS draft text includes bracketed penalty provisions that might exceed the results of a negotiated solution concerning remedies at the WTO. But, at this stage, neither set of negotiations has reached a point where it is clear that there will be such a conflict.

In addition, the paper looks into complex issues surrounding intellectual property rights (IPRs), particularly as they relate to patents and pathogen materials. It underscores that a negotiated framework for the sharing of pathogen materials must address the question of the extent to which

recipients of such materials may apply for and obtain patents and/or the terms and conditions that will be applicable with respect to any patents obtained and provides insights into the different options in the discussions.

Also, the paper points out that issues connected with the sharing of pathogen materials are not confined to relations between developed and developing countries. Exclusive control over biological samples by a single developed country may prevent other developed countries from pursuing alternative avenues of research or from developing and manufacturing drugs and vaccines for their own (or foreign) populations. It may thus be short-sighted to view the creation of a pathogen materials-sharing mechanism solely through the lens of a North-South prism.

In the absence of a negotiated solution at the WHO or elsewhere, the reality is that pathogen materials are largely treated as part of a public domain outside those few countries that have blocked access to them - that is, at least until an individual enterprise is able to patent such materials or their derivatives and exercise exclusive legal control. There is thus a pressing need that these negotiations soon reach a successful and consensual outcome.

Finally, it is important to address other issues that stand in the way of sharing benefits, such as limited production capacity in developing countries. As the WHO Director General stated, "limited manufacturing capacity stands in the way of a completely fair and just system for the sharing of benefits."

ICTSD's Programme on IPRs and Sustainable Development has sought to achieve a better understanding of intellectual property (IP) in the context of sustainable development with a view to ensuring a proper balance between the different interests at stake in designing appropriate IP regimes supportive of development objectives and compliant with international commitments. Another central objective has been to facilitate the emergence of a critical mass of well-informed stakeholders in developing countries – including decision-makers and negotiators, as well as actors in the private sector and civil society – able to define their own sustainable human-development objectives in the field of IP and effectively advance them at the national and international levels.

The premise of ICTSD's work is based on the understanding that IPRs have never been more economically and politically important – or controversial – than they are today. Patents, copyrights, trademarks and geographical indications are frequently mentioned in discussions on such diverse topics as public health, climate change, food security, education, trade, industrial policy, traditional knowledge, biodiversity, biotechnology, the Internet and creative industries. In a knowledge-based economy, a better understanding of IP is indispensable to informed policymaking in all areas of development.

In this context, we hope that you will find this issue paper a useful contribution to ongoing discussions about regimes for pathogen material and benefit sharing in different international fora and processes. We also hope that it will be a valuable input for government negotiators, as well as other stakeholders, to reflect upon and consider in formulating their positions and views in relation to these important issues

Ricardo Meléndez-Ortiz
Executive Director, ICTSD

EXECUTIVE SUMMARY

Access to biological material with human pathogenic potential (pathogen materials) is important because research directed toward the development of new drugs and vaccines is dependent on scientific analysis of the underlying causes of disease. Member States of the World Health Organization (WHO) began to address problems associated with the sharing of pathogen materials when controversy arose in 2007 following Indonesia's decision to withhold samples of biological material containing the H5N1 virus (avian flu) from WHO researchers.

As a general proposition, states have sovereign rights of ownership and control over access to biological resources located within their territories and thus may determine the conditions of access to those resources. This includes ownership and control over access to pathogen materials. Sovereign control over pathogen materials and access to them is complicated by the fact that they have a tendency to spread geographically, and at some stage, to cross national borders in the absence of intentional human intervention.

These sovereign rights, however, do not imply that the host state is not constrained by international legal obligations, such as the obligation to protect human rights related to life and health and the obligation to protect against harm to neighbouring states. By the same reasoning, states have an international legal responsibility as a matter of human rights law to prevent or mitigate serious harm to the life and health of individuals in other states when it is within their capacity, such as by supporting affordable access to vaccines and treatments, particularly under extreme conditions. Distinguishing the potential withholding of pathogen materials, on one hand, and the failure of states to address problems of access and pricing of medicines more generally, on the other, is difficult.

The ownership and control of pathogen materials are regulated at the international level by a set of norms involving: public international law, the Convention on Biological Diversity (CBD), the WHO Constitution and the International Health Regulations (IHR), the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and international human rights norms. Supplemental norms are under negotiation at the WHO (in the Intergovernmental Meeting on Pandemic Influenza Preparedness) under the CBD (in the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing) and at the WTO (as part of the Doha Round).

The reasons pathogen materials may, or may not, be subject to the regime established by the CBD are technically complex from a legal standpoint. The conclusion that pathogen materials probably are covered by the CBD is not intended to suggest that the CBD is better equipped than the WHO to address the sharing of pathogen materials in the public health context, but rather addresses the existing or "default" legal situation. The fact that there may be overlap between the subject matter of the CBD, which regulates conditions of access to biological or genetic resources and imposes obligations on State Parties with respect to the sharing of benefits from the granting of access, and the subject matter under negotiation at the WHO related to the sharing of viruses with human pandemic potential is recognized.

At the time the CBD was concluded, the Parties recognized that the provisions regarding access, benefit sharing and intellectual property were "nonspecific". As a consequence, negotiations have been taking place for the past several years under the auspices of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing (ABS Working Group).

On top of that, negotiations are underway at the WTO on the relationship between the CBD and the TRIPS Agreement. Proposals by WTO Members to further the objectives of the CBD - by

mandating disclosure of the source and origin of genetic resources in patent applications, as well as by requiring evidence of compliance with prior informed consent (PIC) and equitable benefit sharing (EBS) requirements - remain controversial.

It does not appear likely that the results of WTO negotiations would impair a negotiated result at the WHO on the subject of pathogen materials sharing. However, there is at least some appearance of potential conflict between the CBD-ABS negotiations and the WTO negotiations insofar as the ABS draft text includes bracketed penalty provisions that might exceed the results of a negotiated solution concerning remedies at the WTO. But, at this stage, neither set of negotiations has reached a point where it is clear that there will be a conflict.

New rules related to pathogen materials sharing should most appropriately be negotiated at the WHO, because of the specific relationship to public health, which is most closely associated with the WHO charter. Protecting global health will require that countries share at least some categories of pathogen materials. An important element of the WHO negotiations is to define the availability of IPRs protection for the results of research and development. Underlying the WHO negotiations is the question of affordable access to vaccines and treatments for developing countries, which is a presumed condition of a pathogen materials sharing obligation, at least among some WHO Member States.

There is a real risk that the result will be a two-tiered system of access to pathogen materials: one addressing certain influenza viruses under the auspices of the WHO and another addressing pathogen materials more generally under the auspices of the ABS Protocol and/or the CBD. As a practical matter, subjecting states, economic operators and individuals to separate agreements covering the same subject matter may create confusion, particularly if the relationship between the agreements is not clearly specified and the rights and obligations are not in harmony. When public health interests are at stake, it is important to avoid a result that generates legal uncertainty and insecurity.

Recognizing that negotiators at the WHO and the CBD are engaged in substantially independent and complex exercises, greater attention should be focused on how the results of these exercises will relate to each other.

Patents are relevant to pathogen materials sharing, because public and private enterprises may secure (or attempt to secure) patents on “isolated” pathogen materials and/or on derivative products (including drugs or vaccines) of such materials. This patenting possibility has the potential to affect “upstream” research on new drugs or vaccines and the “downstream” production and distribution of necessary drugs or vaccines. The principal international agreements governing patents, the Paris Convention on the Protection of Industrial Property and the TRIPS Agreement, do not definitively determine the rules that are applicable to pathogen materials and derivative products.

Determining the extent to which patents inhibit access to drugs and vaccines is complex, and the methodology used to assess the situation of vaccines may differ from that used to assess the situation of drugs. With respect to pharmaceuticals, the expiration of the patent term and introduction of generic versions of originator drugs, other things being equal, usually results in significant price reduction as a consequence of competition among manufacturers. The situation with respect to vaccines is different. At present, there is a general worldwide shortage of vaccine manufacturing capacity. Therefore, while expiration (or other termination) of patents may be a necessary precondition for reductions in price, at least in the near term it is less likely to generate competition in the market, owing to the shortage of vaccine production facilities.

Nonetheless, while patents may not immediately affect the availability of vaccines, because of the global shortage of production facilities, the shortage problem may be exacerbated if intellectual property restrictions are not resolved promptly. Potential producers of vaccines, particularly in developing countries, may be unwilling to undertake the investment necessary to build new plants in the absence of advance commitments on the availability of technology.

There are thousands of patents granted with respect to pathogen materials or their derivative products, as well as on related technologies involving research and testing materials. It is a virtual certainty that pathogen materials shared in a multilateral framework could be used as the basis for future patent applications. Patents granted with respect to those applications would have the effect of restricting access to pathogen materials and/or derivative products. A negotiated framework for the sharing of pathogen materials must necessarily address the question of the extent to which recipients of such materials may apply for and obtain patents and/or the terms and conditions that will be applicable with respect to any patents obtained.

WHO Member States initiated these negotiations following Indonesia's decision in 2007 to withhold influenza virus samples from WHO researchers. This helps explain why the negotiations have limited their focus to this one, albeit critical, part of the question of access to pathogen materials. Yet, over the longer term it is a certainty that researchers at WHO Collaborating Centres and other public and private institutions will require access to pathogen materials more broadly in order to develop the vaccines and treatments necessary to protect public health.

While negotiators at the WHO have made some progress in refining their approach to an influenza virus-sharing regime, including the preparation of a draft standard material transfer agreement (SMTA), consensus on some broad outlines should not disguise that key questions remain and that failure to agree on answers to those questions may cause the arrangement to unravel.

1. INTRODUCTION

Access to biological materials with human pathogenic potential (referred to here as "pathogen materials"), whether found within or outside the human body, is important because research directed toward the development of new drugs and vaccines is dependent on scientific analysis of the underlying causes of disease, and in some cases it is reliant on the modification and beneficial use of those underlying causes.

Pathogens, or infectious agents that cause human disease, take a variety of forms. These include bacteria, fungi, helminthes (worms), protozoa, viruses and prions.[1] These forms of biological organisms may be benign (and many perform beneficial functions). However, as pathogens they are responsible for many of the most serious and widespread human disease conditions. Tuberculosis is caused by the bacterium *Mycobacterium tuberculosis*. Malaria is caused by the protozoa *Plasmodium*. HIV-AIDS is caused by the *human immunodeficiency virus*. 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.[2] Special risks are presented by pathogens that cause diseases with very high mortality rates in humans, such as the *Ebola* virus.

The development of new drugs is undertaken through various techniques, including screening of compounds for biological activity with respect to the disease-causing agents, analysis of chemical structures and reactions, analysis of genetic sequences, recombining genetic materials, and other techniques. Promising compounds or biological agents are subject to testing, ranging from *in vitro* testing, to *in vivo* testing in animals, and ultimately to clinical trials on human subjects. Vaccine development is dependent upon isolating or creating antigens that initiate an immune response effective against a particular pathogen.[3] The development of vaccines to protect against or mitigate pathogen-based diseases is dependent upon the availability of pathogen samples.

Member States of the WHO began to address problems associated with the sharing of pathogen materials when controversy arose in 2007 concerning WHO access to virus samples containing the H5N1 (avian flu) virus. This virus strain is considered to have significant potential for mutation into a form that would facilitate human-to-human transmission. Such mutation would give rise to a potentially devastating influenza pandemic. Two sets of fundamental problems with existing mechanisms for virus sharing were raised by Indonesia, joined by other developing countries in the context of the above-mentioned WHO deliberations.[4] First, the legal conditions under which virus samples were provided to WHO Collaborating Centres were insufficiently defined and/or enforced. This appeared to permit uses of virus samples that were outside the contemplation of the providing countries, such as the patenting by recipients of virus genetic sequences or derivatives. This was argued to interfere with the sovereign right of states to control natural resources found within their territories. The second set of issues concerned the conditions of access to technology and the end products of research (i.e., drugs and vaccines). At the most practical level, developing countries expressed concern that patented products based on virus materials obtained within their countries are priced beyond the reach of their public-health budgets. Moreover, developing countries are anxious to improve their own capacity to research and develop new drugs and vaccines, but find it a difficult prospect as the technology curve moves further in favour of the developed countries.

The WHO Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (IGM-PIP) was established in

this context. The meeting of the Open-Ended Working Group of Member States (PIP-OEWG) established to formulate proposals (10-12 May 2010) did not result in a set of final proposals, but the 63rd World Health Assembly (WHA) authorized continuation of the Working Group which will report through the Executive Board to the 64th WHA.[5]

IGM-PIP negotiators recognized that influenza viruses other than H5N1 may have "human pandemic potential," and the negotiating texts (while referencing H5N1) have referred more broadly to influenza viruses with pandemic potential.[6] Spread of a different virus, H1N1, was declared a pandemic event by the Director General of the WHO in 2009, causing a good deal of political fallout for the organization.[7] There was limited controversy associated with access to H1N1 virus samples, at least in part because of close working relationships between Mexican, Canadian and US public health officials seeking to rapidly respond to the initial outbreaks.[8] Within the WHO IGM-PIP framework, there has been some progress on draft texts addressing mechanisms for sharing, including the preparation of a draft SMTA.[9]

The IGM-PIP negotiations beg the question of whether it might also be sensible from a public health standpoint to consider whether additional arrangements are required for the sharing of other disease agents that have the potential for widespread impact on human health and economic welfare. This paper broadens the context of the WHO dialogue concerning virus sharing to pathogen materials-sharing. It considers potential mechanisms for the international sharing of pathogen materials by reference to rules and principles of international law and the practice of states, by reference to previously negotiated international mechanisms for establishing the terms of access to resources, as well as by reference to ongoing negotiations in various fora. Much of the development of international law concerns defining access to natural resources, and there is substantial precedent that sheds light on the pathogen materials-sharing problem. At the same time, there are unique features to this problem that require the formulation of new solutions. This does not especially distinguish the pathogen materials-sharing problem from others that have confronted the international community. International law has as one of its defining characteristics the capacity to adapt to evolving circumstances.[10] 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.

It is important to recognize that issues connected with the sharing of pathogen materials are not confined to relations between developed and developing countries. Concerns have previously arisen between developed WHO Members with respect to assertions of control over biological materials in third countries. This control may have inhibited (or threatened to inhibit) research in other developed WHO Members. Assertions of control, seeking to justify exclusive access, may be couched in terms of potential threats to national or international security. Exclusive control over biological samples by a single developed country may prevent other developed countries from pursuing alternative avenues of research, or 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 materials-sharing mechanism solely through the lens of a North-South dialogue.

The sharing of pathogen materials involves risks to public safety in the event that adequate protection against release is not provided. Some WHO Member States may also have concerns about the potential use of pathogen material for research programs directed toward biological weapons. A multilateral system for sharing pathogen materials must take public safety and security concerns into account, in addition to the concerns expressed about unauthorized commercialization. The "basket" of risks complicates analysis in this area.

As used in this paper, pathogen material refers to biological or genetic resources as found in nature. Such resources may be modified through human intervention to produce vaccines or treatments, for pure research, to create bioweapons or for other purposes. Ownership and control over structurally modified biological or genetic resources, such as used in the creation of new drugs and vaccines, is considered separately from ownership and control over pathogen materials as found in nature.

This paper first tackles the question concerning who owns and controls pathogen materials from the standpoint of developing effective preventatives and treatments and assuring their supply. It then turns to the question of the most appropriate forum for negotiating the terms and conditions of access to pathogen materials, including questions regarding IPR protection. Finally, the paper examines some issues connected with the sharing of benefits from use of such resources.

2. OWNERSHIP AND CONTROL OF PATHOGEN MATERIALS

There are three basic options to ownership and control of pathogen materials based on the historic development of public international law.

2.1 State Ownership and Control

Much of the history of the development of public international law is devoted to resolving issues concerning access to and control over natural resources. Up to the latter part of the 20th century, natural resources were generally understood to be non-living resources, such as minerals and petroleum,[11] and some living resources, such as fisheries resources.[12] In the latter part of the 20th century the concept of natural resources extended more broadly to non-living resources, such as clean air,[13] and to living resources, including animals, plant life and the building blocks of those living things.[14]

In the 1950s and 1960s, and as a reaction (in part) to exploitation by colonial powers, developing countries demanded and received affirmation in the United Nations General Assembly of each state's permanent sovereignty over its natural resources.[15] This affirmed the basis for oil-producing states to, for example, assert control over petroleum reserves located within their territories.

The Law of the Sea negotiations that spanned a decade and resulted in the adoption of the United Nation's Convention on the Law of the Sea (UNCLOS) in 1982 was concerned, *inter alia*, with defining rights of states to control the exploitation of resources within their exclusive economic zones, as well as with establishing an international institutional mechanism for the exploitation of certain mineral resources on the deep seabed (which resources were identified as the "common heritage of mankind," discussed below).[16]

By the late 1980s, growing worldwide concern about protection of the environment led to calls for negotiation of international agreements regarding the exploitation of natural resources in ways that would preserve the environment, including its biodiversity. The CBD was adopted in 1992 in connection with the United Nations Conference on Environment and Development.[17] As of May 2010, there are 193 country Parties to the CBD. The United States of America signed the CBD in 1993, but has not ratified it and become a Party. The CBD was adopted to preserve the diversity of biological resources found in nature (including in animals and plants). Preservation of biodiversity allows continuity in the natural evolution of species, continued use of biodiversity as a source of primary material for research and development and maintaining quality of life. The CBD expressly recognizes the sovereign rights of states over their natural resources.[18]

During the late 1990s, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) was negotiated under the auspices of the Food and Agriculture Organization (FAO). This agreement, concluded in 2001 (with entry into force in 2004), was viewed as complementary to the CBD, providing a facility to preserve and establish conditions of access to plant genetic resources for food and agriculture.[19] Like the CBD, the ITPGR affirms the sovereign right of states to exercise control over access to plant genetic resources for food and agriculture located within their territories.[20]

Sovereign control over pathogen materials and access to them is complicated by factors that do not affect comparatively "static" resources, such as oil or copper. Pathogen materials have a tendency to spread geographically, and at some stage, to cross national borders in the absence of intentional human intervention. A virus strain may originate in a particular country, but in many or most cases it will not stay there. It is difficult to argue that, because a virus strain or other pathogen material may originate in a particular country, that country "owns and controls" virus materials that are

transmitted outside the country through the ordinary incidents of human transmission through travel, animal migration or the effects of weather. If that were the case, all countries except the "country of origin" would theoretically be prevented from researching and devising treatments for viruses or other pathogen materials without the consent of the country of origin.

Pathogen materials are not unique in their capacity to traverse national boundaries. Birds and other forms of animal life migrate between countries, and fish and marine mammals routinely move in and out of national territories (including through exclusive economic zones) as well as across the high seas. Nation states have dealt with regulation of transboundary movement of birds, fish and marine mammals in a number of more and less geographically inclusive international agreements. The state in which a fish spawns or a bird hatches does not permanently "own" that resource when it migrates according to its natural proclivity, even if it may assert control while the resource is within its territory.[21] In that respect, the situation of viruses and other pathogens is not completely unique, even though the specific subject matter presents unique problems. In the case of pathogens with pandemic potential, it is not a good idea to force researchers and manufacturers of vaccines and treatments to await the serendipitous movement of pathogen materials to a place where they may be legitimately accessed. It is often important to act quickly, placing a public health premium on rapid access to samples at the originating source.

There are good arguments that pathogen materials are different than other natural resources and that a regime of sovereign control over access presents risks for public health. The global community collectively wants researchers to move as quickly as possible to identify vaccines and treatments. A regime of sovereign control may imply inefficiencies as negotiations over the terms of access take place and as the potential threat of "access withheld" shadows negotiations. These potential problems can be overcome with a pathogen materials-sharing mechanism that has been negotiated in advance. It is precisely this type of pre-negotiated mechanism that WHO Member States are trying to establish in the IGM-PIP. It is the details of the mechanism that remain unsettled; not the basic idea.

2.2 The Public Domain Option

When controversy first arose with respect to control over H5N1 virus samples, based on Indonesia's assertion of state sovereignty, a WHO official responsible for pandemic preparedness reacted by suggesting that virus samples be made freely available to the pharmaceutical industry.[22] That perspective has been subject to intense scrutiny.[23]

There are resources located outside the territorial jurisdiction of individual nation states that are essentially open to exploitation by anyone, a type of public domain, most notably resources of the "high seas" as to which no nation state exercises sovereign control. The UNCLOS negotiations did not address control over genetic resources in the high seas over which no state exercises exclusive control, and that gap remains.[24]

The ITPGR recognizes the sovereign right of states to control genetic resources located within their territories. However, the State Parties to the ITPGR have committed to providing facilitated access to plant genetic materials under their control (for a selected list of agricultural species/varieties) through a Multilateral System that may be freely accessed by researchers.[25] The ITPRG provides that the genetic resources contributed to the Multilateral System are in the "public domain" and not encumbered by intellectual property rights.[26]

The SMTA that is used to share materials contributed to the multilateral system permits the development and protection by IPRs (including patent) of derivative materials conditioned upon payment of royalties into a fund to be allocated for the benefit of

developing country agriculture.[27] The ITPGR provides for the transfer of technology for preservation and improvement of plant genetic resources for agriculture.[28]

Use in the ITPGR of the term "public domain" to characterize the genetic resources in the Multilateral System is somewhat strained because persons accessing those resources make certain commitments about uses to which those resources are put.[29] 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 payment of a royalty to the Multilateral System.

A seemingly straightforward solution to the potential problems arising from sovereign ownership and control over pathogen materials is to reach an international consensus to place them in the public domain, making them widely available to researchers and manufacturers. In a practical sense this was largely the situation that existed prior to Indonesia's assertion in 2007 of sovereign rights over H5N1 virus samples, and from an operational standpoint it may largely reflect the situation today.[30] The problem of transborder migration of pathogen materials should not arise under a public domain system because the geographic point of origin may not be important.

The ITPGR approach under which states have contributed agricultural genetic resources into a Multilateral System that is considered public domain provides a model that might be followed with respect to pathogen materials, although the underlying situations are different. The genetic resources contributed to the ITPGR Multilateral System represent strains of basic foodstuffs that are largely stable. The pathogen materials that would be part of a WHO sharing system presumably may be newly evolved, and in that sense previously unknown. A pathogen materials-sharing system modelled on the ITPGR Multilateral System would require continuing contributions of new materials from WHO Members into the public domain resource pool.

From the standpoint of developing countries such as Indonesia, there appear to be problems with the public domain option, at least in the pure sense of the public domain. Three problems have been identified. First, developing countries with limited financial resources do not obtain sufficient supplies of vaccines and treatments from private (or public) suppliers in the present global public health system. Second, developing countries with limited financial resources are unable to conduct the research and development, and/or build the production facilities, necessary to make their own effective use of pathogen materials. Finally, developing countries with limited financial resources may not benefit financially from the use of their pathogen materials in a pure public domain system (while private sector companies that secure patents and produce products would benefit financially). The pure public domain option generally operates to the benefit of the public and private sectors in developed countries by providing the basis for research and development on vaccines and treatments, the basis for securing patentable inventions and profits from production. 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 modelled 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 plant genetic resources are substantially different.

2.3 The Common Heritage of Mankind

There are resources located outside the territorial jurisdiction of individual nation states that are under the common control of all nation states, most notably mineral resources of the deep ocean seabed located beyond exclusive economic zones as recognized in UNCLOS.[31] Mineral resources on the deep

seabed constitute the "common heritage of mankind" and are subject to a form of collective ownership that manifested itself with the creation of the International Seabed Authority (including a regime for exploitation of mineral resources on the deep seabed). The concept of the common heritage of mankind and collective ownership of resources is not so well entrenched in international law as state sovereignty over natural resources, but it constitutes an option for addressing ownership and control over pathogen materials.

Conceptually, the international community could reach a consensus that pathogen materials are the joint property of all countries. They would not be freely available for use by anyone as under the public domain option. As with mineral deposits on the deep seabed, it would be necessary to negotiate a mechanism for regulating joint ownership, including the conditions of access to resources and the financial obligations of users of the joint property. The problem of transborder migration of pathogen materials might not arise under the common heritage option depending on whether the geographic point of origin of the materials would be considered a relevant factor in allocating benefits derived from using them. A "common heritage" or joint ownership solution might reduce the authority of any given country to block implementation of a sharing system (assuming countries willingly cede such authority to a joint control mechanism in establishing a system). Financial and/or treatment availability benefits from granting access might flow to a pool (such as a pool of developing countries), rather than to a single pathogen materials source country. Since no single country can predict whether it will be the originating point of a future pathogen-based outbreak, every country would have an incentive to pool risks and returns from providing pathogen samples. A "common heritage" or joint ownership-type solution might reduce the incentive for individual states to engage in strategic behaviours.

There are obstacles to the pursuit of a "common heritage" approach. Countries that expect to be the source of pathogen material may resist giving up ownership of potentially valuable resources. Countries whose industries profit from sales of vaccines and treatments may view such a system as burdensome. Finally, as a practical matter there may not be too much difference between the limited public domain option used by the ITPGR and the "common heritage" option once the relevant restrictions are introduced.

2.4 Obligations Inherent in Ownership and Control

A general principle of the sovereign right of states to control pathogen materials within their territory does not imply an absolute right of control. International law recognizes exceptions to the rights of states, for example, in principles of human rights that guarantee certain fundamental rights to individuals regardless of their place of residence.[32] States owe duties to each other under international law, such as an obligation to refrain from the use of force in international relations (absent exceptional circumstances).[33] The CBD expressly acknowledges a balance of rights and responsibilities of states, stating:

> "Article 3. Principle
>
> States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, *and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction*".

International law is a system of "rights" and "obligations." No state has an unfettered right under international law to cause harm to another state.

2.5 International Human Rights

International human rights instruments recognize rights to life and health as among the fundamental rights of individuals.[34] Each state in the international community has an obligation to protect the life and health of individuals for whom it exercises responsibility. As a general proposition, a state would not be responsible for protecting the life and health of individuals in other states because the first state does not have legal authority to regulate or act in other states. However, by analogy to international agreements (including the CBD) that recognize that a state may not engage in activities that threaten or cause harm to other states, international human rights rules should prevent one state from engaging in conduct that may jeopardize enjoyment of human rights (including the right to life and the right to health) in other states.[35] Indeed, it would be paradoxical if international legal rules prevented states from acting to pollute the environment of neighbouring states, but did not prevent them from acting to injure the life or health of individuals in neighbouring states. The invocation of international human rights law with respect to sharing of pathogen materials presents difficulties in "line-drawing."

It may well be that each state has an obligation under international human rights law to take reasonable steps to assist other states in the prevention of pandemic disease.[36] For example, the refusal by a state to share virus samples when the outbreak of a pandemic was imminent could constitute a violation of international human rights standards. However, the refusal to share pathogen materials in non-emergency situations may not raise the same level of human rights concern. While it might be preferable for states to share valuable resources that can be used to alleviate human suffering and improve living conditions, international human rights law probably does not generally operate to assure that states behave in such an enlightened manner. States rich in natural resources are not generally considered obligated to share them with states less fortuitously endowed. In this respect, the question of whether there is an international human rights obligation to share pathogenic materials probably must be assessed from the standpoint of the intensity and immediacy of a threat to public health.

In extreme circumstances, a decision to withhold pathogen materials that jeopardized the capacity of the WHO and its members to address a potential pandemic might constitute an imminent threat of serious harm to individuals and third states. Such a situation could create an international legal responsibility for the withholding state to prevent a threat to international peace and security. Consider, for example, if there was good reason to believe that the lack of a virus sample would preclude the development of a vaccine against an imminent H5N1 influenza pandemic, and that the pandemic could lead to the death of tens of millions of individuals. States likely to suffer from lack of vaccine as a consequence of such refusal might consider the refusal an act that jeopardizes national security.[37]

At the same time, millions of individuals die each year from treatable diseases (including HIV-AIDS) as a consequence of lack of access to medicines. Distinguishing the potential withholding of pathogen materials, on one hand, and the failure of states to address problems of access and pricing of medicines more generally, on the other, is difficult. If Indonesia, for example, has an international human rights obligation to provide H5N1 virus samples to the WHO, do not Europe, Japan and the United States also have international human rights obligations to assure affordability and access to medicines and vaccines? Could this represent a core human rights obligation in extreme circumstances?

Intuitively there may appear to be a distinction between a state, on the one hand, that withholds virus samples as undertaking an affirmative act that may be the proximate cause of harm to individuals in another state, and; a state, on the other hand, that fails to provide access to medicines to individuals in

another state, as a form of passive neglect. It may appear "easier" for a state to withhold a virus sample than to provide access to medicines. But, access to medicines can be facilitated through relatively "easy" actions such as making available to low-cost generic producers rights to use patented technologies, so the distinction may not be so robust.

2.6 World Health Organization Rules

The WHO Constitution obliges Members to "provide statistical and epidemiological reports in a manner to be determined by the Health Assembly" (Article 64) and to "transmit upon the request of the Board such additional information pertaining to health as may be practicable" (Article 65). These provisions may be interpreted to permit the organs of the WHO to direct Member States to provide certain pathogen materials to the organization.

The 2005 IHR of the WHO authorize the Director-General of the WHO to declare an international public health emergency and to make recommendations regarding steps Member States should take to address the event.[38] Member States are expected to implement those recommendations.[39] The IHR places obligations upon WHO Member States to provide information concerning events that may constitute international public health emergencies.[40] Nonetheless, while the IHR requires Member States to provide information, the IHR does not appear to mandate specifically that a Member State share physical samples of biological material, although such a requirement might be implicit in the general undertaking to protect against and provide a response to the international spread of disease.[41]

Assuming for the sake of argument that the IHR places an obligation on WHO Member States to share pathogen materials with the WHO in order to protect, for example, against pandemic influenza, the IHR does not establish detailed methodologies for handling such samples or address issues such as the rights of third parties (public or private) with respect to them.

The foregoing provisions of the IHR and WHO Constitution illustrate that WHO Members have certain obligations with respect to the WHO and third countries, including to aid in the prevention of the spread of disease. But it may be only with some difficulty that such obligations could be enforced against a Member State, particularly in light of the general nature of the obligations. The functioning of the WHO is highly dependent on the cooperation of its Member States.

2.7 Individual Rights

Conceptually, each individual may have a right to determine whether he or she wishes to share, sell or transfer his or her biological material to a third party for use in research. Such a right could provide the basis for transfer of pathogen materials. The question of whether individual human beings have a "property right" in parts of their own bodies is a complex one that has been the subject of domestic court decisions in some jurisdictions.[42] Even if some or all states were to recognize individualized property rights in parts of the human body, those states presumably would still exercise legislative control over the individuals holding those property rights from the standpoint of dealings with third states. While the matter is not entirely free from doubt, it does not appear that recognizing an individual right to control parts of the body would override the sovereign right of states to control access to human biological materials located within their own territories or of their own nationals (just as a state's recognition of an individual right to own real property does not prevent that state from controlling access by foreign nationals to ownership of local real property).

2.8 Some Conclusions

As a general proposition, states have sovereign rights of ownership and control over access to genetic resources located within their territories and thus may determine the conditions of access to those resources. This includes ownership and control over access to pathogen materials. Public international law does not define the relevant terms and conditions of access, which remain to be negotiated by states in their sovereign capacity. Because states have an international legal obligation to prevent or mitigate serious harm to other states from causes under their control, denial of access to pathogen materials under extreme circumstances may entail international legal responsibility. By the same reasoning, states have an international legal responsibility as a matter of human rights law to prevent or mitigate serious harm to the life and health of individuals in other states when this is within their capacity, such as by supporting affordable access to vaccines and treatments, particularly under extreme conditions.

States might choose to adopt a regime under which they contribute pathogen materials into the public domain, or alternatively establish a system of joint ownership over pathogen materials as a "common heritage of mankind." In either case, it would be necessary to adopt appropriate restrictions or limitations on the use of the pathogen materials and to define how benefits from use would be allocated.

In the absence of a negotiated solution at the WHO or elsewhere, the reality is that pathogen materials are largely treated as part of a public domain outside those few countries that have blocked access to them. This is true at least until an individual enterprise is able to patent such materials or their derivatives and exercise exclusive legal control. From the standpoint of the countries of the Organisation for Economic Co-operation and Development (OECD), at least, this may not be an unhappy state of affairs, even if risks remain that in a future case access to pathogen materials may be inhibited.

3. RELEVANT INTERNATIONAL PROCESSES

The international legal regime regulating access to pathogen materials is not limited to that being negotiated at the WHO. As noted above, public international law generally provides sovereign states with ownership and control over natural resources located within their territories. This general principle has been supplemented, particularly with respect to biological or genetic resources, by the CBD that regulates conditions of access to biological or genetic resources, and imposes obligations on State Parties with respect to sharing of benefits from the granting of access. The fact that there may be overlap between the subject matter of the CBD and the subject matter under negotiation at the WHO on sharing of viruses with human pandemic potential is recognized.[43]

There is room for debate concerning whether the CBD, or at least its provisions on ABS, covers viruses, because of specific definitional language in the CBD. There is less room for debate from a semantic standpoint on whether the CBD covers pathogen materials more generally, although there is some room for debate on policy or "object and purpose" grounds. The better view appears to be that, absent a newly negotiated exclusion of pathogen materials from the scope of the CBD, those materials are generally covered by it. That raises questions both in terms of how such coverage potentially affects public health-related access to pathogen materials under the CBD, and how a prospective WHO pathogen materials-sharing arrangement would interact with CBD rules.

Moreover, negotiations are under way at the WTO on the relationship between the CBD and the TRIPS Agreement. It is possible that new rules will be adopted with respect to disclosure in patent applications of the source and origin of genetic resources and/or evidence of compliance with CBD benefit-sharing requirements. This raises questions concerning the relationship between WTO rules and those that may be adopted at the WHO.

There are ongoing negotiations under the CBD to flesh out rules regarding conditions of access to genetic resources and the sharing of benefits (so-called ABS negotiations). Defining the biological or genetic resource subject matter that would be encompassed by the new rules is an important part of the negotiations. However, before considering the potential new rules, it is useful to look at the present situation.

3.1 Pathogen Materials Generally Under the CBD

3.1.1 Biological resources

The reasons pathogen materials may, or may not, be subject to the regime established by the CBD are technically complex from a legal standpoint. The preamble of the CBD "Reaffirm[s] that States have sovereign rights over their own biological resources".[44] The CBD has as one of its objectives "the conservation of biological diversity" (Article 1), and requires Parties to develop strategies for the protection of biological diversity (Article 6), to monitor such diversity (Article 7), and to take measures to conserve it (Articles 8 and 9). "Biological diversity" is defined in Article 2 of the CBD, which provides:[45]

> "'*Biological diversity*' means 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".

CBD Parties are also required to promote and protect sustainable use of "biological resources" (Article 10); to provide economic incentives for their conservation and sustainable use (Article 11) and to promote other activities regarding biological diversity and biological resources, including research and training (Articles 12-14). CBD Parties

undertake to promote transfer of technologies relevant to the conservation and sustainable use of "biological diversity" under agreed terms (Article 16). "Biological resources" is a specifically defined term that includes "genetic resources, organisms or parts thereof … with actual or potential use or value for humanity".[46]

Article 15.1 of the CBD states:

> "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation."

The first clause of Article 15 affirms state sovereignty over "natural resources". The term "natural resources" is not specifically defined in the CBD. "Natural resources" consists of the term "natural" that refers, *inter alia*, to "existing in or formed by nature; consisting of objects or materials of this kind; not artificially made or constructed,"[47] and "resources" that refers, *inter alia*, to "a means of supplying a deficiency; a stock or reserve which can be drawn on when necessary".[48] Used in a general sense, the term "natural resources" is broad. When states refer generally to sovereignty over their natural resources, they appear to be making an inclusive statement with respect to control over natural things located within their territories.[49] The first clause of Article 15 is a general recognition of rights over natural resources.

The second clause of Article 15 operationalizes the recognition of sovereign rights over natural resources with specific reference to "genetic resources" that are generally subject to the ABS regime.

"Genetic resources" is defined in Article 2 of the CBD by these related references:

> "'*Genetic material'* means any material of plant, animal, microbial or other origin containing functional units of heredity.
>
> *'Genetic resources'* means genetic material of actual or potential value".

Pathogen materials may fall within the definition of "biological diversity" or "biological resources," as well as within the definition of "genetic resources." Most pathogen materials would presumably be considered "genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems," and at least some would include functional units of heredity.[50]

3.1.2 Human genetic resources

An issue in connection with the CBD is whether "human genetic resources" are within its scope.[51] Shortly following entry into force of the CBD, the governing body established by the Convention - the Conference of the Parties (COP) - adopted a decision that: "Reaffirms that human genetic resources are not included within the framework of the Convention".[52] As a legal matter, the effect of this decision is not clear because the CBD does not expressly confer on the COP the authority to interpret the treaty.[53]

The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization (Bonn Guidelines), adopted by the CBD COP in 2002, address ABS issues. The Bonn Guidelines do not necessarily dispel ambiguity concerning application of the CBD and the ABS regime to human genetic resources (or to virus materials). They provide that:

> "All genetic resources and associated traditional knowledge, innovations and practices *covered by the Convention on Biological Diversity* and benefits arising from the commercial and other utilization of such resources should be covered by the guidelines, *with the exclusion of human genetic resources*." [italics added]

The Bonn Guidelines do not say that human genetic resources are not covered by the CBD. Instead, the Bonn Guidelines say that they

apply to all genetic resources covered by the CBD, yet excluding human genetic resources. In any case, the Bonn Guidelines are not a "binding" interpretation of the CBD.[54]

As discussed below, proposals were submitted to the Working Group on Access and Benefit Sharing of the CBD and reported by the Ninth COP of the CBD in connection with discussion of a formal international regime on ABS to expressly exclude human genetic resources from the regime, and a proposal to this effect was incorporated as bracketed text in the draft ABS Protocol discussed *infra*.[55] This suggests that, at least among some CBD Parties, the matter of whether human genetic resources are covered by the CBD and the ABS regime is not considered resolved.

3.1.3 Virus materials specifically

As noted above, "Genetic resources" is defined in Article 2 of the CBD by these related references:

> "'*Genetic material'* means any material of plant, animal, microbial or other origin containing functional units of heredity.
>
> *'Genetic resources'* means genetic material of actual or potential value." [underline added]

Virus materials, as a subset of pathogen materials, contain hereditary information and are capable of reproduction, but only within living host cells. Virus materials arguably do not contain "functional units of heredity" since viruses may not reproduce outside of a host organism, so the units of heredity might be considered "non-functional." The line between functional and non-functional units of heredity is difficult to draw. There is no established authoritative interpretation regarding whether viruses contain "functional units of heredity" within the meaning of the CBD.

In the Cartagena Biosafety Protocol, discussed *infra*, living organism is defined as "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids". [underline added][56] This definition, adopted subsequent to the CBD, suggests that parties to the Cartagena Protocol recognized the ambiguity inherent in the definition of genetic resources and sought to clarify the scope of coverage of the Protocol. The Cartagena Biosafety Protocol clearly applies to viruses, but not necessarily because viruses "contain functional units of heredity." Ambiguity in the scope of genetic resources in the CBD persists.

3.1.4 Policy arguments

The argument in favour of coverage of pathogen materials (including virus materials) by the CBD is that the agreement was designed to preserve biological diversity that, among other things, would permit future research and development on biological resources that might yield treatments for disease. Furthermore, the CBD was designed to allow developing countries to share in benefits from exploitation of biodiversity resources (e.g., to inhibit "bio-piracy"). 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.

An argument against considering pathogen materials within the scope of the CBD is that such materials do not have "actual or potential use or value for humanity" (Article 2, CBD). The primary interest of science and public health is to eradicate dangerous pathogens, not preserve them, notwithstanding that they represent a form of biodiversity. The definition of biological resources implies that the subject materials have a "positive value" of their own, and not a "negative value" that may be turned positive only as a means of defeating themselves (e.g., as the basis for a cure for their otherwise adverse effects). Put another way, it can be argued that the drafters of the CBD did not intend to protect biological materials that cause harm to humans and that a "conservation-oriented" agreement, such as the CBD should not have as its objective conservation of inherently dangerous materials. In a more

limited sense, it can be argued that, even if pathogen materials are broadly subject to the CBD, they are not intended to be subject to the ABS regime, as evidenced by the potential definitional exclusion of viruses.

It appears difficult to exclude pathogen materials generally from the scope of the CBD on broad policy grounds given that the CBD was at least in part negotiated to protect developing country interests in securing benefits from ownership, preservation and sustainable use of biodiversity. In addition, prospects for developing drugs and vaccines on the basis of biodiverse resources were well understood at the time of the negotiations.[57] Pharmaceutical decision-making often involves choices between pricing and availability of medicines. Pricing decisions may effectively cut off access to parts of the population. If decisions by states to withhold access to pathogen materials restrict access to vaccines and treatments, that puts their decision-making in line with existing industry practices.

The conclusion that pathogen materials probably are covered by the CBD is not intended to suggest that the CBD is better equipped than the WHO to address the sharing of pathogen materials in the public health context, but rather addresses the existing or "default" legal situation.

3.2 ABS Negotiations Under the CBD

The CBD establishes a general set of rights and obligations with respect to control over access to genetic resources and the sharing of benefits arising from that access. This includes general references to patents and other IPRs.[58] At the time the CBD was concluded, the Parties recognized that the provisions regarding access, benefit-sharing and IP were "non-specific," and the US gave as one of its principal reasons for refusing to ratify the agreement that it created uncertainty with respect to patents.

As a consequence of the general nature of the rights and obligations established in the text, the COP has engaged in or sponsored negotiating exercises designed to add specificity and/or clarify the nature of rights and obligations. The first major result was the Bonn Guidelines, mentioned above. But these were non-binding recommendations and remained fairly general. For the past several years, negotiations have been taking place under the auspices of the ABS Working Group. These negotiations are intended to establish a more detailed framework for access to and sharing of benefits with respect to genetic resources, but this time in the form of a Protocol to the CBD that would have binding effect (i.e., the Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity or "draft ABS Protocol").

The draft ABS Protocol would confirm the obligation to secure prior informed consent and enter into a benefit-sharing agreement as a condition of access to genetic resources. Negotiators are working towards the establishment of an internationally recognized certificate of compliance with ABS requirements that would assist with the tracking and monitoring of genetic resources, combined with requirements imposed on national regulatory authorities (such as patent offices) to consult those certificates when requested to approve applications (see Article 13, draft ABS Protocol). National governments would be obligated to establish "focal points" from which persons seeking access and information concerning relevant approvals could be assured of obtaining complete information (Article 10, *id.*), and an ABS Clearing-House would be established to provide such information internationally (Article 11, *id.*).

One of the open questions is whether that ABS regime will expressly exclude "human genetic resources" and/or "human pathogens".[59]

Proposed exclusions must be understood in the context of the full scope of the agreement, addressed in Article 3:

> "Scope
>
> This Protocol shall apply to genetic resources within the scope of the Convention on Biological Diversity and to the benefits arising from [any][the] utilization of such resources [that were acquired after the entry into force of this Protocol for a Party with Parties providing such resources] [or its derivatives]. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention on Biological Diversity and to the benefits arising from the utilization of such knowledge.
>
> [This Protocol does not apply to:
>
> a) human genetic resources;
>
> ...
>
> f) human pathogens;...]"

As with the Bonn Guidelines discussed earlier, the provision on scope does not purport to exclude human genetic resources and/or human pathogens from the CBD, but rather from the Protocol. In this regard, adoption of the exclusion might merely leave states in the same position with respect to human genetic resources and human pathogens as they were before its conclusion. This would be a very curious result, particularly in light of Article 6 which might establish a relationship between the Protocol and WHO rules and agreements.

Presumably "human pathogens" is intended to refer to external pathogens that may be harmful to humans, not to pathogens that are human. Exclusion of "human genetic resources" from the scope of the Protocol would not necessarily exclude pathogen materials found within humans from the scope of "biological resources" and "genetic resources" covered by the CBD and the ABS regime. Exclusion of "human pathogens" would presumably go further to cover pathogens that may be harmful to humans, but even this would leave ambiguity as pathogen materials may affect both humans and other life forms, and may mutate between strains that will and will not affect humans. Use of the term "human pathogens" for a potential exclusion is presumably intended to cover virus materials that may be harmful to humans. If that is the intent, it would be preferable to use language that encompassed pathogens that may become harmful to humans (i.e., with human pathogenic potential) because pathogens move between the animal and human worlds. It may further be useful to look more closely at the definition of "living organism" in the Cartagena Protocol, discussed above, to clarify what is encompassed by the term "pathogen."

Interestingly enough, and despite the great public attention given to intellectual property within the framework of the CBD,[60] the draft ABS Protocol addresses rights and obligations with respect to IPRs 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. It does include a proposal that "[When a genetic resource or associated traditional knowledge is utilised without mutually agreed terms, the country of origin and/or indigenous and local community involved shall be entitled to one hundred percent of the benefits generated, including any intellectual property, plus punitive damages.]"[61] It also indicates that the terms of a benefit-sharing agreement shall (or may) include IPRs,[62] and that monetary benefits may include joint ownership of IPRs.[63] The status of the bracketed language on damages remains to be determined.

The most specific reference to pathogen materials and relationship between the draft ABS Protocol and ongoing WHO negotiations is in Article 6 of the draft ABS protocol, providing:[64]

> [CONSIDERATIONS RELEVANT TO [NON-COMMERCIAL] RESEARCH AND EMERGENCY SITUATIONS
>
> "In the development and implementation of their national legislation on access and benefit sharing, Parties shall:

...

(b) [Pay due regard to emergency situations including serious threats to public health, food security or biological diversity, according to national legislation.][Provide immediate access to [pathogens][genetic resources] falling also under the scope of relevant international organizations and conventions, such as the World Health Organization, the International Plant Protection Convention, or the World Animal Health Organization, and which are of particular public concern for the health of humans, animals or plants, in ways and for uses provided for in existing and future rules, procedures or practices on the sharing of pathogens and related benefits established under those international organizations and conventions[, taking into consideration [the legal, structural and/or administrative obstacles to the optimal implementation of] the World Trade Organization paragraph 6 system]";

The first bracketed sentence would create a general though non-specific obligation to take external circumstances regarding pathogen materials into account in formulating and implementing national legislation, but would do little to clarify the relationship between the ABS Protocol and/or the CBD, on one side, and interests involving the WHO, on the other.

The second bracketed sentence is substantially more specific, although it leaves significant questions. Unless pathogen materials are expressly excluded from the scope of the ABS Protocol, this provision does not remove them from regulation under the draft Protocol. The first clause refers to providing "immediate access", but it does not explain how that obligation would relate to other obligations in the draft ABS Protocol, such as the obligations in Article 5 for obtaining prior informed consent and negotiating the terms of benefit-sharing agreements (unless these requirements are waived by the country where access is sought). The phrase "in ways and for uses provided for in existing and future rules, procedures or practices on the sharing of pathogens and related benefits established under those international organizations and conventions" may be intended to signal that WHO rules will take priority over ABS Protocol rules. By leaving the relevant pathogen materials subject to the ABS Protocol, the provision appears to constitute the ABS Protocol and the CBD as the "default regime" regarding access to pathogen materials in the event Member States are unable to reach alternative agreements at the WHO. It might also serve as a "gap filler" when WHO rules do not cover a specific issue. If pathogen materials are excluded from the scope of the ABS Protocol under the current formulation of draft Article 3, they might remain subject to the CBD (but not the Protocol), mooting application of Article 6 of the draft ABS protocol, with greater uncertainty all around.

While ABS Protocol negotiators have recognized some of the potential issues raised by overlapping subject matter, there is a lack of clarity as to precisely what they think ought to be done about it, and this assumes that the bracketed second sentence of Article 6(b) above is adopted in some reasonably proximate form.

Optimistic statements have been made by facilitators of the draft ABS Protocol regarding its imminent completion. In light of the many bracketed key provisions, it is not clear whether this assessment is realistic. If it is realistic, negotiators in the ABS Protocol forum and at the WHO in the IGM-PIP should focus attention on concrete ideas concerning how the two systems are expected to operate simultaneously with respect to the same subject matter. This does not appear to be a situation in which "constructive ambiguity" will operate for the public benefit.

It is finally worth noting that because the US is not a party to the CBD, it would not be subject to the ABS Protocol. The country that invests the most capital in research and development related to vaccines and treatments would not be part of the resulting arrangement.

3.3 World Trade Organization Negotiations

In the Doha Ministerial Declaration, the TRIPS Council was instructed "to examine, *inter alia*, the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to TRIPS Article 71.1".[65] At the Hong Kong Ministerial Conference, the WTO Director-General was directed to intensify consultations on this subject. The General Council would "review progress and take any appropriate action no later than 31 July 2006".[66] The latest results of those consultations were reported by the Director-General at the Geneva March 2010 stock-taking of the Doha Round. He reported only that "while my consultations have not created convergence they have certainly shed clearer light on the divergences".[67]

Proposals by WTO Members to further the objectives of the CBD by mandating disclosure of the source and origin of genetic resources in patent applications, as well as by requiring evidence of compliance with prior informed consent (PIC) and equitable benefit-sharing (EBS) requirements, remain controversial.[68] The positions of WTO Members fall roughly into three categories.

A substantial group of developing countries argues that mandatory disclosure of source and origin is necessary to assure that patent examiners take into account information relevant to assessment of patentability (including novelty and inventive step), as well as in making determinations of inventorship. Evidence of compliance with PIC and EBS is argued to assure consistent implementation of the TRIPS Agreement and CBD requirements. The penalty for failure to comply with mandatory disclosure and evidence requirements may include patent forfeiture.

A second group of countries sees merit in the proposal to impose a requirement to disclose the source and origin of genetic resources, but expresses concern with the potential remedy of patent forfeiture. Alternative remedies are suggested to include the civil assessment of compensation (e.g. royalties). Concern is also expressed with the potential bureaucratic complexities involved in evidencing compliance with the PIC and EBS.[69]

A third group of countries considers that complementarity between the TRIPS Agreement and the CBD can be adequately addressed through contractual arrangements between countries housing genetic resource stocks and bio-prospecting enterprises and argues against the imposition of a mandatory disclosure and/or evidence requirement. This group argues that the source and origin of genetic resources are not relevant to determinations of patentability or inventorship and that disclosure and/or evidence requirements would be unduly burdensome and create harmful uncertainty regarding the enforceability of patents.

It does not appear likely that the results of WTO negotiations would impair a negotiated result at the WHO on the subject of pathogen materials-sharing. The principal objective of the WTO negotiations from the standpoint of developing countries has been to assure that patent offices have the information necessary to make informed decisions regarding patentability as well as to assure that the country sources of genetic resources are able to identify resulting patent filings. A negotiated WTO solution may include potential remedies that may be taken against patent applicants neglecting to provide information, but it seems unlikely that such a control mechanism would interfere with the operation of a WHO pathogen materials-sharing arrangement. The current subject matter of WTO negotiations appears to be complementary to the WHO negotiations.

There is at least some appearance of potential conflict between the CBD-ABS negotiations and the WTO negotiations insofar as the ABS draft text includes bracketed penalty provisions that might exceed the results of a negotiated solution regarding remedies at the WTO. But, at this stage, neither set of negotiations has reached a point where it is clear that there will be a conflict.

3.4 Norms and Fora

The foregoing review and analysis indicates that the subject matter of ownership and control over pathogen materials is regulated at the international level by a set of norms involving, at least:

- Public international law (including UN General Assembly Declarations)
- The CBD
- The WHO Constitution and the IHR
- The WTO TRIPS Agreement (and related WIPO Convention rules)
- International human rights norms
- Supplemental norms under negotiation at the WHO (in the IGM-PIP), under the CBD (in the ABS Working Group) and at the WTO (as part of the Doha Round)

New rules related to pathogen materials sharing should most appropriately be negotiated at the WHO because of the specific relationship to public health, which is most closely associated with the WHO charter.[70] Negotiations in other fora largely, though not exclusively, address terms of voluntary access to biological resources. Protecting global health necessitates that countries share at least some categories of pathogen materials. WHO negotiations must address the role of WHO Collaborating Centres that typically are the initial recipients of shared pathogen materials and define the role of various other downstream public and private research centres. An important element in the WHO negotiations is to define the availability of IPRs protection for the results of research and development. The WHO negotiations should establish specific terms of technology transfer in relation to vaccines and treatments. Underlying the WHO negotiations is the question of affordable access to vaccines and treatments for developing countries, which is a presumed condition of a pathogen materials-sharing obligation, at least among some WHO Member States. There is a unique financing component to the negotiations.

Viewing the WHO as the most appropriate forum for rules and negotiations related to pathogen materials sharing does not answer residual questions:

- If WHO Member States fail to reach an agreement on the sharing of influenza viruses with human pandemic potential, or more broadly on sharing of pathogen materials, what regime will govern access to those materials?
- Should the CBD and/or the ABS Protocol expressly exclude any or all parts of pathogen materials from their scope, or should those agreements serve as "gap fillers" where WHO rules do not address a particular subject matter? Should a person seeking pathogen materials from a State Party to the ABS Protocol be required to comply with national legislation implementing access and benefit sharing with respect to genetic resources? Should pathogen materials be the subject of an international certificate evidencing compliance? Should patent offices in ABS Protocol Parties require an international certificate prior to processing a patent application? Would current ABS Protocol obligations interfere with the efficient functioning of the WHO system that is being designed to provide rapid access?
- What regime or rules will govern IPRs in pathogen materials? Will WHO rules assume a priority with respect to the specific subject matter?
- What will be the result if "human pathogens" are excluded from the ABS Protocol, but not from the CBD?

At the moment, the draft WHO IGM-PIP text and the draft CBD ABS Protocol include bracketed provisions that address some aspects of the relationship between the agreements.[71] Substantially more attention is required to clarify the prospective relationship.

4. INTELLECUTAL PROPERTY AND PATHOGEN MATERIALS

4.1 Patents and Other IPRs

The development and production of drugs and vaccines typically requires a range of financial, scientific and material resources. The intellectual property rules that regulate the development and distribution of drugs and vaccines may influence the private and public investment of capital, access to research tools (including biological materials), encouragement of innovation by scientists, transfers of technology, the ability of vaccine producers to successfully enter the market and ultimately the extent of access to drugs and vaccines by states and individuals.

The "patent" is the form of IP most important in the development and production of drugs and vaccines.[72] A patent is a set of rights granted to the inventor of a new, inventive and useful product or process.[73] The patent authorizes the inventor to prevent third parties from making, using, selling, offering for sale or importing[74] the invention for a minimum term of 20 years from the filing of the patent application. Patents are granted with respect to specific national (and occasionally regional) territories, and a patent holder typically may exercise its exclusive rights only as to those territories.

The principal international agreements governing patents do not definitively determine the rules that are applicable to pathogen materials and derivative products. The Paris Convention on the Protection of Industrial Property does not define the subject matter of patent protection. The TRIPS Agreement provides that patents must be granted with respect to inventions in all fields of technology, and further provides that an invention should be new, inventive and useful.[75] The TRIPS Agreement provides that WTO Members need not provide patent protection for plants and animals, except for microorganisms.[76] The general guidance of the TRIPS Agreement leaves significant room for determining the nature of inventions for which patents will be granted.[77]

The discovery of a natural phenomenon is not patentable.[78] There is substantial support among commentators for the proposition that genetic material and information in the form found in nature cannot be patented.[79] A number of states have authorized the patenting of genetic material and information that has been isolated from the human body and reproduced in the laboratory.[80] This practice of some states does not bind other states to adopt similar rules with respect to the patentability of genetic material and information in forms found in nature.

A drug or vaccine may be comprised of a product that is "derivative" of a product found in nature, such as a structurally or genetically modified virus.[81] The process by which a particular drug or vaccine (or class or group of them) is manufactured/synthesized may be subject to a "process" or "method" patent.

Because derivative drug or vaccine products are modified by human intervention to be different from those found in nature, such products may be patentable subject matter (depending upon satisfaction of the criteria of patentability). It may be that a particular drug or vaccine represents a modification of a naturally occurring material by well-known processes such that its invention would not be considered "inventive" or "non-obvious" and therefore would not satisfy a principal criterion of patentability.[82] Whether derivative drug or vaccine products or production processes will be subject to patenting depends on a case-by-case assessment of each claimed invention. The result of the assessment may differ among countries depending on which standards are used.

"Research tools" used in the development of drugs or vaccines may also be subject to patenting. Diagnostic tools that identify specific genetic sequences signalling predisposition to particular cancers have been patented (and continue to be highly controversial).[83] The US Court of Appeals for the Federal Circuit

has rejected the patenting of "expressed sequence tags" (ESTs) that claimed as their utility the identification of locations of particular nucleotide sequences on DNA strands, but without indicating the function of those sequences.[84] As with patented drug or vaccine products and production processes, the question whether particular research tools used in their development will be patented depends on a case-by-case, country-by-country assessment.

In a closely watched case involving patents to genetic sequences identifying a propensity toward breast cancer, a federal district court in the US, in 2009, ruled that such patents are invalid because they merely identify products or properties of nature and do not incorporate inventive modifications.[85] Discoveries of products or properties of nature are inherently unpatentable. While this decision is on appeal, it confirms what many patent experts have long suggested: the patenting of genetic sequences found in nature is inconsistent with fundamental patent principles.

Patents are not the only form of IP with the potential to affect the development, production and/or distribution of drugs and vaccines. A 'trade secret' protects undisclosed commercially valuable information that a business has taken reasonable steps to protect.[86] Trade secrets may protect production processes used for drugs and vaccines. The TRIPS Agreement also obligates countries to protect undisclosed information regarding new chemical entities in the pharmaceutical sector submitted for the purpose of securing regulatory approval against "unfair commercial use".[87] Regulatory data protection has been implemented in the form of marketing exclusivity rules by some countries (and regions). Marketing exclusivity granted to the originator of a novel drug or vaccine based on the submission of regulatory data could affect the production and availability of that drug or vaccine.

Patents are relevant to the problem of pathogen materials sharing because public and private enterprises may secure (or attempt to secure) patents on "isolated" pathogen materials and/or on derivative products (including drugs or vaccines) of such materials. This patenting possibility has the potential to affect "upstream" research on new drugs or vaccines and the "downstream" production and distribution of necessary drugs or vaccines.

4.2 Patents, Innovation and Access

Enterprises investing (or contemplating investment) in the development of novel drugs and vaccines indicate that patent protection is required to (a) stimulate research by holding out the prospect for reward, and (b) to induce investment in development and production.[88] They suggest that without the prospect for substantial return, enterprises (and their investors) will not engage in the high-risk business of developing drugs and vaccines.[89] The grant of patents is intended to promote innovation, and investment in innovation, by providing the framework in which innovators may profit sufficiently from their work. The extent to which the patent system as presently administered effectively promotes innovation in the pharmaceutical sector is much debated. Yet regardless of the extent to which the system is operating effectively, patents are the principal means of encouraging private sector investment in the development of new drugs and vaccines.

Determining the extent to which patents inhibit access to drugs and vaccines is complex, and the methodology used to assess the situation of vaccines may differ from that used to assess the situation of drugs.[90] Patents protect inventors of new drugs or vaccines from direct competition in the market by equivalent products.[91] The extent of the market power of a pharmaceutical patent holder depends on whether there are alternative therapies in the market, and how effective those therapies are in comparison to the patented product. Other factors, such as price, may affect market power, but when a patent holder controls the only available therapy, consumers are relatively price insensitive. In the pharmaceuticals market the expiration of the patent term and introduction of generic versions of originator

drugs, other things being equal, usually results in significant price reduction as a consequence of competition among manufacturers. With respect to pharmaceuticals, analyzing the impact of patent protection is relatively straightforward. When patents are granted for new drugs for which there is a significant purchasing public, prices for those drugs will be higher than in a purely competitive market. To the extent that individuals or public health authorities are unable to afford those prices, access to pharmaceuticals is restricted. The extent of the restriction will vary based on a number of factors.

The situation with respect to vaccines is different. At present, there is a general worldwide shortage of vaccine manufacturing capacity.[92] This situation is markedly different from the pharmaceutical products sector where, in general, there is surplus manufacturing capacity.[93] In the current environment, the production of vaccines is most likely to be significantly limited by inadequate production capacity, particularly in developing countries. Eliminating patents on vaccines may permit third parties to enter the market, but there may still be a significant lead-time in the construction of new production facilities. Therefore, while expiration (or other termination) of patents may be a necessary precondition to reductions in price, at least in the near term it is less likely to generate competition in the market because of the shortage of vaccine production facilities.

Nonetheless, while patents may not immediately affect the availability of vaccines because of the global shortage of production facilities, the shortage problem may be exacerbated if IP restrictions are not resolved promptly. Potential producers of vaccines, particularly in developing countries, may be unwilling to undertake the investment necessary to build new plants in the absence of advance commitments on the availability of technology. The participation of multilateral institutions, such as the WHO, in vaccine-related capacity building projects does not by any means assure that public or private sector holders of relevant patents will make technology adequately available.

There are thousands of patents granted with respect to pathogen materials or their derivative products, as well as on related technologies involving research and testing materials. It is a virtual certainty that pathogen materials shared in a multilateral framework could be used as the basis for future patent applications. Patents granted with respect to those applications would have the effect of restricting access to pathogen materials and/or derivative products. A negotiated framework for the sharing of pathogen materials must necessarily address the question of the extent to which recipients of such materials may apply for and obtain patents and/or the terms and conditions that will be applicable with respect to any patents obtained.

Specifically with respect to present IGM-PIP discussions regarding H5N1 virus sharing, at the WHO's request, WIPO prepared an Expert Report on patent issues related to influenza viruses and their genes[94] as well as commissioning from Public Interest Intellectual Property Advisors (PIIPA) a "Patent Landscape of H5N1 Virus".[95] The WIPO Expert Report highlighted a significant increase in patent application filings with respect to H5N1-relevant inventions during the first nine months of 2007 compared with previous periods.[96] On one side, the increase in patent activity reflected growing research and development intensity with respect to H5N1 is favourable from the standpoint of improving available vaccines (and treatments). On the other side, increased patent application filings evidence the potential for upstream and/or downstream roadblocks to arise as patents are granted and vaccines are developed. Published patent applications may themselves deter research and development by third parties worried about pursuing a field already occupied by a competitor.

At that stage, none of the patent applications reported claim to "invention" of the genetic sequences of the H5N1 virus.[97] In other words, no party had attempted to claim the virus itself. There was speculation by authors of the

PIIPA H5N1 Patent Landscape that researchers may recognize that patents covering such naturally occurring materials would not be granted, and may appreciate that attempting to obtain such patents would generate adverse publicity.[98] However, there are a substantial number of patent applications directed to products (vaccines and treatments) to address influenza. Most of the patent applications are directed toward "vaccine design".[99]

One key unresolved question in the IGM-PIP negotiations draft texts is whether and under what conditions private sector enterprises will be allowed to obtain patents on genetic materials supplied under the regime, or on genetic materials or information derived from such materials. There is a current proposal that patenting will be permitted, provided the patent holder agrees to provide the WHO with a royalty-free, nonexclusive, transferable license, that the Director General may use to license developing countries "with appropriate terms and conditions",[100] and several alternatives to the specific formulation have been proposed.[101] Such solutions are in line with current efforts to form "patent pools" that can be used to license suppliers of medicines to developing countries, such as for the treatment of HIV-AIDS. In fact, as discussed below, it may be reasonable to contemplate using the model of the patent pool that is developed by UNITAID as a vehicle for holding patents secured on the basis of materials shared under the WHO pathogen-sharing regime.

Patenting of vaccines and treatments derived from pathogen materials that meet the traditional criteria of patentability should be permitted within an appropriate framework of benefit-sharing, unless invention takes place under some separate inducement-system that defines the rights of the inventor differently. Inducement is required for the capital formation needed to stimulate investment in research and development. But this does not mean that the inducement cannot be appropriately tailored to meet global public health requirements.

4.3 Existing Flexibilities

No country is without authority to override patents that have been granted within its territory. The Paris Convention on the Protection of Industrial Property and the TRIPS Agreement each make express provision for the grant of licenses to use patents without the consent of the patent holder.[102] The WTO Waiver Decision of 30 August 2003 and the Article *31bis* amendment to the TRIPS Agreement include authority for countries without adequate drug or vaccine manufacturing capacity to request exports under compulsory license from third states (for countries that have not elected to "opt out" of the system).[103] Even without the treaty based authority described above, every sovereign state has the right and responsibility to protect its population against imminent public health threats based upon general principles of public international law.[104] U.S. Secretary of Health and Human Services, Michael Leavitt, said as much in testimony before the U.S. Congress precisely in relation to securing adequate supplies of antiviral treatment for potential H5N1 influenza.[105] Secretary Leavitt's "do everything necessary to protect them" doctrine represents the law of common sense.

In addition, international patent rules including the Paris Convention and TRIPS Agreement allow countries to adopt research exemptions that permit the use of patented technologies in the development of drugs and vaccines. The US Supreme Court, for example, has affirmed a broad research exemption in the pharmaceutical sector based upon statutory US patent law.[106]

WTO rules regarding the protection of regulatory data are significantly more flexible than the mechanisms that have been used to implement those rules by some countries. Article 39.3 of the TRIPS Agreement applies only to pharmaceutical products that utilize "new chemical entities." A vaccine derived from genetic pathogen material might not constitute a new chemical entity. In addition,

Article 39.3 obligates WTO Members only to protect against the "unfair commercial use" of regulatory data, and use of data, for example, in the approval of a drug or vaccine to be supplied by a public health program may not constitute "unfair commercial use." The waiver of otherwise applicable marketing exclusivity rules based on regulatory data submission in connection with the issuance of compulsory patent licenses is necessary to make such licenses effective. The European Union in its regulation implementing the WTO 30 August 2003 Decision expressly waives the application of marketing exclusivity rules in the context of compulsory licensing for export.[107]

5. BENEFIT-SHARING: OPTIONS AND CHALLENGES

A key unresolved question in the WHO IGM-PIP that would affect negotiations regarding pathogen materials more broadly, is the type and level of support that will be provided to developing countries in terms of securing access to vaccines and treatments, including transfer of technology that may enable local research and development and production of vaccines and treatments. One proposal regarding access involves a commitment by the recipient of influenza virus samples in the IGM-PIP framework to make available a percentage of dosages produced at cost to the UN system for provision to developing countries.[108] That does not answer the question of how the UN system will pay for treatments "at cost", but it is a conceptual start.

5.1 No IPRs

If the recipient of pathogen material from the facility does not file for or obtain patent protection with respect to a product or a process based on or derivative of that material, but instead makes its technology freely available, further benefit-sharing obligations with respect to that recipient might be appropriately limited. This is the approach taken under the ITPGR.

5.2 IPRs protected

There exists a "private market" system for the development and production of drugs and vaccines that largely relies on the availability of patents to provide the financial incentive for innovation, and the availability of market pricing for drugs and vaccines to stimulate the translation of innovation into marketable and, ultimately, delivered products.[109] This private market system may be considered by some governments to be an adequate solution to the problems of innovation and access, needing no modification (as to their own national requirements) from the standpoint of a multilateral pathogen materials-sharing mechanism. It may be necessary or desirable to establish a multilateral framework that recognizes alternative forms of participation in the system. The multilateral framework need not be designed as a "one-size-fits-all" solution, provided that "all" are encompassed within the solution by a "size" that is adequate for their public health needs.

It is generally accepted (though perhaps not universally) that patents should not be granted with respect to genetic materials as found in nature. WHO Members might agree that IPRs may not be secured on pathogen materials (including genetic resources and information) in forms unmodified from that found in nature. Such a commitment would be reflected in the SMTA. However, Parties may be authorized to secure patents on inventions related to derivative products or processes under national laws governing such inventions.

Proposals have already been made in the context of the IGM-PIP SMTA negotiations for the granting of a non-exclusive royalty free license to the WHO for making available additional productive resources in developing countries, as have proposals for requiring that some percentage of a patent holder's production be made available at cost to the United Nations institutions.[110]

Persons that commercialize patented inventions based on or derivative of pathogen materials might incur an obligation to pay a royalty into a fund to be managed by the WHO (or other institution), for example, for purposes of purchasing vaccines and/or treatments, to improve research and development and/or production in developing countries.[111] Some such proposals already are formulated, and include designation of a "solidarity fund" or "solidarity mechanism".[112]

An alternative mechanism for dealing with patents would be to establish a multilateral patent pool (or series of pools) into which patents based on or derivative of materials

from pathogen materials would be placed. Use of patented technologies from the pool might be allocated across different geographic, income level and/or public/private sector criteria. So, for example, a multinational originator company contributing to a patent to the pool might retain exclusive rights to exercise that patent in developed countries, while producers in developing countries might be given rights to use the patented technology for sale or distribution of drugs in developing countries upon the payment of royalties established according to a scale based on local incomes and needs. The royalties could either flow back to the contributing patent holder, or be retained by the pool for uses such as enhancing developing country technological capacity.

UNITAID has established an independent voluntary patent pool for medicines with an initial focus on increasing access to newer antiretroviral medicines (ARVs) that will be useful to study as a potential model.

5.3 Capacity Building

One of the key elements to a successful pathogen materials-sharing mechanism is providing means to increase production of drugs and vaccines particularly in developing countries. This may well be a precondition of securing participation by developing countries that presently are faced with inadequate access to drugs and vaccines.

In an optimally synergistic system, financial contributions from the development of drugs and vaccines derived from shared pathogen materials would be used to finance the construction of production facilities and transfer of technology.[113] In some cases royalty payments from patent holders based on sales of new drugs might be sufficient to provide funding for new pharmaceutical production facilities. Most likely this would occur when a new drug finds a substantial market in developed countries. This is not, however, a realistic approach with respect to at least some vaccines or to drugs developed to treat diseases prevalent in poorer developing countries (i.e., drugs for neglected diseases). Financial return on research and development of a new vaccine would come only after the vaccine enters production. Yet planning and construction of a vaccine production facility is a long-term enterprise. It cannot wait for speculative returns on private sector investment in new technologies. Sales of drugs to treat neglected diseases are unlikely to generate significant financial returns because of the lack of a paying market.

This suggests that an autonomous funding source for capacity building is needed as a component of the proposed pathogen materials-sharing mechanism. The requirements of such a funding source are likely to be substantial.

Conceivably, multilateral organizations like the World Bank could extend credit for the construction of production facilities with repayment tied into royalties from sales of drugs and vaccines. As noted above, this is not to suggest that royalty payments are likely to be adequate to fully pay the costs of such construction, particularly with respect to vaccines and drugs provided to markets with modest purchasing power. It is virtually inevitable that the costs of “ramping up” global production capacity to address, for example, a potential H5N1 influenza pandemic on developing countries will be paid for by public funding. There is no realistic developing country “private market” for global pandemic preparedness because, *inter alia*, a pandemic is a low probability event with a very high potential cost.[114] Even if, in theory, individuals in developing and least developed countries possessed adequate financial assets to cover the cost of vaccines for this low probability event, it is unlikely they would be willing to expend scarce resources on this contingency. At the same time, a pandemic would not be limited to developing and least developed countries. Countries with adequate financial resources will be acting in their own interests to protect against a pandemic arising in countries lacking those resources.

An alternative to multilateral institutional funding is the creation and imposition of some form of global taxation system that would collect revenues and distribute them for prevention and treatment of pandemic disease outbreaks. The French government, for example, has implemented an airport tax on international fliers to fund contributions to UNITAID. There are numerous questions that arise in the context of contemplating a potential global taxation framework specifically addressed to one "shared problem," i.e. the potential spread of pathogen materials-based disease.

The WHO already has devoted considerable attention to the subject of mechanisms for increasing the supply of vaccines to address supply constraints in addressing the threat of an H5N1 pandemic,[115] and is also devoting attention more generally to the financing of research and development.[116] A non-paper by the Co-chairs of the PIP Open-Ended Working Group identifies a few potential sources of financing, although at a relatively preliminary and nonspecific stage.[117]

5.4 Security

On 29 January 2000, the COP of the CBD adopted the Cartagena Protocol on Biosafety to supplement the CBD.[118] As of May 2010, there were 158 Parties to the Protocol. According to Article 1 of the Protocol:

> "The objective … is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements".

The Protocol provides a mechanism for notification by exporting parties to designated national authorities of importing parties prior to the "intentional transboundary movement of a [covered] living modified organism" (Article 8, Protocol). This is the "advanced informed agreement procedure." The Protocol establishes various obligations regarding safe handling of covered materials, based on the precautionary principle. It provides for the establishment of a "Biosafety Clearing-House" (BCH) (Article 20, Protocol). The BCH is established and operational.[119]

In considering potential multilateral arrangements for the sharing of pathogen materials, it is important to recognize that significant attention already has been paid outside the WHO framework to issues of safety and security with respect to handling biological materials and that future work from the WHO standpoint may - in addition to the biosafety protocols of the WHO - build on this experience.

The fact that governments may experiment with and/or develop biological weapons that make use of pathogen materials as found in nature cannot be ignored. A significant part of US federal government research and development expenditure on vaccines and antiviral treatment is directed toward defensive applications regarding pathogen materials, and these expenditures are doubtless being undertaken for a purpose. It is probably unrealistic to suggest that governments will disclose the pathogen materials being used in defensive programs or agree to share those pathogen materials under a negotiated mechanism. Whether state parties to a pathogen materials-sharing agreement would want to include an explicit "security exception" is an interesting question. The inclusion of such an exception would imply that states are entitled to maintain defensive biological weapons programs.

6. THE WAY FORWARD

Negotiators at the WHO have made some progress in refining their approach to an influenza virus-sharing regime. They have accepted that some commitment should be made with respect to sharing of viruses, though significant differences remain regarding the bindingness of such commitments.[120] They appear to have accepted the general proposition that the present mechanisms for assuring access to vaccines and treatments in developing countries is inadequate, and that the new regime should address this problem.[121] They are reported to have tentatively accepted that public-sector institutions will not attempt to secure patents on genetic resources in virus samples. They have tentatively agreed on a form of instrument - the SMTA - that should act as the vehicle for transferring pathogen materials, at least under some circumstances.[123] But, this agreement on some broad outlines should not disguise that key questions remain unresolved and that failure to agree on answers to those questions may cause the arrangement to unravel.

WHO Member States initiated these negotiations following Indonesia's decision in 2007 to withhold influenza virus samples from WHO researchers. This helps explain why the negotiations have limited their focus to this one, albeit critical, part of the question of access to pathogen materials. Yet, over the longer term it is a certainty that WHO Collaborating Centres and other public and private researchers will require access to pathogen materials more broadly in order to develop vaccines and treatments necessary to protect public health. Currently, governments are negotiating access to biological resources, and the sharing of benefits, under the auspices of the CBD. The CBD ABS Protocol negotiations are not specifically focused on public health requirements, although there is some effort to address them.

There is a real risk that the result will be a two-tiered system of access to pathogen materials: one addressing certain influenza viruses under the auspices of the WHO and another addressing pathogen materials more generally under the auspices of the ABS Protocol and/or the CBD. As a practical matter, subjecting states, economic operators and individuals to separate agreements covering the same subject matter may create confusion, particularly if the relationship between the agreements is not clearly specified and the rights and obligations are not in harmony. When important public health interests are at stake, it is important to avoid a result that generates legal uncertainty and insecurity.

Recognizing that negotiators at the WHO and the CBD are engaged in substantially independent and complex exercises each in their own right, greater attention should be focused on how the results of these exercises will relate to each other. Moreover, negotiators at the WHO should be cognizant of the fact that the current IGM-PIP negotiations are not taking place in a legal vacuum. This not only suggests that increased effort should be made to bring the current negotiations that address influenza viruses to a satisfactory conclusion, but also that these negotiations should be followed by a broadened effort to more generally address pathogen materials.

ENDNOTES

1 *See* S. Cleaveland, M.K. Laurenson and L.H. Taylor, *Diseases of Humans and their Domestic Mammals: Pathogen Characteristics, Host Range and the Risk of the Emergence*, PHIL. TRANS. SOC. LOND. B. (2001) 356, 991-99.

2 *See, e.g*, Samuel K Cohn Jr., 4 Epidemiology of the Black Death and Successive Waves of Plague, MED HIST SUPPL. 2008; (27): 74–100, PMCID: PMC2630035. While influenza viruses may present a special risk of developing into pandemics, the possibilities for rapid and wide transmission of deadly disease are not limited to influenza or other viruses. Well-known "plagues" affecting human civilization appear to have been caused by bacterial agents. One need not be alarmist to note that extreme multi-drug-resistant tuberculosis (bacterial-based) has the potential to evolve into a more widespread global public health problem.

3 There are different scientific methods for creating vaccines, including deactivation and reproduction of the pathogen, and more recently developed "reverse genetics" (or "reverse vaccinology") and bioinformatic-based techniques. *See, e.g., Vaccine Update, Influenza* (at pgs. 89-94) and Herve Tettelin, Rino Rappuoli and Clair Fraser-Liggett, *Using Genomics to Identify Novel Vaccine Candidates Against Pathogens* (at pgs. 37-42), in US Department of Health and Human Services (National Institutes of Health and National Institute of Allergy and Infectious Diseases), *The Jordan Report: Accelerated Development of Vaccines 2007* (May 2007).

4 WHO practice involved obtaining virus samples from countries where infected patients are located and distributing those samples to Collaborating Centres that worked, *inter alia*, on identifying appropriate vaccine candidates and/or treatments. The Collaborating Centres, pursuant to their terms of reference, made available to the WHO the results of research and support regarding virus samples. Those Collaborating Centres also provided virus samples (and research data) to private sector companies that develop vaccines and/or treatments. See Third World Network, *Sharing of Influenza Viruses*, Briefing Paper, May 2007 (hereinafter "TWN Briefing Paper"), at 2-3, including indications from Indonesia that WHO Collaborating Centres had violated WHO procedures requiring prior informed consent to sharing of viruses outside the Global Influenza Surveillance Network (GISN)(id., at 6-7). There was no express restriction placed upon the use of the virus samples (other than to exercise good research and clinical practice) and nothing to prevent a private sector company from obtaining a patent with respect to information (e.g., genetic sequences) in the sample (or derivatives of data from the sample), or the biological material itself (and/or derivatives), subject to the ordinary requirements of patent law.

The WHO and its Member States recognized before Indonesia's decision that the global system for creating and distributing vaccines to mitigate the impact of pandemic influenza is inadequate. See, e.g., WHO, Departments of Immunization, Vaccines and Biologicals, and Epidemic and Pandemic Alert and Response, *Global Pandemic Influenza Action Plan to Increase Vaccine Supply*, WHO/IVB/06.13, WHO/CDS/EDR/GIP/2006.1, September 2006. The technology to create and produce effective vaccines exists (and is continually improving), see, e.g., WHO Scientific Consultation, *Options for the Use of Human H5N1 Influenza Vaccines and the WHO H5N1 Stockpile*, WHO/HSE/EPR/GIP, 2008.1 (1-3 Oct. 2007) (hereinafter "WHO Options for Use"), at 3, and; Jordan Report 2007. There is substantially inadequate production capacity to meet the needs of the global population and the existing capacity is almost exclusively based in developed countries. This creates enormous public health risks for more economically vulnerable populations throughout the

world. The WHO Director-General indicated her appreciation of the reasons for Indonesia's demand that the situation be improved - concerns shared by other developing countries. *See,* e.g., WHO Options for Use, *id.*, at 22. As a transitional measure, the IGM adopted an Interim Statement on "Sharing of influenza viruses and access to vaccine and other benefits" that continued to facilitate sharing of virus samples coincident with the establishment of an Influenza Virus Tracking System. See Influenza Virus Tracking System, Interim version launched, January 22, 2008, at http://www.who.int/csr/disease/avian_influenza/aivirus_tracking_system/en/index.html. Indonesia apparently resumed providing virus samples to the WHO pending completion of negotiations on a new virus-sharing mechanism in the IGM. *See, e.g., Indonesia Resumes Sharing of Bird Flu Samples*, VOA News (Online), February 27, 2008, available at http://www.voanews.com/english/archive/2008-02/2008-02-22-voa16.cfm?CFID=12778571&CFTOKEN=81795065. As an alternative to participation in the WHO virus-sharing system, Indonesia reportedly negotiated an arrangement with a private US-based pharmaceutical company to provide virus samples in exchange for production technology. *See, e.g., Jakarta Bird Flu Deal Questioned*, BBC News (Online), February 7, 2007, regarding arrangement with Baxter International, at http://news.bbc.co.uk/2/hi/asia-pacific/6337435.stm, and: *Indonesia Privatizes Bird Flu*, Foreign Policy Passport, February 8, 2007.

5 *See* Emma Broster, *The WHO's Complex Path On Counterfeiting, R&D Financing, Pandemics*, IP-Watch, July 27, 2010.

6 As of the date of this paper, the most recent "formal" negotiating texts may be found at *Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits*, Outcome of the resumed Intergovernmental Meeting, Report by the Director-General, Sixty-Second World Health Assembly, A62/5 Add.1, Provisional agenda item 12.1, May 18, 2009, available at http://apps.who.int/gb/pip/e/E_Pip_oewg.html (hereinafter "IGM-PIP"). However, various proposals, including a "Proposed Co-chairs Non-paper on the Pandemic Influenza Preparedness," dated May 5, 2010, were made available at Kaitlin Mara, *WHO Members To Act On Research Financing, Pandemic Preparedness,* IP-WATCH, May 14, 2010.

7 Dr. Margaret Chan, *Open Letter to the Editors of the British Medical Journal (BMJ)*, 8 June 2010, responding to allegations of conflict of interest, and noting date of declaration of H1N1 pandemic June 11, 2009, available at http://www.who.int/mediacentre/news/statements/2010/letter_bmj_20100608/en/index.html.

8 *See, e.g.*, Testimony of Secretary Napolitano Before the United States Senate Committee on Homeland Security and Governmental Affairs, *H1N1 Flu: Monitoring the Nation's Response* (Written Testimony), Release Date: October 21, 2009.

9 *See* Kaitlin Mara, *supra* note 6 and texts referenced therein.

10 Public international law is by its very nature evolutionary as it reflects the customary practices of states that vary over time. Treaties and other international agreements are routinely negotiated to address evolving technologies. Previously negotiated agreements are subject to new interpretations based upon change circumstances. *See, e.g., United States - Import Prohibition of Certain Shrimp and Shrimp Products*, AB-1998-4, WT/DS58/AB/R, October 12, 1998 (hereinafter "Shrimp-Turtles Decision"), referring to principles of evolutionary interpretation.

11 There have been a significant number of decisions by international tribunals with respect to continental shelf boundaries that fundamentally are concerned with delimiting rights to undersea oil exploration and exploitation. *See, e.g.,* North Sea Continental Shelf Cases

(Federal Republic Of Germany/Denmark; Federal Republic Of Germany/Netherlands), International Court of Justice, Judgment of February 20, 1969, at http://www.icj-cij.org/docket/files/52/5561.pdf, for example of dispute concerning delimitation of continental shelf relevant to petroleum exploitation.

12 *See, e.g.*, Fisheries Case (United Kingdom v. Norway), International Court of Justice, Judgment of December 18, 1951, at http://www.icj-cij.org/docket/files/5/1809.pdf, for example of a dispute concerning access to fish resources (although nominally a dispute concerning coastal boundaries).

13 *See, e.g.*, Report of WTO Appellate Body, *United States - Standards for Reformulated and Conventional Gasoline*, AB-1996-1, WT/DS2/AB/R, 29 April 1996 (left standing panel determination that clean air constitutes exhaustible natural resource)

14 See discussion of evolution of the definition of "exhaustible natural resources" in *Shrimp-Turtles Decision*, supra note 10, at paras. 127-31. The Appellate Body states, *inter alia*:

> "We do not believe that "exhaustible" natural resources and "renewable" natural resources are mutually exclusive. One lesson that modern biological sciences teach us is that living species, though in principle, capable of reproduction and, in that sense, "renewable", are in certain circumstances indeed susceptible of depletion, exhaustion and extinction, frequently because of human activities. Living resources are just as "finite" as petroleum, iron ore and other non-living resources." (Id., at para. 128)

15 United Nations General Assembly Resolution 1803 (XVII) of 14 December 1962, "Permanent Sovereignty Over Natural Resources", stating, *inter alia:*

> "Bearing in mind its resolution 1515 (XV) of 15 December 1960, in which it recommended that the sovereign right of every State to dispose of its wealth and its natural resources should be respected,
>
> Considering that any measure in this respect must be based on the recognition of the inalienable right of all States freely to dispose of their natural wealth and resources in accordance with their national interests, and on respect for the economic independence of States, …
>
> 1. The right of peoples and nations to permanent sovereignty over their natural wealth and resources must be exercised in the interest of their national development and of the well-being of the people of the State concerned.
>
> …
>
> 7. Violation of the rights of peoples and nations to sovereignty over their natural wealth and resources is contrary to the spirit and principles of the Charter of the United Nations and hinders the development of international co-operation and the maintenance of peace."
>
> Available at http://www2.ohchr.org/english/law/resources.htm.

16 *See* Edward Guntrip, The *Common Heritage of Mankind: An Adequate Regime for Managing the Deep Seabed?,* 4 MELBOURNE J. INT'L L. [] (2003), and; The United Nations Convention on the Law of the Sea (A historical perspective), UN Division for Ocean Affairs and the Law of the Sea, at http://www.un.org/Depts/los/convention_agreements/convention_historical_perspective.htm. U.S. President Truman's unilateral Declaration in 1945 of US control over its continental shelf resources commenced development of new doctrines of public international law relating to state control over undersea resources.

17 *Edith Brown Weiss, Introductory Note, United Nations Conference on Environment and Development*, 31 I.L.M. 814 (1992) (and agreement texts following, including Convention on Biological Diversity at 31 I.L.M. 818 (1992). The Convention on Biological Diversity (CBD), adopted June 5, 1992, available at http://www.cbd.int. The status of ratifications and acceptances is available at http://www.cbd.int/convention/parties/list.shtml. *See* Françoise Burhenne-Guilmin and Susan Casey-Lefkowitz, *The Convention on Biological Diversity: A Hard Won Global Achievement*, 3 (1992) YBIEL 43 (1993).

18 Sovereignty provides an economic incentive to states for preserving biological diversity and genetic resources, and should enhance economic welfare in countries that house genetic resource stocks. The CBD gives effect to these objectives by (i) establishing prior informed consent (PIC) of host countries as a condition of access to genetic resources, and (ii) providing for the equitable sharing of benefits arising from the utilization of such resources. The CBD places a number of obligations on its Parties with respect to the responsible use of biodiversity, including ensuring that activities within Parties do not cause environmental damage to other states.

19 *See generally* Gerald Moore and Witold Tymowski, Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture (2004), at http://www.iucn.org/bookstore/HTML-books/EPLP057-expguide-international-treaty/cover.html. On the relationship with the CBD, Article 1.1 of the ITPGR states:

> "The objectives of this Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security".

20 Article 10.1 of the ITPGR provides:

> "10.1 In their relationships with other States, the Contracting Parties recognize the sovereign rights of States over their own plant genetic resources for food and agriculture, including that the authority to determine access to those resources rests with national governments and is subject to national legislation".

21 *See generally,* Bernard Oxman, *Complementary Agreements and Compulsory Jurisdiction*, 95 AJIL 277 (2001).

22 *See*, US Information Service, *Indonesia Still Not Sharing Virus Samples for Avian Flu Vaccines,* November 8, 2007, reporting remarks of David Heymann, WHO Assistant Director General for Communicable Diseases, calling for open sharing of virus samples with industry in August 2007. The author of this paper notes that he was informally consulted by the World Bank shortly following Indonesia's decision to withhold virus samples regarding the legal status of Indonesia's claims. The author noted that Indonesia's assertion of sovereign rights over genetic resources was more plausible than WHO officials appeared to be giving credit.

23 Virus samples located within the territory of a particular nation state appeared to at least fall within a "borderline" definitional area of the CBD, and more broadly, to constitute natural resources located within the territory of a state, thereby being subject to national sovereign control. Even assuming that virus samples somehow escaped categorization as natural resources, exercise of state sovereignty over national territory would seem to give Indonesia or any other state the right to control physical access to resources located within its territory, enabling control over the underlying resources.

24 See UNU-IAS Report, *Bioprospecting of Genetic Resources in the Deep Seabed: Scientific, Legal and Policy Aspects* (2005), an excellent study with analysis relevant to this one, summarizing its conclusions that:

> "there is currently a legal lacuna with regard to commercially-oriented activities targeting the biodiversity of seabed areas beyond the limits of national jurisdiction. The current international legal framework, composed of provisions to be found in several instruments, including the United Nations Convention on the Law of the Sea (UNCLOS), the Convention on Biological Diversity (CBD), intellectual property rights instruments, and regional marine related instruments, does not address, in an exhaustive and integrated manner, the conservation of, access to, and benefit-sharing related to, deep seabed resources.

Some of the legal gaps highlighted by the study relate to, *inter alia*:

- the uncertain legal status of deep seabed genetic resources, which are excluded from the regime of the Area, defined under UNCLOS as the seabed and ocean floor and its subsoil beyond the limits of national jurisdiction, and are therefore not considered as common heritage of humankind;
- whether, on the basis of the distinction between sedentary and non-sedentary species, deep seabed genetic resources fall under the regime of living resources in the High Seas under UNCLOS;
- the lack of an international definition of bioprospecting, which is difficult to distinguish, in practice, from pure marine scientific research – for which an internationally agreed definition is also required;
- issues raised by the uncertain delineation of the Area;
- treatment of information and research results, as well as possible conflicts between the provisions of UNCLOS addressing treatment of research results from marine scientific research and those of intellectual property rights instruments;
- the legitimacy of asserting intellectual property rights over resources deemed of public interest, and what constitutes a patentable invention with regard to genetic resources; and
- the principle for, and modalities of, sharing of ensuing benefits, including through technology transfer, capacity building, information sharing and disclosure requirements within patent applications". (at 7)

25 Articles 11-12, ITPGR.

26 Article 11.2 of the ITPGR indicates that plant genetic resources forming part of the Multilateral System are "in the public domain".

27 Parties obtaining materials pursuant to the SMTA undertake not to seek patents (or other IPRs) with respect to those materials in the form received. (Paragraph 12.3(d) provides that "Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System." This does not, however, preclude securing IPRs over derivative products as implicit in the payment obligation. Paragraph 6 of the SMTA provides, *inter alia*:

> "6.7 In the case that the Recipient commercializes a Product that is a Plant Genetic Resource for Food and Agriculture and that incorporates Material as referred to in Article 3 of this Agreement, and where such Product is not available without restriction to others for further research and breeding, the Recipient shall pay a fixed percentage of the Sales of the commercialized Product into the mechanism established by the Governing Body for this purpose, in accordance with *Annex 2* to this Agreement".

28 Article 13, ITPGR.

29 This is not so different than the GNU General Public License used in respect to "public domain" computer software that nonetheless requires users to make freely available the source code of modifications. See Lawrence Lessig, *Open Source Baselines: Compared to What?* in GOVERNMENT POLICY TOWARD OPEN SOURCE SOFTWARE (Robert W. Hahn ed. 2003, at 50.

30 Outside countries that are following the Indonesian model of restricted access.

31 *See generally* Guntrip, *supra* note 16, and UNU-IAS, supra note 25.

32 *See, e.g.*, Filártiga v. Peña-Irala, 630 F.2d 876 (2d Cir. (U.S.) 1980):

> "There now exists an international consensus that recognizes basic human rights and obligations owed by all governments to their citizens . . . There is no doubt that these rights are often violated; but virtually all governments acknowledge their validity. Department of State, Country Reports on Human Rights for 1979, published as Joint Comm. Print, House Comm. on Foreign Affairs, and Senate Comm. on Foreign Relations, 96th Cong. 2d Sess". (February 4, 1980), Introduction at 1.

33 Charter of the United Nations, Art. 2(4) (prohibition on use of force); see also Chapter VII (threats to international peace and security), including Art. 51 (individual and collective self-defense).

34 A human right to health is identified in a number of human rights instruments. Article 25 of the Universal Declaration of Human Rights refers to health, well-being, and medical care as the objectives of an adequate standard of living. Article 12(1) of the International Covenant on Economic, Social, and Cultural Rights (ICESCR) provides: "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." The preamble to the Constitution of the World Health Organization states, *inter alia*:

> "The States Parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples: Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.
>
> The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition".

The WHO Constitution is of particular importance because of virtually universal state membership of the organization. Article XI of the American Declaration on the Rights and Duties of Man provides: "Every person has the right to the preservation of his health through sanitary and social measures relating to food, clothing, housing and medical care, to the extent permitted by public and community resources." A number of other

international agreements recognize a "right to health.".The Committee on Economic, Social, and Cultural Rights has provided a detailed interpretation of the right to health established under Article 12, ICECSR in its General Comment No 14 (2000) on "The right to the highest attainable standard of health." See Frederick M. Abbott, *TRIPS and Human Rights: Preliminary Reflections*, in INTERNATIONAL TRADE AND HUMAN RIGHTS: FOUNDATIONS AND CONCEPTUAL ISSUES 145 (eds. F. Abbott, C. Breining-Kaufmann and T. Cottier) (U. Mich. Press 2006) and *The 'Rule of Reason' and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS*, in HUMAN RIGHTS AND INTERNATIONAL TRADE 279 (T. Cottier, J. Pauwelyn and E. Bürgi, eds. 2006) (Oxford).

35 *Accord,* Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Paul Hunt, Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, A/HRC/7/11, 31 Jan. 2008, available at http://www2.ohchr.org/english/issues/health/right/annual.htm, stating:

> "61. As a minimum, all States have a responsibility to cooperate on transboundary health issues and to 'do no harm' to their neighbours. High-income States have an additional responsibility to provide appropriate international assistance and cooperation in health for low-income countries".

36 *Compare* David Fidler, *Indonesia's Decision to Withhold Influenza Virus Samples from the World Health Organization: Implications for International Law*, 11 ASIL INSIGHT, Issue 4, Feb. 28, 2007, suggesting that the "precise obligations created by the right to health remained unsettled, particularly the duty to participate in international cooperation."

37 A threat to the security of the state(s) may be brought before the UN Security Council for action, or it might entitle the threatened state(s) to act in self-defense under Article 51 of the UN Charter. Although this may appear an "extreme scenario", it is possible to imagine that an imminent public health threat on a massive scale would be considered a hostile act by an affected state(s). It is possible to imagine the imposition of economic sanctions or, in a worst case, a threat or use of force to obtain necessary virus samples.

38 IHR, Art. 12.

39 IHR, preamble and Art. 2.

40 International Health Regulations (2005) ("IHR"), WHA58.3, 23 May 2005, at Art. 6.

41 IHR, Art. 2 and 3(3). *Accord*, Fidler, *supra* note 37.

42 *See, e.g., John Moore v. Regents of Univ. of California*, Sup. Ct. of California, USA, 51 Cal. 3d 120 (1990).

43 See cross-referenced provisions in draft negotiating texts, *infra* note 71.

44 *See also* Article 3 of the CBD providing:

> *"Principle*
>
> States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction".

45 Virus materials may also be part of the variability among living organisms within the definition of "biological diversity." Viruses may be included within "living organisms" because they replicate within host biological organisms.

46 Article 2 of the CBD provides: *"Biological resources"* include genetic resources, organisms or parts thereof, populations or any other biotic component of ecosystems with actual or potential use or value for humanity.

47 The New Shorter Oxford English Dictionary (1993 ed.), at 1888-89, def. 4.

48 Id., at 2565, def. 1.

49 See generally WTO Shrimp-Turtles Decision, supra note 10, interpreting the terms "exhaustible natural resources", at, e.g., paras. 127-34.

50 The terms "genetic resources, organisms or parts thereof" appear to create a wider scope of subject matter coverage for "biological resources" than "genetic resources" standing alone since the term "parts" refers to less than the whole.

51 The answer to whether human genetic resources are covered will not resolve all subject matter/scope issues under the CBD because pathogen materials are often found external to human beings. Nonetheless, pathogen materials may be found within human tissues or blood.

52 COP 2 Decision II/11, Jakarta, 6-17 Nov. 1995, at para. 2 (available at http://www.cbd.int/decisions/?m=COP-02&id=7084&lg=0).

53 See Art. 23, CBD, establishing authority of COP. This decision may constitute an agreement among the parties on the interpretation of the treaty within the meaning of Article 31(3) of the Vienna Convention on the Law of Treaties. In any case, as a formal statement of the intent of the negotiating parties relatively contemporaneous with conclusion of the CBD, this decision should play a meaningful role in its definitive interpretation.

54 The Introduction to the Bonn Guidelines, prepared by the Executive Secretary of the CBD Secretariat states:

> "Although they are not legally binding, the fact that the Guidelines were adopted unanimously by some 180 countries gives them a clear and indisputable authority and provides welcome evidence of an international will to tackle difficult issues that require a balance and compromise on all sides for the common good".

Secretariat of the Convention on Biological Diversity (2002). Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. Montreal: Secretariat of the Convention on Biological Diversity (at page iv).

55 *See* text at note 59, *infra*.

56 *Infra* note 121.

57 Indeed, the first widely reported access and benefit-sharing agreement involved access by a major pharmaceutical company to resources in a developing country. See, e.g., Michele Zebich-Knos, *Preserving Biodiversity in Costa Rica: The Case of the Merck-INBio Agreement,* 6 J. ENV'T & DEV 180 (1997).

58 Notably at Article 16, CBD, stating:

> 3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that

are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

59 See Article 3 of the draft ABS Protocol. At least some members of the Working Group on Access and Benefit-Sharing of the CBD would include viruses and other pathogenic organisms, as well as potentially pathogenic organisms and genetic sequences, within the scope (Report of the 8th Meeting of the ad hoc open-ended Working Group on ABS, November 2009). Other members of the Working Group on Access and Benefit-Sharing, however, have proposed excluding "human pathogens." (Report on the First Part of the Ninth Meeting of the Ad Hoc Open Ended Working Group 0n Access and Benefit-Sharing, March 2010).

60 *See, e.g.*, Frederick M. Abbott, *Preservation and Use of Genetic Resource Assets and the International Patent System, A Study for the Ministry of Foreign Affairs of Norway,* Draft of March 31, 2005 rev 1.2, Hong Kong Ministerial Revision, available at http://FrederickAbbott.com.

61 Article 4(1), draft ABS Protocol,

62 Article 5(f)(ii), id.

63 Annex I(1)(j), id.

64 *See also* Article 3bis that includes more general language regarding relationships with other international agreements.

65 Adopted 14 Nov. 2001, WT/MIN(01)/DEC/1(20 Nov. 2001), at para. 19.

66 WT/MIN(05)/DEC (18 Dec. 2005), at para. 39.

67 WTO: 2010 News Items, 22 March 2010, Trade Negotiations Committee, *Lamy Opens Stocktaking Week with Hope for Strong Signal on Concluding the Round*, available at http://www.wto.org/english/news_e/news10_e/tnc_dg_stat_22mar10_e.htm.

68 *See* Note by the WTO Secretariat, The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, Summary of Issues Raised and Points Made, Revision, IP/C/W/368/Rev.1, February 8, 2006. For the developing country proposal Doha Work Programme – The Outstanding Implementation Issue on the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, Communication From Brazil, China, Colombia, Cuba, India, Pakistan, Peru, Thailand And Tanzania, WT/GC/W/564/Rev.2, TN/C/W/41/Rev.2, IP/C/W/474, July 5, 2006.

69 Members of the first and second group of countries transmitted a paper entitled "Draft Modalities for TRIPS Related Issues" dated June 17, 2008, to the Trade Negotiations Committee of the WTO that reflected their positions in a general way, but leaving specifics for future negotiation. TN/C/W/52, July 19, 2008.

70 *See, e.g.*, Open-Ended Working Group (OEWG) Proposed Co-chairs Non-paper on the Pandemic Influenza Preparedness, May 5, 2010, supra note 6.

71 See IGM-PIP, bracketed preambular paragraph PP12. Regarding the WTO, see bracketed pre-ambular paragraph PP13. The provisions of the draft ABS Protocol, including Article 6(b), are discussed in the preceding text.

72 See also, WIPO Life Sciences Division, Expert Report, *Patent Issues Related to Influenza Viruses and Their Genes*, commissioned by WHO pursuant to WHA Resolution 60.28 (hereinafter "WIPO Expert Report"). While the present paper was prepared independently, the analysis of IP issues in the present paper and the Expert Report by the WIPO Life Sciences Division is similar in virtually all material respects. The present paper does not provide a footnote cross-referencing to each similar point made in the WIPO Expert Report.

73 The international patent system is described in detail in FREDERICK ABBOTT, THOMAS COTTIER & FRANCIS GURRY, INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY (Aspen Publishers 2007), in Chapters 1, 2 and 6 (hereinafter "Abbott, Cottier & Gurry").

74 The right to exclude importation does not extend to "parallel imports" of patented inventions lawfully placed on the market outside country if the country has adopted "international (or regional) exhaustion" of patent rights.

75 TRIPS Agreement, Art. 27.1.

76 Id., Art. 27.3(b).

77 *Accord,* WIPO Expert Report, at 15-18.

78 *See* Abbott, Cottier and Gurry, at 131-34, referring, *inter alia*, to Diamond v. Chakrabarty 447 U.S. 303 (1980) (U.S. Supreme Court).

79 *See, e.g.*, WIPO Expert Report, at 12 and 18-19.

80 See Abbott, Cottier and Gurry, at 132-33, citing, *inter alia*, Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213 , 30/07/1998 0013 – 0021, Art. 5(2), and Amgen v. Hoechst Marion Roussel, 2006 U.S. App. LEXIS 19799 (Fed. Cir. 2006), rehearing en banc denied, 2006 U.S. App. LEXIS 29284).

81 *See, e.g.*, the definitions of "living modified organisms" and "modern biotechnology" from Article 3 of the Cartagena Protocol, which provide:

> (g) "Living modified organism" means any living organism that possesses
>
> a novel combination of genetic material obtained through the use of
>
> modern biotechnology;
>
> …
>
> (i) "Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection".

82 *Accord,* WIPO Export Report, at 15-23.

83 *See Myriad awarded new cancer gene patents*, Datamonitor, May 16, 2001, at http://www.datamonitor.com/industries/news/article/?pid=349489ED-C6A1-41FA-B2E7-35D0D0C84B27&type=NewsWire; *but see also Xavier Bosch, Myriad Loses Rights to Breast Cancer Gene Patent*, LANCET 2004; 363:1780 and European Patent Office, *Patent on "Breast Cancer Gene 2" Patent Maintained in Amended Form after Public Hearing,* June 29, 2005 (at http://www.epo.org/about-us/press/releases/archive/2005/29062005.html).

84 *See* In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005).

85 *Association for Molecular Pathology v. U.S. Patent and Trademark Office,* 669 F.Supp.2d 365 (S.D.N.Y., 2009).

86 *See* Abbott, Cottier and Gurry, at 591-96.

87 *Id.*, at 595-97.

88 Also, because patent applicants must disclose their inventions to the public, the public benefits from learning about the invention/vaccine.

89 *See, e.g.*, Harvey E. Bale, Jr., Annex 4, IFPMA Comments on intellectual property rights and vaccines for developing countries, in I*ntellectual Property Rights and Vaccines in Developing Countries*, Meeting Report April 19-20, 2004, WHO Department of Immunization, Vaccines and Biologicals, WHO/IVB/04.21.

90 *See generally, Intellectual Property Rights and Vaccines in Developing Countries*, Meeting Report, April 19-20, 2004, WHO Department of Immunization, Vaccines and Biologicals, WHO/IVB/04.21.

91 "Generic" producers of vaccines may not produce and market equivalent products that otherwise would drive down prices through market competition, other things being equal.

92 *See, e.g.*, WHO, Departments of Immunization, Vaccines and Biologicals, and Epidemic and Pandemic Alert and Response, *Global pandemic influenza action plan to increase vaccine supply, supra* note 4.

93 *See, e.g.* Jim Miller, *Biomanufacturing Pendulum Swings Toward Overcapacity*, BioPharm International.com, May 1, 2008; Daisy Wang, *China's API Sector sees Severe Overcapacity*, Asia-Manufacturing.com, January 18, 2009.

94 See WIPO Expert Report, *supra*.

95 PIIPA, *Patent Landscape of H5N1 Influenza Virus: Its Genome and Gene Products* (March 31, 2008) (hereinafter "PIIPA Landscape").

96 The WIPO Expert Report, prepared prior to the PIIPA Landscape based upon a preliminary patent landscape, states:

> "the general trend is striking: of all relevant international applications since the first instance recorded in 1983, some 35% were published in the first 9 months of 2007. These publications therefore disclose relatively recent research and development activity, in the form of inventions that were first applied for between late 2005 and early 2006. There is considerable diversity in this activity, with publications from over 100 different actors representing a mix of private firms, individual inventors, public sector institutions and government agencies". (at [11])

97 The PIIPA Landscape states with respect to the section of the paper dealing with "Influenza HA and NA genes and gene products that specifically claim or may encompass H5N1 sequences," that "Most importantly, none of the patent applications in this section claims native DNA or protein sequences of any of the H5N1 influenza isolates…. The remaining applications in this section are directed to fragments or non-native sequences derived from H5N1 virus." (id., at [7]).

It is important that because of limitations on access to data, neither the WIPO nor the PIIPA includes information regarding the patent situation in a significant number of developing countries.

98 *See* Conclusions, PIIPA Landscape.

99 *Id.*

100 IGM-PIP Draft SMTA, para. 6.3.

101 See Mara, IP-Watch, May 14, 2010, *supra* note 6.

102 Paris Convention, Art. 5(A); TRIPS Agreement, Art. 31.

103 Frederick M. Abbott and Rudolph V. Van Puymbroeck, *Compulsory Licensing for Public Health, A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, WORLD BANK WORKING PAPER NO. 61 (2005), and Frederick M. Abbott, *Introductory Note to World Trade Organization: Canada First Notice To Manufacture Generic Drug For Export,* 46 I.L.M. 1127(2007). The implementing legislation for the August 30 Decision of several WTO Member prospective exporting countries/regions contemplates production and export of vaccines.

104 In the preamble to the WHO Constitution its members acknowledge this state responsibility, stating:

> "The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States.
>
> …
>
> Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures".

This right is acknowledged in Paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health, stating: "we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' *right to protect public health* …" (italics added).

105 US Representative Joe Barton (R-Tx) Holds a Hearing on Pandemic Flu Preparedness, House Energy And Commerce Committee, FDCH Political Transcripts, November 8, 2005,

exchange between HHS Secretary Michael Leavitt and Representative Tom Allen, Lexis-Nexis News database.

"LEAVITT: Mr. Allen, let me just make clear that, in a pandemic situation, I think all those who have modeled and studied it believe that you'll get what's produced domestically.

That's one of the reasons we have pushed so hard for Roche to develop domestic manufacturing capacity, which they have agreed to do and are in the process of developing.

LEAVITT: I don't believe that will be an issue in a pandemic, because I think people who have it within their borders will keep it.

ALLEN: That may well be if it's global and not concentrated in one country or another.

Back when we had the anthrax scare here and Cipro was the available drug to treat it, Secretary Thompson said -- essentially threatened the compulsory licensing. Would you be prepared to do the same?

And now I grant you -- what you said before -- I grant you the manufacturing process is long and difficult and complicated, but would you be prepared to issue a compulsory license if Roche failed to provide an adequate authority to expand production here?

LEAVITT: I do not contemplate that being a circumstance that would present itself. It is important, however, that people of this country know we will do everything necessary to protect them."

106 *Merck v. Integra Lifesciences*, 545 U.S. 193 (2005) (U.S. Sup. Ct.).

107 Regulation (EC) No816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, OJ L 157/1, 9 June 2006, available at <http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=2&procnum=COD/2004/0258>, analyzed in Frederick M. Abbott and Jerome H. Reichman, Study, *Access to Essential Medicines: Lessons Learned Since the Doha Declaration on the TRIPS Agreement and Public Health, and Policy Options for the European Union,* Directorate General External Policies of the European Union, EXPO/B/INTA/2007/14 June 2007 PE 381.392 (prepared for the International Trade Committee, European Parliament) (hereinafter Abbott & Reichman Study), at 21.

108 IGM-PIP Draft SMTA, para. 6.4.

109 This overstates to a certain extent the separation between public and private even as to countries that most prominently advocate private market solutions. In the United States, for example, a substantial part of vaccine research is carried out by institutions funded by the National Institutes of Health. In addition, a large part of vaccine distribution and administration is carried out through publicly supported programs at the state or federal level. It is doubtful that any WHO member country today employs a purely private market solution to the development and distribution of vaccines.

110 IGM-PIP Draft SMTA, para. 6.3-6.4.

111 The system could leave distribution of the drugs and vaccines in the hands of the patent holders, but with a predetermined pricing schedule that would require differential pricing depending upon the economic capacity and public health requirements of the purchasing country.

112 See documents referenced in Mara, *supra* note 6.

113 The WHO formed an expert group to make recommendations regarding financing mechanisms for research and development of new medicines. The work of the initial expert group ended in disarray as questions were raised about its independence and methodologies of work. However, a new procedure has been established that may result in something better.

114 There is a private market for pandemic influenza in the number of developed countries, particularly as major corporations invest in protection against foreseeable risk.

115 See, e.g., a study prepared for the WHO with funding from the Gates Foundation, Oliver Wyman, *Options for the Design and Financing of an H5N1 Vaccine Stockpile: Key Findings and Study Methodology,* February 2009.

116 See Establishment of a consultative expert working group on research and development: financing and coordination, WHA63.28, May 21, 2010.

117 See Non-Paper, *supra* note 6.

118 Available at http://bch.cbd.int/protocol/.

119 See BCH Central Portal, at http://bch.cbd.int/.

120 IGM-PIP, Para. 5.1.

121 *Id.*, para. 6.

122 Kaitlin Mara, *WHO Members to Act On Research Financing, Pandemic Preparedness*, IP-WATCH, 14 May 2010.

123 *Id.*, para.5.4.

REFERENCES

Abbott, F. M., *Introductory Note to World Trade Organization: Canada First Notice To Manufacture Generic Drug For Export*, International Legal Materials, Issue 47, (2007).

Abbott, F. M., *Preservation and Use of Genetic Resource Assets and the International Patent System, A Study for the Ministry of Foreign Affairs of Norway,* Draft, (31 March 2005) rev 1.2, Hong Kong Ministerial Revision, available at http://www.frederickabbott.com/.

Abbott, F. M., *TRIPS and Human Rights: Preliminary Reflections*, in Abbott, F. M., Breining-Kaufmann, C. and Cottier, T. *International Trade and Human Rights: Foundations and Conceptual Issues*, (University of Michigan Press: 2006).

Abbott, F. M., *The 'Rule of Reason' and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS*, in Cottier, T., Pauwelyn, J. and Bürgi, E. *Human Rights and International Trade*, (Oxford University Press: 2006).

Abbott, F. M., Cottier, T. and Gurry, F., *International Intellectual Property in an Integrated World Economy*, (Aspen Publishers: 2007).

Abbott, F. M., and Reichman, J. H., Study, *Access to Essential Medicines: Lessons Learned Since the Doha Declaration on the TRIPS Agreement and Public Health, and Policy Options for the European Union*, Directorate General External Policies of the European Union, EXPO/B/INTA/2007/14 June 2007 PE 381.392 (prepared for the International Trade Committee, European Parliament).

Abbott, F. M. and Van Puymbroeck, R. V., *Compulsory Licensing for Public Health, A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, World Bank Working Paper No 61, (2005).

BBC News (Online), *Jakarta Bird Flu Deal Questioned,* (7 February 2007), available at http://news.bbc.co.uk/2/hi/asia-pacific/6337435.stm).

Bosch, X., *Myriad Loses Rights to Breast Cancer Gene Patent*, (Lancet: 2004).

Broster, E., The *WHO's Complex Path On Counterfeiting, R&D Financing, Pandemics,* IP-Watch, (27 July 2007), available at http://www.ip-watch.org/weblog/2010/07/27/the-whos-complex-path-on-counterfeiting-rd-financing-pandemics/.

Brown, L. (ed.), *The New Shorter Oxford English Dictionary*, (1993).

Brown Weiss, E., *Introductory Note, United Nations Conference on Environment and Development,* International Legal Materials, Issue 31, (1992).

Burhenne-Guilmin, F. and Casey-Lefkowitz, S., *The Convention on Biological Diversity: A Hard Won Global Achievement,* 4 Yearbook of International Environmental Law, Issue 43, (1992).

CBD, *Report on the First Part of the Ninth Meeting of the Ad Hoc Open Ended Working Group 0n Access and Benefit-Sharing*, (March 2010).

Chan, M., *Open Letter to the Editors of the British Medical Journal (BMJ)*, (8 June 2009), available at http://www.who.int/mediacentre/news/statements/2010/letter_bmj_20100608/en/index.html.

Cleaveland, S., Laurenson, M. K. and Taylor, L. H., *Diseases of Humans and their Domestic Mammals: Pathogen Characteristics, Host Range and the Risk of the Emergence*, Philosophical Transactions of the Royal Society B: Biological Sciences, (2001).

Cohn, S. K., Jr., *Epidemiology of the Black Death and Successive Waves of Plague,* Medical History Supplement, Issue 27, (2008).

Datamonitor, *Myriad awarded new cancer gene patents*, (16 May 2001), available at http://www.datamonitor.com/industries/news/article/?pid=349489ED-C6A1-41FA-B2E7-35D0D0C84B27&type=NewsWire.

European Patent Office, *Patent on 'Breast Cancer Gene 2' Patent Maintained in Amended Form after Public Hearing,* (29 June 2005), available at http://www.epo.org/about-us/press/releases/archive/2005/29062005.html.

European Union, *Regulation (EC) No 816/2006 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, OJ L 157/1, (9 June 2006)*, available at http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=2&procnum=COD/2004/0258.

Influenza Virus Tracking System, Interim version launched, (22 January 2008), available at http://www.who.int/csr/disease/avian_influenza/aivirus_tracking_system/en/index.html.

Fidler, D., *Indonesia's Decision to Withhold Influenza Virus Samples from the World Health Organization: Implications for International Law,* American Society of International Law Insights, Issue 4, (28 February 2007).

Foreign Policy Passport, *Indonesia Privatizes Bird Flu,* (8 February 2007).

Guntrip, E., *The Common Heritage of Mankind: An Adequate Regime for Managing the Deep Seabed?*, Melbourne Journal of International Law, Issue 4, (2003).

Heymann, D., *Indonesia Still Not Sharing Virus Samples for Avian Flu Vaccines*, US Information Service, (8 November 2007).

Hunt, P., Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, A/HRC/7/11, available at http://www2.ohchr.org/english/issues/health/right/annual.htm.

Lessig, L., *Open Source Baselines: Compared to What? in Hahn, R. W., Government Policy Toward Open Source Software* (AEI-Brookings Joint Center for Regulatory Studies: Washington DC: 2002).

International Court of Justice, *Federal Republic of Germany vs. Denmark; Federal Republic of Germany vs. Netherlands,* (North Sea Continental Shelf Cases), Judgment of February 20 1969, available at http://www.icj-cij.org/docket/files/52/5561.pdf.

International Court of Justice, *United Kingdom v. Norway* (Fisheries Case), Judgment of 18 December 1951, available at http://www.icj-cij.org/docket/files/5/1809.pdf.

Mara, K., *WHO Members To Act On Research Financing, Pandemic Preparedness,* IP - Watch, (14 May 2010), available at http://www.ip-watch.org/weblog/2010/05/14/who-members-to-act-on-research-financing-pandemic-preparedness/.

Miller, J., *Biomanufacturing Pendulum Swings Toward Overcapacity*, BioPharm International.com, (1 May 2008), available at http://biopharminternational.findpharma.com/biopharm/Outsourcing+Insights/Biomanufacturing-Pendulum-Swings-Toward-Overcapaci/ArticleStandard/Article/detail/512668.

Moore, G. and Tymowski, W., *Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture,* (2004), available at http://www.iucn.org/bookstore/HTML-books/EPLP057-expguide-international-treaty/cover.html.

Napolitano, J., *H1N1 Flu: Monitoring the Nation's Response,* Testimony of Secretary Napolitano Before the United States Senate Committee on Homeland Security and Governmental Affairs (Written Testimony), (21 October 2009).

Oxman, B., *Complementary Agreements and Compulsory Jurisdiction*, American Journal of International Law, Issue 95, (2001).

PIIPA, *Patent Landscape of H5N1 Influenza Virus: Its Genome and Gene Products* (31 March 2008).

Tettelin, H., Rappuoli, R., and Fraser-Liggett, C., *Using Genomics to Identify Novel Vaccine Candidates Against Pathogens:* in U.S. Department of Health and Human Services (National Institutes of Health and National Institute of Allergy and Infectious Diseases), *The Jordan Report: Accelerated Development of Vaccines*, (May 2007).

Third World Network, *Sharing of Influenza Viruses*, Briefing Paper, (May 2007).

United Nations, Division for Ocean Affairs and the Law of the Sea, *United Nations Convention on the Law of the Sea (A historical perspective*), available at http://www.un.org/Depts/los/convention_agreements/convention_historical_perspective.htm.

United Nations, *General Assembly Resolution 1803 (XVII) Permanent Sovereignty Over Natural Resources*, (14 December 1962), available at http://www2.ohchr.org/english/law/resources.htm.

United Nations University, *Bioprospecting of Genetic Resources in the Deep Seabed: Scientific, Legal and Policy Aspects, UNU-IAS Report*, (2005).

VOA News (Online), *Indonesia Resumes Sharing of Bird Flu Samples,* (27 February 2008), available at http://www.voanews.com/english/archive/2008-02/2008-02-22-voa16.cfm?CFID=12778571&CFTOKEN=81795065.

Wang, D., *China's API Sector sees Severe Overcapacity,* Asia-Manufacturing.com, (18 January 2009).

WHO, *Global Pandemic Influenza Action Plan to Increase Vaccine Supply*, WHO/IVB/06.13, WHO/CDS/EDR/GIP/2006.1, Departments of Immunization, Vaccines and Biologicals, and Epidemic and Pandemic Alert and Response, (September 2006).

WHO, *Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits,* Director-General Report, Sixty-Second World Health Assembly, Outcome of the resumed Intergovernmental Meeting, A62/5 Add.1, Provisional agenda item 12.1, (18 May 2009), available at http://apps.who.int/gb/pip/e/E_Pip_oewg.html.

WHO, *Options for the Use of Human H5N1 Influenza Vaccines and the WHO H5N1 Stockpile*, WHO/HSE/EPR/GIP, 2008.1 (1-3 October 2007).

WHO, Department of Immunization, Vaccines and Biologicals, *Intellectual Property Rights and Vaccines in Developing Countries*, Meeting Report, (19-20 April 2004).

WTO: 2010 News Items, Trade Negotiations Committee, *Lamy Opens Stocktaking Week with Hope for Strong Signal on Concluding the Round,* (22 March 2010), available at http://www.wto.org/english/news_e/news10_e/tnc_dg_stat_22mar10_e.htm.

WTO, Report of the Appellate Body. *United States - Import Prohibition of Certain Shrimp and Shrimp Products*. WT/DS58/AB/R, 12 October 1998.

WTO, Report of the Appellate Body. *United States - Standards for Reformulated and Conventional Gasoline*. AB-1996-1, WT/DS2/AB/R, 29 April 1996.

WTO, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, Summary of Issues Raised and Points Made, Revision*, IP/C/W/368/Rev.1, (8 February 2006).

Wyman, O., *Options for the Design and Financing of an H5N1 Vaccine Stockpile: Key Findings and Study Methodology,* (February 2009).

Zebich-Knos, M., *Preserving Biodiversity in Costa Rica: The Case of the Merck-INBio Agreement,* Journal of Evnironmental Trade and Development, Issue 6, (1997), 180.

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