Intellectual Property and Sustainable Development Series



Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health

By Frederick M. Abbott
Florida State University College of Law

ICTSD Global Platform on Climate Change, Trade Policies and Sustainable Energy

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Published by

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Acknowledgments:

This paper was commissioned under the ICTSD Programme on Intellectual Property Rights and Sustainable Development and the Global Platform on Climate Change, Trade Policies and Sustainable Energy - An initiative supported by DANIDA (Denmark); Ministry of Foreign Affairs of Finland; the Department for International Development (U.K.); the Ministry for Foreign Affairs of Sweden; the Ministry of Foreign Affairs of Norway; and the Commonwealth Secretariat. ICTSD is grateful for their support.

Preliminary versions of this paper were presented at an ICTSD Dialogue on Climate Change, Transfer of Technology and IPRs: The Challenge of Evidence-based Policy, Geneva, 27 Mar. 2009, and at a workshop co-sponsored by ICTSD at UNFCCC COP 14, Poznan, Poland, 5 Dec. 2008. Comments from a number of individuals at those presentations helped to improve the final text.

The paper also benefited from review and comments from Ahmed Abdel Latif, John Barton and Pedro Roffe, as well as from the Intellectual Property team at UNCTAD.

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

Citation: Abbott, Frederick M (2009). *Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health*, ICTSD's Programme on IPRs and Sustainable Development, Issue Paper No. 24, International Centre for Trade and Sustainable Development, Geneva, Switzerland.

The views expressed in this publication are those of the author and do not necessarily reflect the views of ICTSD or the funding institution.

ISSN 1684-9825

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ABBREVIATIONS AND ACRONYMS

AERs	Alternative Energy Resources
APIs	Active Pharmaceutical Ingredients
DNDi	Drugs for Neglected Diseases initiative
EU	European Union
GATT	General Agreement on Tariffs and Trade
IPRs	Intellectual property rights
LDCs	Least Developed Countries
MTs	Climate change mitigation technologies
NAFTA	North American Free Trade Agreement
NGOs	Non-governmental organizations
OECD	Organisation for Economic Cooperation and Development
PEPFAR	President's Emergency Program for African Relief
PPPs	Public-private partnerships
R & D	Research and Development
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNEP	United Nations Environment Programme
UNFCCC	United Nations Framework Convention on Climate Change
UPOV	International Union for the Protection of New Varieties of Plants
US	United States
U.S. NIH	US National Institutes of Health
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

FOREWORD

Transfer and diffusion of environmentally sound technologies (EST), in particular to developing countries, is a key element of any effective international response to the global climate change challenge and one of the pillars of the United Nations Framework Convention on Climate Change (UNFCCC). More recently, the Bali Plan of Action called for "enhanced action on technology development and transfer to support action on mitigation and adaptation, including, inter alia, consideration of effective mechanisms and enhanced means for the removal of obstacles to, and provision of financial and other incentives for, scaling up of the development and technology to developing country Parties in order to promote access to affordable EST."

In this context, the role of intellectual property rights (IPRs) has been the subject of increased attention in climate change discussions since Bali. Different views and positions have emerged pointing to the role of IPRs in either facilitating or hindering the transfer of EST.

In this regard, the parallel is often made, explicitly or implicitly, by government officials, and other stakeholders, with the access to medicines issue either to reinforce arguments about the role IPRs as a significant obstacle to the transfer of EST or to dismiss them, in view of the differences between the relative importance of IPRs for the pharmaceutical sector and the renewable energy sector.

Indeed, such differences are difficult to be overlooked. In the pharmaceutical sector, an individual patent may have a very substantial impact because a specific drug may not have any substitutes. In contrast, in the renewable sectors, the basic approaches to solving the specific technological problems have long been off-patent. What are usually patented are specific improvements. Thus, there is competition between a number of patented products, in addition to the competition with the cheaper traditional sources of energy, and the normal result is to bring prices down.

However, the fact that IPRs play a distinct role in the renewable energy sector arena than in the pharmaceutical sector, does not mean that they are entirely neutral to the diffusion and dissemination of EST. IPRs constitute a relevant factor in the innovation process and in decisions to invest in R&D activities. At the same time, they have implications on the rate of technological diffusion and the cost of technology acquisition, as they involve high transaction costs of obtaining information as well as negotiating and acquiring proprietary technologies. This should be taken into account in efforts towards promoting access to affordable EST, particularly to developing countries.

Thus, beyond simplistic comparisons and rhetorical statements, analysis and research are critically needed to examine, in a constructive and objective manner, lessons to be drawn from the debate on intellectual property and public health to better inform discussions on innovation, technology transfer and IPRs in the context of the climate change negotiations. This is precisely the objective of the Issue Paper commissioned to Professor Frederick M. Abbott: *Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health*.

This new paper examines different categories of IPRs and the ways they may have different effects and implications for EST as compared with pharmaceutical technologies.

It also points to a number of lessons that can be drawn from the public health-related negotiations, at the WTO and other forums, that may be useful to negotiators and policy makers in addressing climate change, transfer of technology and IPRs.

In this connection, the paper underlines that public health negotiations suggest that zero-sum bargaining is unlikely to be productive from the standpoint of developing countries. Focus should be placed in establishing frameworks for mutually beneficial joint venture economic arrangements between developed and developing country enterprises to stimulate innovation and concrete transfers of technology to address climate change.

To the extent possible, technology transfer commitments resulting from climate change negotiations should be specific and concrete. "Soft" commitments on transfer of technology typically do not bear fruit.

Even if current multilateral IPRs rules incorporate flexibilities and exceptions adequate to address most foreseeable obstacles to technology transfer, the paper suggests that a declaration comparable to the Doha Declaration on the TRIPS Agreement and Public Health with respect to IPRs and climate change may be useful in the progressive development of international law, so that it properly balances the rights of innovators and access by the public to the benefits arising from new technologies.

Finally, the paper reflects on the urgent need for further evidence based analysis to inform current discussions on climate change, technology transfer and IPRs.

For this purpose, and building on previous research in this area, the International Centre for Trade and Sustainable Development (ICTSD) has joined forces with the European Patent Office (EPO) and the United Nations Environment Programme (UNEP) to undertake a joint project to examine the role of patents in the development and transfer of EST, in particular in the field of energy generation. This initiative is expected to provide input into ongoing discussions on technology transfer in the context of the UNFCCC at COP-15 in Copenhagen.

Ultimately, it is important to recall that IPRs are only one among many other factors which impact technology transfer. Other factors such as the enabling environment, in particular financing, adequate incentives and institutions, do play an essential role and require also vigorous action.

This paper was commissioned under the ICTSD Programme on IPRs and Sustainable Development as part of ICTSD's Global Platform on Climate Change, Trade and Sustainable Energy which is specifically aimed at contributing to effective international cooperation towards addressing climate change, by advancing analytical capacity of stakeholders and their interaction with policy makers such that effective solutions can be built and agreed by the international community at the Copenhagen COP-15, in December 2009.

ICTSD's Programme on Intellectual Property and Sustainable Development has sought to achieve a better understanding of IP in the context of sustainable development with a view to ensure 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, but also 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 policy making in all areas of development.

In this context, we hope that you will find this issue paper a useful contribution to ongoing discussions about the transfer of EST, with a view to achieve their wide and affordable diffusion, particularly to developing countries. 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 at the UNFCCC discussions on these important issues.

Ricardo Meléndez-Ortiz
Chief Executive, ICTSD

EXECUTIVE SUMMARY

This paper examines issues surrounding the development and transfer of technologies for addressing the problem of climate change based on the experience of developing countries in addressing problems of innovation and access in the field of medicines.

It looks at alternative energy resources (AERs) and climate change mitigation technologies (MTs), at the forms of intellectual property rights (IPRs) used to promote and protect innovation, and at the ways these IPRs may have different effects and implications for AERs/MTs as compared with pharmaceutical technologies. It is generally assumed that the originator pharmaceutical sector is highly dependent on strong patent protection, mainly because of the high cost involved in developing novel drug therapies and the low cost of reverse engineering these new drugs. Preliminary research suggests that most AERs/MTs industries may be less dependent on strong patent protection, and/or that patents are less likely to cause significant bottlenecks in the development and transfer of AERs/MTs. While it is premature to come to a definitive conclusion because researchers are only now focusing on the evidence, there is some basis for anticipating that IPRs will present fewer risks for developing countries in the context of climate change than for public health.

Developing country negotiators understood that the GATT Uruguay Round negotiations on trade related aspects of intellectual property rights would affect access to medicines. The resulting WTO TRIPS Agreement did, in fact, present serious risks to public health. These risks were addressed through negotiation of the Doha Declaration on the TRIPS Agreement and Public Health, the Article 31bis amendment and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. The "Doha Declaration process" broadly speaking has resulted in some positive movement.

There are a number of lessons that can be drawn from the public health-related negotiations, at the WTO and other forums, that may be useful to developing country negotiators addressing IPRs and climate change. Some of these lessons are relatively straightforward: economic and political power substantially influences the outcome of negotiations; the involvement of NGOs and other stakeholders is essential; it is important to shape public opinion through effective communication. Other lessons may be somewhat less evident.

Public health negotiations suggest that zero-sum bargaining is unlikely to be productive from the standpoint of developing countries, and that appeal to "equity" as the basis for demanding concessions is not enough. The private sector in the developed countries controls most pharmaceutical technology and AERs/MTs. Governments in developed countries are unlikely to "order" that technology be transferred by the private sector. Developing countries therefore might usefully focus on establishing frameworks for mutually beneficial joint venture economic arrangements between developed and developing country enterprises that will stimulate innovation and concrete transfers of technology to address climate change.

To the extent possible, technology transfer commitments resulting from climate change negotiations should be specific and concrete. "Soft" commitments on transfer of technology typically do not bear fruit.

A number of developing countries and NGOs have proposed that a declaration comparable to the Doha Declaration on the TRIPS Agreement and Public Health be adopted with respect to IPRs and Climate Change. Even if current multilateral IPRs rules incorporate flexibilities and exceptions adequate to address most foreseeable obstacles to technology transfer, a declaration may be useful in the progressive development of international law so that it properly balances the rights of innovators and access by the public to the benefits arising from new technologies.

INTRODUCTION

The international community has recognized an urgent priority to address the problem of climate change resulting from accumulation of greenhouse gases. Human activity, mainly resulting from the combustion of hydrocarbon-based fuels (coal and petroleum), is contributing substantially to the accumulation of carbon dioxide in the Earth's atmosphere, increasing heat capture and retention.[1] This results in global warming. A major objective in addressing climate change is to reduce the emission of greenhouse gases by developing and implementing alternative methods for energy-generation, such as through use of photovoltaic cells, wind turbines, biomass fuels, nuclear fuels, geothermal heat sources and tidal changes. These alternative "clean energy" resources are sometimes referred to as "renewable energy" resources, or "green energy" resources. This paper will generally use the term "alternative energy resources" or "AERs" to refer to energy generation resources that will reduce the output of greenhouse gases as compared with existing hydrocarbon-based fuel sources.

Mitigation of greenhouse gases may be addressed through means other than development of AERs. This, of course, includes products that make use of AERs, such as hydrogen fuel vehicles, and it also includes technologies that would reduce overall use of fuels, such as environmental control systems, improved energy transmission materials, insulating materials and so forth. Also, new technologies will need to be developed and implemented to address the effects of climate change, such as seawater desalinization technologies to improve irrigation of arid land for cultivation. There is a wide range of technologies that may be involved in addressing the effects of climate change, ranging from computer programs to genetic recombination to weather forecasting instruments. This paper will generally refer to these climate change mitigation technologies as "mitigation technologies" or "MTs". Thus, in shorthand, this paper will use AERs/MTs to generally refer to the fields of technology involved in addressing the impact of climate change.

There are two distinct, yet linked, aspects to development and implementation of AERs/MTs. The first is encouragement of innovation, that is, the development of technological solutions to existing or new problems, such as the development of new photovoltaic cells that capture and convert increasing percentages of solar energy and the development of more efficient wind turbines. The second is diffusion of these new technologies on a worldwide basis, addressing and overcoming barriers created by uneven distributions of wealth and technological capacity. This second aspect may be referred to as the "technology transfer" problem.

The aspects of innovation and technology transfer are linked, at the very least, because innovation of AERs/MTs may occur anywhere in the world. Although highly capitalized corporations in the developed countries may be the best positioned to develop new technologies in certain fields, farmers in least developed countries (LDCs) may well develop agricultural techniques that reduce resource consumption and/or improve crop yields and reduce strains on agricultural land. Innovation must take into account different geographic, wealth and environmental conditions because technologies suitable for implementation only in wealthy developed countries may result in a shift of greenhouse gas output to less wealthy regions. While improvement will result from addressing greenhouse gas output in the developed countries, it is important that the situation be addressed on a global basis because "global warming" is not limited to a particular geographic region. This will require development and transfer of suitable technologies.

1. LESSONS FROM ACCESS TO MEDICINES FOR CLIMATE CHANGE

The purpose of this paper is to identify the "lessons" that may be derived from development and implementation of policies at the international level regarding innovation, technology transfer and access to medicines, and to suggest how those lessons might be useful to consider in current discussions on innovation, technology transfer and access to AERs/MTs. One of the principal objectives is to consider whether "intellectual property rights" or IPRs, such as patents, copyrights, trademarks and trade secrets will help or hinder any of the principal objectives in addressing climate change, and whether the development and implementation of policies with respect to IPRs in the field of public health suggest any particular strategies with respect to climate change.

There has been considerable discussion among developing country delegations to the United Nations Framework Convention on Climate Change (UNFCCC) and among nongovernmental organizations (NGOs) regarding the possibility of a governmental declaration regarding the use and/or extension of IPRs-related legal flexibilities to promote access to climate change technologies comparable to the Doha Declaration on the TRIPS Agreement and Public Health adopted by the Ministerial Conference of the WTO in November 2001. This paper will examine, in its concluding section, potential benefits and drawbacks of negotiations regarding such a declaration.

The objective of identifying the *lessons of public health* does not imply that international action with respect to IPRs and public health has been a "categorical success" that will naturally provide a positive roadmap for climate change. The lessons of public health are both of success and failure. International action regarding IPRs and public health during the past decade has improved the situation of a large number of individuals. Use of generic antiretroviral medicines in Africa and elsewhere has widely expanded the pool of patients under treatment for HIV-AIDS and relieved budgetary constraints. Focus on driving prices down through transition to generic treatment has influenced government policy at all levels of economic development. New structural mechanisms for promoting innovation aimed at preventing and treating "neglected diseases", for example in the form of public-private partnerships (PPPs), have developed.

Nonetheless, the success of the access to medicines movement should not be overstated. From the revenue standpoint, the global pharmaceutical market remains dominated by a small number of originator companies selling high-priced products, straining public and private budgets. Return on R&D in terms of new treatments has been poor over the past two decades, driving or exacerbating the trend toward industry consolidation. China and India have emerged as key producers of active pharmaceutical ingredients (APIs), but are not major pharmaceutical originators. Other developing countries remain highly dependent on foreign sources of originator products.

It is well accepted among IPRs experts in the fields of law and economics that IPRs have different effects for different fields of technology, whether those effects concern rates of innovation, economic and/or social welfare impacts.[2] The intention of the OECD industry *demandeurs* pressing the GATT Uruguay Round of trade negotiations in the 1980s and early 1990s was to minimize differences in the way patents were treated when applied to different fields of technology. This demand was spearheaded by the pharmaceutical industry that wanted to eliminate government policies that excluded pharmaceuticals from some or all types of product patent protection.[3] But, the result in the 1995 WTO TRIPS Agreement did not provide the strong rule against treating different technologies differently that was sought. Instead, it provided a rule against "discrimination" among different fields of technology that opens the door to differential treatment based on legitimate policy distinctions.[4]

There are many examples of different fields of technology being treated differently as among

the major *patenting powers* -- the United States (US),[5] European Union (EU)[6] and Japan[7] -- and innovating developing countries follow similar paths. If it is concluded that AERs/MTs technologies require specific forms of treatment from an IPRs standpoint, it does not necessarily follow that new international norms must be negotiated - though such a recommendation is not precluded. Rather, there may be sufficient scope within existing international IPRs norms to encompass a range of policies with respect to AERs/MTs taken at the national and regional implementation level. It is critical that the time and energy needed to negotiate changes to international IPRs rules be expended only if genuine practical constraints are identified, and that negotiations not be initiated based on flawed assumptions.

2. IPRS AND THE DEVELOPMENT OF TECHNOLOGY

IPRs[8] are directed at solving the problem of the incomplete appropriability of knowledge.[9] Because most technologies can be "reverse engineered" after they are publicly disclosed, it is extremely difficult for technology developers to maintain control over their innovations. Theoretically, the inability to maintain control over technology reduces the incentive to invest in innovation. IPRs establish legal boundaries or fences that permit technology developers to control innovations, reducing third-party appropriation or free riding, thereby encouraging investment in innovation. IPRs also provide a means by which technology may be "securitized" for purposes of out-licensing, thereby providing alternative mechanisms for earning financial returns on investment and potentially enhancing the distribution of innovation.[10]

a. Patents

The form of IPR classically associated with technological innovation is the "patent". The patent is a bundle of rights granted to the inventor of a new product or process that allows the inventor to exclude third parties from making, using, offering for sale, selling or importing the patented product, using the patented process, or importing a product made with the patented process, for a period -- typically of 20 years -- from the filing of the patent application. Patents are granted on a country-to-country basis (and in a limited number of circumstances on a regional basis), and the patents so granted are *independent* of one another. A patent is granted to the first person that makes an invention (and/or files a patent application on the invention), permitting that first person to exclude subsequent inventors of the same product or process from the market, even if those subsequent inventors had no knowledge of the first person's activities, and even if they finalized their invention the day after the first person. This arguably harsh treatment of second comers characterizes the patent as a "hard" form of IPR.[11]

The policy assumption underlying the grant of patents is that providing the possibility of a significant financial reward in terms of market exclusivity will encourage investment in innovation, yet leave decision-making as to where and how innovation should take place in the hands of individual decision-makers not under direction of the government.[12] Under the patent system, individual decision-makers typically assume the financial risk of investment in innovation. If the invention fails, the loss falls on the inventor, not on the government and public. Conversely, if the inventor succeeds, the public pays a "higher than competitive market price" for the resulting product or process, the extent of the inventor's pricing power dependent upon factors such as the availability of substitute technologies.

As part of the *patent bargain*, the inventor is required to disclose the relevant technology in the patent application. This disclosure should permit persons reasonably conversant with the technical field to practice the invention without undue experimentation.

b. Trade Secret and Regulatory Data Protection

The second form of IPR customarily used to protect technological innovation is the "trade secret". Trade secrets protect confidential commercially valuable information that its holder has taken reasonable steps to protect from disclosure. Trade secrets may take many forms, including customer lists, recipes and computer software design. From the standpoint of AERs/MTs, trade secrets may likely involve production process technologies that are used in the making of new materials.

Trade secret protection has the distinct advantage over patent in that it has an indefinite duration. As long as secrecy is maintained, trade secret protection endures. Moreover, trade secret protection (by definition) does not require disclosure of the invention to the public (as does

patent). The distinct disadvantage of trade secret protection is that it does not prevent against reverse engineering. It is not a hard form of IPR, as is patent protection.

Trade secret often acts as a complement to patent protection. While, in principle, the disclosure in a patent application permits a third-party to make and/or use the invention without undue experimentation, as a practical matter this requirement is often not met. Patent disclosures are often framed in terms of alternative means of implementation. While, at least in the US, the patent applicant is required to disclose the "best mode" of making or using the invention, patent applications are rarely rejected based on failure to provide the best mode. The European requirement is "sufficiency" of disclosure, intended to assure that the invention can, in fact, be made or used.

Trade secret protection can and does promote innovation in the development of production processes that are not apparent to the public when the invention is sold.

Another related form of data protection operates in the pharmaceutical field. This involves protection of undisclosed data submitted in the course of seeking regulatory approval of new chemical entities. Mandatory application of this form of protection is restricted under the TRIPS Agreement to pharmaceutical and agricultural chemical products.[13] Protection is afforded against disclosure by the relevant government agency and against "unfair commercial use". There is no prescribed period of such protection, though in practice the US has granted five years (plus extension based on new clinical submissions) and the EU has granted 10 years (plus one based on new clinical submission) of "marketing exclusivity".

Regulatory data protection has been highly controversial with respect to its potential for reducing generic competition in the pharmaceutical sector. However, unless AERs/MTs are required to obtain regulatory approval, and unless governments specifically adopt data protection policies that would cover these technologies, this form of protection should not be relevant to AERs/MTs.

Regulatory data protection must be distinguished from "regulatory barriers" that may be erected by countries to inhibit the introduction of foreign-produced products onto the national market. Differences among countries in regulatory standards applicable to the manufacture and sale of pharmaceutical products can and do act as significant barriers to trade in pharmaceuticals. Such differences in internal regulation might act as a formidable restraint of trade and technology transfer in the AERs/MTs sector as well.[14]

c. Utility Models and Industrial Designs

The protection of utility models varies from country to country. In general, utility model or *petit patent* protection is available for minor but useful changes to existing technologies that may not meet the criteria for ordinary (or "utility") patent protection (although application for utility model protection does not mean that the technology would otherwise have been disqualified from utility patent protection). This may be because the incremental change is not sufficiently significant to meet the inventive step requirement, or because the technology may be new in the country granting protection, but is not new worldwide (i.e., a relative standard of novelty is applied). Utility model protection is typically for a shorter term than utility patent protection.

At the present time, utility model protection is not a major IPR factor in most developed countries. However, it is possible to envisage a further development and refinement in this area so that forms of "quasi-patent" evidencing minor technological developments might be substituted in a number of situations for full utility patents.[15] For example, in the field of pharmaceuticals, a lesser form of protection might be accorded to minor modifications of existing compounds. This

would continue to encourage a sufficient level of investment in those modifications, but might encourage a redirection of some investment toward breakthrough products.

The protection of industrial design is mandated by the TRIPS Agreement for a period of 10 years, but the form of such protection is within the discretion of each WTO Member. Countries protect industrial designs through a variety of different IPRs mechanisms. This includes design patent, trademark and trade dress, copyright and *sui generis* design registration systems. Design protection is typically afforded to new and nonfunctional ornamental characteristics of products. It is not easy to distinguish form from function in many cases. An AER/MT such as a wind turbine might embody a new ornamental design and therefore be protectable, but in order to enjoy such protection the design could not be functional to the extent of providing a competitive advantage in the marketplace.

d. Copyright

Although typically associated with expression by authors and artists, since the mid-1970s copyright has been the principal IPR used to protect computer software (although patent protection has also played an important role in some countries and circumstances). There are variations among countries with respect to the types of computer program information that may be protected by copyright. Yet, in all cases, copyright protection should apply only to the manner in which a program is written (i.e., its expressive form) and not to the manner in which the program functions. Copyright protection is of long duration (e.g., the life of the author plus 70 years in Europe and in the United States).

Copyright protects against unauthorized reproduction of an author's or artist's expressive work, thereby providing an opportunity for the author or artist to profit from his or her creation. Copyright is intended to stimulate the creation of expressive works by authors and artists for the benefit of society. Because many AERs/MTs will include computer programs within their technological implementation, it is important to consider copyright policy among those that may encourage innovation.

e. Plant Variety Protection

In some national legal systems new plant varieties are protectable by patents. New varieties may also be protected by a *sui generis* form of plant variety protection that typically involves the award of "breeder's rights". Plant variety protection is regulated at the international level by the TRIPS Agreement. A plant variety or breeder's certificate of protection will permit the holder to prevent others from reproducing and selling the protected variety for a term of years that varies depending upon the type of plant matter. Pursuant to the UPOV system of protection, national governments are permitted to authorize "farmer's rights" under which seeds may be replanted, so long as this does not unreasonably interfere with the legitimate commercial opportunities of the certificate holder.

Plant variety protection is relevant to AERs/MTs because new varieties of plant may be developed for use in generating energy, and new varieties of plant may be developed to mitigate the impact of climate change (such as plants that exhibit improved drought-resistant characteristics).

f. Flexibilities and exceptions

Intellectual property rights are mechanisms of industrial policy. Although IPRs are regulated at the international level, the specifics of implementation remain controlled at the national (and, in some cases the regional) level. National governments traditionally are unwilling

to surrender sovereignty over the specific implementation of IPRs, just as they are unwilling to surrender sovereignty over their budgets or their military institutions. National courts play an important role in the interpretation and application of IPRs rules, providing a balance among rival claimants to rights and interests.

Reflecting this traditional reservation of sovereign control, the WTO TRIPS Agreement and the IPRs agreements adopted under the auspices of WIPO are drafted in a manner that preserves significant government flexibility in the implementation of norms.[16] Such agreements also include provisions allowing governments to adopt and implement "exceptions" to the rights to exclude that are otherwise granted to private individuals and enterprises.

Some of the most detailed international norms regarding exceptions are found in the TRIPS Agreement, in particular in its Articles 30 and 31. These provisions deal, respectively, with the forms of general exception that may be adopted in respect to patents and with the mechanism of compulsory and government use patent licensing. The compulsory and government use licensing provisions of Article 31 of the TRIPS Agreement authorize governments to grant such licenses on the grounds of their own choosing. These provisions provide maximum flexibility in the grant of government use licenses, including by eliminating any requirement for prior negotiations with patent holders as a precedent to granting licenses.[17] Article 31 requires that patent holders be paid adequate remuneration in the circumstances of the case, although that requirement may be subject to curtailment in regard to licenses issued as remedy for anticompetitive conduct.[18]

Each of the forms of IPRs regulated by the TRIPS Agreement is subject to limitations and exceptions, as expressed directly in the text or as a matter of customary legal interpretation.[19] The Doha Declaration on the TRIPS Agreement and Public Health discussed further, *infra*, was adopted in large measure to clarify for governments and the public the nature and scope of exceptions and limitations authorized under the TRIPS Agreement in relation to public health.

g. Alternatives to IPRs

Each form of IPR provides its holder with a right to exclude third parties from making, distributing and/or using the protected technology or expression. The extent of that right to exclude differs. But in all cases the presumptive effects are to limit the dissemination of the technology or expression, and to allow the IPR holder to charge a higher than fully competitive market price. That is the IPR *reward* or *incentive* for technological progress.

It has long been recognized that there are alternative policy mechanisms for encouraging innovation.[20] The principal alternative is the subsidy that involves payment (direct or indirect) by the government to the innovator for pursuing new technologies. As contrasted with the patent, the risk of loss in the case of subsidy falls at least partly on the government (and, by definition, the general public).

Another alternative mechanism for promoting innovation is the "prize".[21] The prize mechanism involves establishing a predetermined award for the person or persons that achieve the goal(s) defining the prize. The prize mechanism typically contemplates that the person seeking the prize will expend his or her own resources in that endeavor.

Each of the subsidy and prize is distinguished from the patent by the establishment of predetermined objectives. In a field such as public health, the establishment of defined objectives may aid in the rational and cost-effective expenditure of research funds because particular diseases or conditions can be targeted.[22]

Governments routinely subsidize innovation in certain fields, such as for the development of military technologies. Virtually all of the development in the US of vaccines and treatments

to address bioweapons threats is being undertaken pursuant to government subsidy.

Although the prize has been used throughout history -- for example, for the development of a timekeeping mechanism that could be used on sea voyages[23] -- it has recently reemerged in fields such as private space exploration.

The main general critique of subsidies is that government officials oversee the selection of subsidy candidates, both in terms of field of application and direction of research. There are those who argue that bureaucrats are not well suited to either of these roles. It is further argued that because subsidies shift the risk of failure to the government, innovators under subsidy are likely to be less efficient than privately- funded innovators.

Until recently, less attention was paid to the prize incentive as an alternative for stimulating innovation. We do not have very much information about the scale of prize incentives necessary to stimulate innovation in particular fields. Nevertheless, as experimentation in this area proceeds, prizes may become a more common and accepted mechanism for promoting innovation.

3. PATENTS IN PHARMACEUTICALS AND ALTERNATIVE ENERGY RESOURCES AND MITIGATION TECHNOLOGIES

It is often stated that patent protection plays an unusually significant role in the pharmaceutical sector because of the particular characteristics of pharmaceutical technology.[24] Up until recently, innovation of new medicines involved the application of synthetic organic chemistry to create new chemical molecules or compounds. Although the development of such new molecules or compounds, as well as subjecting them to clinical testing, was expensive, the state-of-the-art in analysis of such compounds permitted their relatively easy reverse engineering by those seeking to duplicate the work. The principal invention of the research-based pharmaceutical company was a single molecular structure (though that initial "new chemical entity" might subsequently be subject to various incremental changes involving additional and/or multiple patenting). The combination of high R&D costs with the low reverse engineering costs made the research-based pharmaceutical companies particularly dependent on strong patent protection because the incentives for reproduction of their products was high, and their technology quite vulnerable.

The initiation of bioengineered medicines places additional obstacles in the way of reverse engineering because substantially more complex molecular structures are involved than is the case with synthetic organic chemistry.[25] Yet, the extent of these obstacles is not so clear because the basic problem for the reverse engineering firm is determining the process by which the genetic structure is modified so as to produce the complex bioengineered molecule, not actually "constructing" that molecule with component parts. In other words, the process involves introducing changes into the genetic codes that are creating the new complex chemical structures, not figuring out how to replicate what the genetic codes are doing. For this reason, potential generic competitors in the biotechnology sector using "biosimilars" suggest that the research-based biotechnology companies may be overstating the difficulties that must be addressed. It may therefore be that patent protection is equally important to the biotechnology companies as it was (and is) to the synthetic chemistry companies. That is, one or two patents may suffice to control access to a therapeutic field, and without those patents biotechnology companies are highly vulnerable.

Patents have a decidedly mixed record as a policy instrument for encouraging innovation in the field of public health (and particularly pharmaceuticals). First, the rate of innovation in the field of pharmaceuticals has been low for the past two decades.[26] Arguably, there are a number of benign explanations for this phenomenon -- such as the unanticipated complexity of applying genetic engineering to treat human disease -- that are short-term *bumps in the road* on the way to a new era of accelerating innovation. But, it may be that there are more fundamental problems with the design of pharmaceutical innovation policy.[27]

Second, whether as effect or cause, the low number of new "breakthrough" pharmaceutical technologies (i.e., in the sense of development of new therapeutic classes of treatment) has led to a focus by the originator industry on product line extension through development of incremental modifications to existing products. This focus on product line extension, customarily referred to as the practice of "evergreening", frequently involves changing the characteristics of previously developed compounds to provide a modestly improved experience for the patient-consumer, such as reducing the frequency with which the medicine must be taken. When combined with aggressive marketing campaigns to doctors and patients, these "new and improved" products can be used to freeze out generic competition in the same therapeutic class, thereby maintaining high prices.[28] Minor modifications are desirable (when they are safe and effective), but the focus of investment capital on these minor modifications, in addition to foreclosing price competition, also means a reduced focus on developing new therapeutic classes of treatment.

Third, patents provide certain unhealthy incentives in the pharmaceutical sector. Because pharmaceutical innovator companies are seeking the largest consumer market for their products, they are encouraged to focus their attention on the most financially popular treatments, which tend to include lifestyle treatments (e.g., for erectile dysfunction, hair restoration and cosmetic skin care). Patient-consumers are complicit in this focus because they demand the lifestyle treatments, so the industry cannot be unduly faulted for addressing that demand. But, the net result is that decisions regarding pharmaceutical product development are not based on meeting genuine public health needs, but rather on consumer preferences. This has a particular impact on tropical developing countries where disease patterns are different than those in the OECD and whose populations suffer from a lack of treatments for diseases such as Dengue fever, Chagas disease, and certain types of malaria, as well as from multi-drug-resistant (MDR) tuberculosis.

Fourth, the financial resources available to multinational pharmaceutical originator companies based on returns from sales of patented products create distortions in the political and legal markets that are very difficult for potential generic competitors, developing country governments and consumer-oriented non-governmental organizations to overcome. This leads to an entrenchment of innovation policy and reluctance among policymakers to consider and/or adopt alternatives.

It is widely considered that the role played by patents in the AERs/MTs field is significantly different from that in the pharmaceutical field.[29] First, a wide range of technological solutions is used in the various subject matter areas of AERs/MTs. To take energy supply as an example, end-users typically make use of energy in the form of electricity or combustion. There are many ways to generate electricity, and many materials that can be used to generate combustion. End-users of energy can often switch between sources of supply and materials. If an energy supplier attempts to raise its price, competing suppliers and sources will enter the market. Because much energy is "fungible", this restricts the potential power of patent holders. To put it in economics terms, energy is a product with a relatively high degree of price elasticity both on the supply and demand side. This elasticity characteristic has limits. Once a large-scale infrastructure commitment has been made with respect to a particular form of energy supply, it may become more difficult for users to switch between sources of supply. And, if a relatively small number of companies become embedded as suppliers this may give them the economic power to foreclose market entry by new competitors.[30] Patents may be part of an anticompetitive effort to foreclose competition, but they may be used as part of broader anticompetitive arrangements.

Much of the foundational technology of the AERs/MTs field is presumed to be well known. The mechanisms by which photoelectric cells are stimulated by sunlight to release electrons are understood; the main technical problems to be solved are incremental. These may involve improving the types of materials used in the construction of solar panels, and improving current conversion technologies. The basic idea of using wind to turn the blades of a turbine that generates electricity is common, evolving from an ancient history of using water and wind to turn waterwheels and windmills to grind grains into flour. There may be many ways to improve the efficiency of wind turbines (or water turbines), but these improvements will be incremental. Similarly with insulating material, climate control systems, computer software, and so forth, there appears to be a presumption that there are less likely to be single "blocking patents" that control the competitive environment.[31]

Pharmaceutical innovators very typically seek to maintain direct control of manufacturing and distribution of their products worldwide, without out-licensing their patented technologies to third parties.[32] Only the "thin reed" of the patent allows the originator to serve distant markets from a few production locations. This may help account for the strong reliance by pharmaceutical originators on patent protection. Although this question requires more investigation, it is not clear that

AERs/MTs innovators are equally reluctant to out-license their technologies.[33]

Assuming that patents currently play a lesser role in the AER/MTs arena than in the pharmaceutical sector, this does not mean that IPRs such as patents might not act as an obstacle to the diffusion of AERs/MTs. As discussed earlier, the financial advantages that accrue to technological "first movers" may become embedded by different mechanisms than patents alone, such as agreements among potential competitors to share markets. Historically, patents have been used as a mechanism for market allocation even when, conceptually, market entry by third parties would otherwise be feasible. This occurred, for example, in the case of electric lamps through the use of restrictive patent pools.[34]

4. ASSESSING THE IMPACT OF MULTILATERAL NEGOTIATIONS ON PUBLIC HEALTH

Up until the mid-1980s, national policies with respect to innovation and access to medicines were largely within the discretion of national governments. Governments were free to choose the form of incentive preferred for the promotion of innovation, such as whether to provide pharmaceutical product patent protection or subsidies for innovation. Governments were able to adopt policies favoring local generic production of medicines, regardless of what might be the patent status of medicines in other countries. Up through the mid-1980s, virtually all new medicines were first brought to market by major multinational companies based in a few developed countries. Larger developing countries such as Argentina, Brazil and India manufactured copies of those new medicines and distributed them at comparatively low prices.

That situation was regarded as unsatisfactory by the major multinational pharmaceutical originators because potential profits in the larger developing country markets were lost to local generic producers. The potential financial benefits of investments in research and development in the developed countries were not fully realized through sales in developing markets. To redress this situation, the major multinational originators joined certain other industry sectors (such as the U.S. computer software industry) in demanding rule changes at the multilateral level. These demands were translated into government action, and the Uruguay Round of trade negotiations included patents and other intellectual property rights relevant to the pharmaceutical industry.

Negotiators from developing countries such as Argentina, Brazil and India, understood quite well that demands for patent protection for pharmaceutical products would transform their domestic pharmaceutical sectors. The logical consequence of extending patent protection would be to strengthen the market position of foreign originator companies, and to increase local prices of pharmaceutical products. These countries strongly resisted rules in the TRIPS Agreement that would require extension of pharmaceutical product patent protection, but they ultimately were not successful because of other elements of the trade negotiations. Promises made to Argentina and Brazil, which are highly dependent upon agricultural exports, to increase market access in developed countries and to reduce export subsidies,were sufficient to overcome objections by their local pharmaceutical producers. India was the last holdout and succeeded in ameliorating the transition through negotiation of the "mailbox system", but ultimately India did not have the bargaining power to block adoption of the TRIPS Agreement.[35]

During the Uruguay Round, conflict of policies was largely among governments, with the support of industry. There was little or no "access to medicines" constituency advocating during the Uruguay Round.[36] The most striking difference between negotiations during the Uruguay Round and negotiations in today's Doha Round is the presence today of NGOs at virtually all levels of negotiation.

The "pushback" against the TRIPS Agreement rules involved a complex set of circumstances. The major impetus was provided by a legally unjustified invocation of the TRIPS Agreement by multinational pharmaceutical originator companies to challenge legislation adopted by the government of South Africa in 1997. This action was supported by the US and EU governments, and was accompanied by threats to impose trade sanctions (though the United States eventually withdrew its support for the originators).[37] This led to worldwide protests and condemnation, a good deal of which was directed at the WTO and the TRIPS Agreement. The difficulties in South Africa were followed by a WTO dispute settlement action initiated by the US against Brazil's compulsory licensing statute, again drawing scrutiny of the TRIPS Agreement from a public health standpoint.

Developing countries considered it vitally important to obtain the assurance that the TRIPS Agreement did not and would not stand in the way of protecting public health. In June 2001, the first TRIPS Council meeting was convened specifically to consider the relationship between the TRIPS Agreement and Public Health. This was followed by a proposal by developing countries for a declaration that would enshrine the basic principle that the TRIPS Agreement would not stand in the way of addressing public health matters.

Developing countries governments, strongly supported by NGOs, placed a great deal of pressure on the WTO leadership to pursue a relaxation of TRIPS Agreement rules so as to alleviate the wide public perception that those rules interfered with the protection of public health. Yet through August 2001, the United States, Australia, Canada, Japan and Switzerland remained opposed to a developing country-friendly declaration, and it is difficult to predict what the result might have been in the absence of intervening events. The terrorist attack on the US of September 11, 2001 resulted in a dramatic change in the negotiating environment at the WTO.[38] Although the Declaration was the product of intensive work, by developing country governments and NGOs, the intervening external event was critical to its adoption in a favorable form.[39]

The negotiations under Paragraph 6 were more difficult than those resulting in the Doha Declaration because there was no corresponding external event to weaken the position of the originator pharmaceutical industry. After two years, a waiver of TRIPS Agreement restrictions was adopted (to be followed by a corresponding amendment).[40] However, the waiver and amendment contain a number of limitations that make its use somewhat difficult.

The experience of developing countries and NGOs during the WTO negotiations on public health stimulated further proposals at the WHO to further their interests in promoting innovation of particular interest to developing countries, as well as to promoting access. This ultimately resulted in adoption at the WHO of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. The Global Strategy and Plan of Action are at their early implementation phase and it is difficult to draw conclusions regarding their ultimate effect. It does, however, seem reasonable to conclude that the long struggle at the WTO provided impetus for action at the WHO. A number of proposals for using IPRs-related mechanisms and alternatives to IPRs to further innovation and technology transfer to developing countries have been made in the context of the WHO Global Strategy deliberations. These include the formation of patent pools and the use of prize mechanisms. There has also been discussion of increasing transparency of the patent system, such as through the creation of patent databases. Discussions regarding these mechanisms are, however, at relatively early stages.[41]

Matters that received attention during the WTO public health negotiations, such as research on "neglected diseases", have since been the subject of positive development. A number of PPPs, such as the Drugs for Neglected Diseases initiative (DNDi), have been formed, and are making some progress. The decision by the US government to establish the President's Emergency Program for African Relief (PEPFAR), which has been one of the most important contributors to addressing the HIV-AIDS pandemic, certainly benefited from the attention brought by the access to medicines movement during the WTO negotiations. Other initiatives, such as UNITAID, have also benefited from public interest in the access to medicines problem initially generated during the WTO dialogue.

In the overarching sense of influencing public perceptions and the attitude of governments toward addressing critical public health needs (particularly in developing countries), the "Doha Declaration process" without doubt has had a positive influence. However, this assessment must be tempered with objective analysis of the global pharmaceutical sector. The originator pharmaceutical industry remains dominated by a handful of companies based in the OECD.

The industry has in fact been consolidating over the past decade. A number of the more successful local generic producers in India have been acquired by the OECD originators or by multinational generic producers. The basic "numbers" regarding pharmaceutical revenues remain roughly the same -- approximately 85 percent of global pharmaceutical revenues are accounted for by patented originator products controlled by OECD companies, with 15 percent of global pharmaceutical revenues accounted for by generic products. Tremendous inequalities regarding access to medicines continue to persist based on income and geography.

Originator multinational pharmaceutical companies do not "transfer technology" to developing countries or their producers except within the context of traditional commercial arrangements. The originator companies do not typically out-license rights to lucrative patented products. The limited instances of technology transfer from the originator companies are taking place within public-private partnership structures that to a large measure represent potential "win-wins" for the originators. As discussed above, they out-license technologies that would not otherwise be pursued, in exchange for back-end rights to market resulting products in developed countries, leaving the PPP partners to manufacture and sell for developing country markets. The originators provide limited financial support and assume limited risk.

Changes to the structure and functioning of the pharmaceutical industry as a result of multilateral negotiations have been effective only at the margins. The basic structure of the industrial sector has not significantly changed. This reinforces the observation made earlier that the private sector tends to control economic activity throughout the world, and that government policies are influential only at the margins. For this reason, it is important that negotiators and governments consider arrangements providing satisfactory incentives to channel private sector initiative into areas where change is needed.

As a broad generalization, the Doha Declaration process has positively influenced governments and multilateral organizations toward taking greater responsibility for assuring that populations and developing countries have adequate access to medicines. This is an important evolutionary change. The Doha Declaration process has influenced the pharmaceutical industry at the margin. Structure and behavior have largely remained constant, with some exceptions.

5. SOCIAL WELFARE AND IPRS

IPRs play perhaps a unique social welfare role in respect to pharmaceuticals because access to medicines may mean the difference between life and death for the individuals who need them. If there is no innovation and no treatment available, the failure of the innovation system results in disease and death. If the price of a necessary medicine is out of reach, the fact that the treatment exists is of no benefit. The very direct link between pharmaceutical products and health places a heavy burden on those who make and implement IPRs policy in this field.

Of course, not all medicinal treatments represent the difference between life and death, or prolonged suffering. We do not pay as much attention to whether the patent system inhibits access to a slightly improved headache remedy as we to an effective new treatment for malaria.

Until recently, the relationship between new technologies and climate change may not have been considered a matter of life and death. And, it is probably fair to say that there is only a small percentage of the global population that views a solution to adverse climate change with the same immediacy of concern as the problem of HIV- AIDS or malaria. Yet, it is also probably fair to say that the level of social concern about climate change is rising as hurricanes and typhoons appear with greater intensity, and as glaciers melt more rapidly.

It is easier to draw an immediate link between energy prices and social welfare than climate change and social welfare, and from the standpoint of those seeking solutions to climate change problems the recent rise in energy prices (now having fallen) was a positive development because it strongly encouraged thinking about ways to reduce levels of consumption of hydrocarbon-based resources for energy. In addition, high energy prices threatened a devastating impact on developing countries (and especially least developed countries) whose budgets were severely impacted by those prices.

While it is comparatively easy to generalize about the effects of weak innovation in the field of medicines and the impact of high medicines prices, it is very difficult to generalize about the social welfare impacts of climate change because those impacts - and the timeframe over which they are to be experienced - are as yet comparatively uncertain. A worst-case scenario on climate change may be apocalyptic. A less-worst-case may involve impacts on isolated communities. There is some opinion that certain geographic zones will benefit from climate change in terms of increased arability of land.

6. KEY NEGOTIATING LESSONS FROM PUBLIC HEALTH

Examination of the public health-related negotiations during the GATT Uruguay Round and throughout the TRIPS Council discussions during the Doha Round suggests some key lessons for negotiation with respect to climate change issues.[42] These are as follows:

a. Economic and political power matters

This lesson may be considered self-evident, but it nonetheless remains at the heart of trade and intellectual property negotiations. Countries that offer access to large wealthy markets, and/or that control access to financial resources (through, e.g., voting rights at the IMF), are more equal than others when it comes to determining the outcome of negotiations. In the WTO arena, where consensus decision-making operates, economic and political power at the least enables rules and policies to be blocked. The EU or the US may not always be able to drive their preferred agenda through the membership, but in most cases they can prevent their own interests from being adversely affected by exercising a veto. This is not true for smaller less powerful countries that nominally enjoy the authority to exercise a veto, but may not have the power to exercise it.

Developing countries had limited success in moderating the power of the OECD countries in the GATT Uruguay Round TRIPS negotiations. Although a small coalition of countries (including Argentina, Brazil, Egypt, India and Nigeria) attempted to prevent the adoption of protective patent rules, their significant level of dependence on access to OECD markets precluded effective resistance.

From the conclusion of the Uruguay Round negotiations in 1993 forward, the balance of power in world trade has shifted to a modest extent so that China, India and Brazil are somewhat better able to exercise authority in trade and IPRs related negotiations.[43] Each of these countries is in a position to block forward progress, just as the US and EU. In that sense, power has diffused to permit a larger number of countries, including transitional developing countries, to protect their own economic and political interests.

The consequences of the diffusion of power are evident in multilateral negotiating forums. Progress in intellectual property rights negotiations at WIPO and in multilateral trade negotiations at the WTO has been slow. The US and EU are no longer able to apply diplomatic pressure toward achieving their preferred objectives sufficient to overcome the reluctance of major developing country powers. One of the more significant consequences of this multilateral slowdown has been redirection toward bilateral and regional negotiations (see discussion following).

This transition undoubtedly has consequences for climate change negotiations, though it is difficult to anticipate what those consequences are. The presence of five or six economic powers able to block consensus, with significantly different economic and social interests, certainly suggests that the possibilities for stalemate are high. It also suggests that compromise will be needed from each of these sides, perhaps more so than in previous economic negotiations. Earlier negotiations on climate change, such as on the Kyoto Protocol, indicate that it is possible to achieve agreement among a limited group of countries. The fact that several countries have the effective power to block a consensus does not preclude conclusion of an agreement, as would be the case at the WTO. However, as the Kyoto Protocol also illustrated, a climate change agreement that excludes an important block of carbon-emitting countries does not effectively address the climate change problem.

b. Stakeholder involvement is essential

One of the most significant changes in the nature of international intellectual property negotiations since the conclusion of the GATT Uruguay Round is the active participation of nongovernmental organizations (NGOs) in the process. This participation takes a variety of forms, including the preparation and distribution of policy papers, convening of informational meetings and associating with country delegations. Stakeholder participation has dramatically improved the negotiating effectiveness of smaller and less economically capable countries as their technical capacity has been expanded.[44]

NGO involvement is important in the formulation of policy proposals for consideration by government delegations. It is also important in the information arena that traditionally has been dominated by well-financed industry groups.

Environmental NGOs were active in connection with the Rio Conference on Environment and Development in 1992, the NAFTA negotiations among Canada, Mexico and the United States in the early 1990s, and during the later part of the GATT Uruguay Round negotiations. Thus, the importance of NGO involvement is not a new lesson for the climate change negotiations. It might well be argued that environmental NGOs provided the model for NGO involvement in multilateral public health negotiations. Still, it is not clear that NGOs have so far gravitated to the climate change and IPRs issue as they did to the access to medicines campaign. Moreover, while public health NGOs were largely united in demands at the WTO, there does not as yet seem to be an issue that is cohesively motivating NGOs interested in the climate change problem. This perhaps may be one reason why a number of NGOs are interested in pursuing a declaration on IPRs and climate change -- to provide a rallying point for NGO interest.

It is worth identifying a rather recent trend. This is the financing of seemingly public-interested NGOs by corporations and industry groups as a form of counter-propaganda aimed at public-interest NGOs. It is often very difficult to identify the financing source of an NGO and, as industry has learned, the choice of a consumer-friendly name is not limited to consumer-friendly groups.[45]

Up to this point, NGOs have tended to use governments as a mechanism to promote the NGO agenda. Governments may consider whether they should begin to place greater demands on the NGOs in terms of advancing governmental interests.

c. Zero-sum bargaining is unlikely to be successful

The experience of developing countries in the 1970s and 1980s strongly suggests that demands for redistributing global wealth based on appeals to equity are not likely to succeed. Similar demands with respect to public health in the late 1990s, and up until now, have made only modest inroads into improving global conditions. Inducing meaningful change is most likely a matter of finding solutions in which all parties perceive themselves to benefit -- that is, non-zero-sum solutions. To illustrate, developing countries may well consider that an equitable approach to mitigating climate change involves “free transfer” of technology from developed to developing countries. Developing countries may further consider that the benefit to developed countries from concessionary arrangements will be an overall reduction in carbon emissions that ultimately benefits developed countries. This may be correct as a matter of principle. However, economic activity in developed countries is largely controlled by private sector companies. It is not controlled by governments. In order to induce private-sector companies to invest and make technologies available, it is necessary to establish incentives. It is important to envision and establish joint venturing agreements under which both sides benefit.

d. Technology transfer requires concrete mechanisms[46]

It is not uncommon for *soft* commitments on transfer of technology to be included in multilateral and/or bilateral agreements. These soft commitments usually involve an undertaking to use best efforts and/or to meet in the future regarding areas of potential cooperation. Soft commitments on technology transfer are not a substitute for concrete projects. Private sector companies do not engage in *preferential* technology transfer arrangements in favor of other private sector companies, in favor of developing countries or in favor of the public sector out of a spirit of goodwill. Private sector companies are interested in increasing their profits, not in creating competitors. In order to induce private sector out-licensing and/or provision of technology it is necessary to provide meaningful financial incentives. Alternatively, advanced technologies must be acquired by governments and transferred under well-defined programs. These *hard* technology transfer commitments can be established as part of treaty bargaining.

The TRIPS Agreement illustrates the difficulty associated with non-specific transfer of technology commitments. Article 66.2 of the TRIPS Agreement establishes an obligation on the part of developed country Members to provide incentives to enterprises and institutions to transfer technology to LDCs "to enable them to create a sound and viable technological base". This provision has not given rise to any meaningful transfer of technology in favor of LDCs.

One comparatively successful form of technology transfer between the private sector and non-profit organizations has involved the establishment of public-private partnerships such as the Drugs for Neglected Diseases initiative (DNDi). In these arrangements, originator pharmaceutical companies have made available parts of their compound libraries for further R&D by the partnership entity. Although there is no "standard form" licensing template, one type of arrangement allocates future distribution markets along geographic lines, giving the originator the wealthy OECD markets and the nonprofit entity the developing country markets. This allocation might also involve distinctions between the types of recipient of the product, for example, as between public health service providers and private sector providers. Because the originator is making available compounds as to which it might not pursue further research, the result is a win-win because the originator gains through shared R & D, while the nonprofit gains access to a technology that may not otherwise be available. If a new medicine is successfully developed, the patient is the ultimate winner.

Thus public private partnerships could play a useful role in favor of the diffusion of climate change technologies and their potential should be more fully utilized in this area and on a wider scale.

e. Communication to the public shapes the political environment

Governments (particularly democratic ones) care about the way their proposals are presented in public media. This is because politicians depend upon public support (to varying degrees) to acquire and remain in power, and because media reports influence public perceptions. External communication is important in connection with the results of multilateral meetings, and public understanding of the results of the meeting is shaped by the way it is presented by the media. For this reason, it is important to governments that they formulate relatively concise media messages that their officials can convey with some degree of consistency, and that they seek out opportunities for presenting their positions to media representatives.

Internet communication played an enormous role in the 2008 presidential election cycle in the United States, suggesting that a significant shift in the way public perceptions are shaped has taken place even since the timeframe of the Doha

Declaration. It may be that major media outlets such as the New York Times, Wall Street Journal, Financial Times and CNN are playing a reduced role as shapers of public opinion as more diffuse Internet communication takes on a greater role. This phenomenon needs to be factored into the communications planning of negotiators and stakeholders.

f. Forum shifting can undermine gains

It should not be assumed that forcing negotiations to a stalemate in one forum, or achieving negotiating gains in one forum, represents the ultimate outcome of bargaining. Sophisticated government and industry actors can shift negotiating forums as a means of circumventing obstacles and/or to reverse previous concessions.

Forum shifting may take place between multilateral institutions (such as in the field of public health, between WHO, WIPO and the WTO).

By way of illustration, the WIPO Standing Committee on the Law of Patents (SCP) agreed in March 2009 to include "patents and the environment, with a particular attention to climate change and alternative sources of energy", in a non-exhaustive list of issues to be analyzed (as a follow-up to its June 2008 meeting that adopted a programme of work). This does not suggest that the WIPO exercise will adversely impact progress on climate change and transfer of technology issues. But, at minimum, negotiators must now pay attention to ensuring coherence and complementarity between future discussions at WIPO and at the UNFCCC.

Forum shifting may also take place between multilateral, regional and bilateral forums. Negotiations regarding public health at the WTO were succeeded by negotiations at a bilateral and regional level. While there were a number of reasons why these alternative forums were adopted, one of those reasons was to revisit the TRIPS Agreement rules and interpretations adopted at the WTO, and to reverse gains achieved at the WTO. Although climate change is a global problem and logic suggests that global solutions are preferable, there are bilateral and regional arrangements that could nonetheless have a substantial impact.

For example, the EU and the US could, in theory, move toward adoption of "carbon taxes" or "carbon tariffs" that would seek to offset economic benefits countries can achieve through use of carbon-emissions intensive manufacturing processes. Although negotiations that would allow such taxation would be unlikely to progress at the WTO, it is not inconceivable that countries negotiating with the EUor the US on a bilateral or regional basis could accept such commitments. This would establish a new form of trade preference in favor of countries willing to apply carbon tax-related rules. While such rules might be challenged in WTO dispute settlement, such challenges would be time-consuming and the outcome is not preordained. There are other areas where technical standards could be used as part of a regional or bilateral program to reduce carbon emissions and served to inhibit extra-regional imports of products or technologies. The "net" of the above is that countries negotiating under the UNFCCC or in other multilateral forums should not assume that driving a hard bargain in one forum produces the optimal result. A result that is more generally tolerable to all of the negotiating parties may for this reason be preferable.

Again, developing country governments and environmental NGOs are familiar with the phenomenon of bilateral and regional negotiations, and the possibilities for forum shifting. NGOs became heavily involved in the NAFTA negotiations in the early 1990s in an effort to prevent the formation of a free trade area from undermining national environmental standards.

g. Competition law is underemployed

Government regulators in the US and the EU have made significant use of competition law in overseeing and bringing enforcement actions with respect to the pharmaceuticals market. This has been evident particularly in respect to potential misuse of patents and regulatory requirements to block entry of generic products onto the market. The US Federal Trade Commission issued an influential report on this subject in 2002,[47] and in late 2008 the European Commission Competition Directorate issued a preliminary report on the same general theme.[48]

Encouraged and supported by NGOs, South Africa's Competition Commission successfully pursued actions against major originator suppliers of antiretroviral medicines and obtained significant licensing concessions as a consequence of those actions. However, as a general rule, developing country government authorities have been less active then OECD authorities in making use of competition law and remedies as a means of promoting access to generic drugs. The TRIPS Agreement provides considerable leeway to government authorities in the adoption and implementation of competition laws, and also is flexible in terms of private causes of action.[49] This is not a lesson especially drawn from the past decade of public health negotiations, but is important because competition law may prove quite important in the context of transfer of technology for AERs/MTs.

h. Human rights values influence the dialogue

There has been a great deal of discussion in multilateral organizations and among NGOs regarding the role of international human rights in addressing access to medicines. International human rights rules have the capacity to exert a persuasive influence at the international level. The Doha Declaration affirms the right of states to protect public health, and in that way recognizes the fundamental importance of the human right to health. Although specific human rights treaties did not play a substantial role in the Doha and related public health negotiations, international human rights values without doubt influenced the overall negotiating environment.

Within national legal systems, the values of human rights are more typically given effect through national constitutional provisions, specific implementing legislation and regulations. Protective provisions have played an important role in South Africa, for example, where the courts required the national drug authorities to implement a national antiretroviral roll-out.

7. THE ROLE OF IPRS IN INNOVATION AND TECHNOLOGY TRANSFER FOR AERS/MTS

An important lesson from public health negotiations and debates at the international level with respect to IPRs may be that it is necessary to identify precise obstacles and negotiating objectives prior to initiating negotiations. A great deal of time and energy can be spent negotiating about matters that will not result in concrete changes on the ground.

This suggests some preliminary questions for objective analysis:

- Is the rate of innovation in the fields of AERs/MTs adequate? Is there a difference in the rate of innovation among developed and developing countries? What is the source of that differential? Are IPRs responsible for that differential?

- Assuming *arguendo* that the rate of innovation is adequate, is there indication that relevant technologies are not making their way to developing countries? If technologies are not moving from developed to developing countries, what are the obstacles? Are they obstacles relating to IPRs, or are they arising from other factors such as lack of financial resources or regulatory barriers?

- What type of voluntary licensing is taking place in the AERs/MTs environment?

- The WTO TRIPS Agreement provides flexibility for developing country governments to overcome specific barriers created by IPRs, such as through the use of compulsory and government use licensing. Is there a reason to believe that such flexibilities would not be adequate to address barriers in the transfer of AERs/MTs technologies?

- Do developing countries require additional resources for training in the use of IPRs as incentive mechanisms?

- Do developing country competition laws allow the government and/or private sector to address identified barriers? Are additional resources needed to improve competition law implementation?

Studies undertaken so far with regard to specific technologies suggest that patents and other IPRs may not be acting as barriers to market entry.[50] The studies undertaken to date are by no means conclusive, but suggest that further work must be done to identify specific barriers and potential barriers as a predicate to developing policy solutions.[51]

The technologies relevant to AERs/MTs are primarily, though by no means exclusively, held by private firms. Concentration of technology in the private sector is encouraged in the United States by Bayh-Dole and other legislation that permits private recipients of public research funds to apply for and own resulting patents. A number of countries and regions have adopted or are planning to adopt legislation that emulates the US system. As noted previously, because technology is largely owned by private-sector firms, proposals to encourage or mandate technology transfer cannot merely rely on licensing of government-owned patents or other technical data.

It should also be noted that U.S. Bayh-Dole legislation furthers domestic industrial property objectives by generally requiring that holders of patents granted on the basis of government funding (including the federal government) license that technology for manufacturing in the United States.[52] It seems likely that other governments will follow the lead of the US in this regard and seek to use domestic subsidization of innovation to advance local industrial development and/or mercantilist trade policies. Restrictions on the export of technology may have significant consequences for the diffusion of AER/MTs.

As a practical matter, OECD governments will not "direct" their companies to supply technology

to developing countries. There are both constitutional and political economy reasons why such an approach would not work. Moreover, it is doubtful that OECD governments would be inclined to adopt such an approach. There continue to be strong mercantilist and nationalist biases among governments that favor policies designed to strengthen national industries, whether or not that is at the expense of foreign industries. And, as noted earlier, history instructs that governments and the private sector do not respond concretely to appeals to "equity" and "rebalancing global wealth".[53]

This strongly suggests that proposals for transfer of technology to address climate change should seek to take advantage of private incentive mechanisms. Business joint ventures that combine OECD working capital and technology with developing country local resources and capacity, and which provide a good rates of return on investment, are needed. The resources of multilateral institutions might be used to develop business models that will achieve an adequate distribution of benefits for each side. Mediation and dispute settlement facilities might encourage continuity in project development. In fact, many of the resources necessary for facilitating joint venture negotiation and ongoing management already have been established. For example, in the area of dispute settlement, the WIPO Arbitration and Mediation Center has facilities specifically designed to accommodate disputes with respect to technology licensing, while World Bank ICSID facilities are available for investment-related disputes. WIPO is looking toward establishing additional mechanisms that will allow it to serve as a technology clearing-house.

There are a number of models of innovation that seek to harness the combined innovation capacity of multiple actors.[54] These include the formation of patent pooling arrangements. Such pooling arrangements may be government-sponsored, or they may be established by private initiative. Patent pooling arrangements may encourage technology sharing both at the basic R&D phase and in the commercialization phase. It is reasonable to expect that governments funding multiple enterprises seeking to achieve the same objective would desire that the results be made generally available. However, as Barton has pointed out, the use of a pooling mechanism may have the unintended consequence of reducing individual enterprise commitment because of the lack of potential for achieving competitive advantage. In addition, as evidenced in regulatory guidance by US and European competition authorities, there are anticompetitive risks associated with patent pooling arrangements.[55]

As a general proposition, reliance upon private sector and/or joint public-private partnership innovation and technology transfer mechanisms to address AER/MTs will require increased attention to application of competition law principles by government authorities. It is in the nature of private enterprise to seek the exclusion of competition as a means to improve returns on capital. Competition law generally recognizes that the elimination of competition through product improvements, efficiencies and price reductions, better marketing and so forth is beneficial. However, history demonstrates that large industrial firms may see advantages to allocation of markets, the fixing of prices among horizontal competitors, and other anticompetitive conduct as a means to extract surplus rents from consumers.

Up until now, competition policy in the major developed country markets (i.e., US and EU competition law) treats foreign markets as unregulated zones of potential anticompetitive conduct.[56] Only when anticompetitive conduct abroad has a direct and substantial effect on the whole market will competition authorities and courts intervene. These policy choices might well be re-examined in the context of AER/MTs and climate change if technology transfer is to be encouraged.

8. FINANCING MECHANISMS

Experience with medicines-related financing at the multilateral level may be instructive with respect to AERs/MTs.

a. Innovation

There is a mix of sources of funding for investment in R&D with respect to new medicines. At a global level, approximately $100 billion per year is spent on pharmaceutical R&D. About $30 billion of that comes from public sources, mainly the US National Institutes of Health (NIH) that is primarily funding "basic research". The remainder comes from private sector investment, principally from a small group of multinational originator companies, but also from private investment in emerging companies (today principally in the biotechnology sector). In the OECD countries there is also a considerable amount of "off the books" ancillary funding coming from universities, research institutes, teaching hospitals, and so forth, that also engage in R&D. Pharmaceutical R&D is increasing in emerging developing countries such as Brazil, China and India.

The funds from U.S. NIH are essentially subsidies, often given to public institutions, but with resulting research that may be appropriated by the private sector through ownership or licensing of patents. This takes place under U.S. Bayh-Dole legislation that authorizes recipients of federal research funding to patent the results of their efforts unless the government chooses to undertake the patenting (and still out-license the technology). Bayh-Dole and related legislation applies also to AERs/MTs-related research.[57] That is, it is not limited to the pharmaceutical sector.

The global pharmaceutical R&D economy therefore functions through a mix of private and public funding. Patents are the principal mechanism used to promote private sector R&D investment. Government subsidies are a significant secondary source of funding. These subsidies are supplemented by funding from private foundations, such as the Gates Foundation. Ancillary mechanisms such as prizes play a modest role. Multilateral institutions, such as the World Bank, are not major contributors to investment in pharmaceutical R&D, the World Health Organization (WHO) invests modestly in research on subjects such as tropical disease.

The UNFCCC Expert Group on Technology Transfer (EGTT), and other Convention bodies, are discussing proposals for the financing of transfer of technology. This paper is not intended to develop or analyze a specific proposal within the framework of that Expert Group. It rather considers the subject of financing from a more general perspective.

Up until now, it appears that the level of global R&D in respect to renewable energy has been significantly lower than the level of investment in the pharmaceutical sector. For example, a study by UNEP indicates that in 2006 a total of $16.3 billion was spent on renewable energy research and conservation research[58] (This does not, however, appear to reflect R&D investment in the petroleum sector that may be substantial). Though the data is at this stage is preliminary, it appears that public subsidy is a significant part of investment in AERs/MTs, and appears to be increasing.[59]

It is reasonable to anticipate that financing for R&D in the development of AERs/MTs will continue to be based on a mix of private sector and public investment. The recent spike in petroleum prices (though followed by an even more recent fall) raised government and private sector interest in AERs/MTs R&D, and the new presidential administration in the US has indicated a strong interest in pursuing development of AERs/MTs. It would appear that the US government intends to pursue AERs/MTs as part of a fiscal stimulus package, so that substantial subsidization may be foreseen.

One key lesson regarding R&D in the pharmaceutical sector is that the possibility to establish effective patent monopolies and preserve them through product line extensions may discourage investment in "breakthrough technologies". It may therefore be useful to look at a system of incentives that would reward more significant technological developments with a higher rate of return them less significant developments. This could be done by using a form of "quasi-patent" that would be more limited in duration for technologies that were not significantly innovative, but are nonetheless useful. An alternative is to implement higher thresholds for meeting the inventive step criteria of patentability.[60]

In all events, it is self-evident that the development of new technologies to address climate change requires the availability of investment capital. Whether that capital is made available from government budgets (e.g., collected from taxation) or from the private sector (e.g., raised from private investors) may be important to the way the "output" of R&D is distributed. Governments may be more inclined to make technology available to a wide group of enterprises than private-sector investors. Whatever may be the source of capital, its availability is critical. For this reason, it is important that those interested in technology transfer focus on potential inducements to capital formation.

b. Access

For purposes of this discussion, access to medicines will be addressed in terms of "affordability" from a price standpoint.

The introduction of generic competition is the single most important factor leading to price reductions for medicines. And, prices tend to decrease as more generic competitors enter the market. That is, it is important that more than two competing suppliers be present as generic producers may be able to exploit pricing power in a duopoly.

The second principal mechanism for assuring affordability of medicines is price controls. Such controls are favored by many OECD countries, including the EU, Canada and (through reimbursement controls) Australia. Price controls have their principal price-reducing effect on originator/patented products for which competition may be limited in the relevant therapeutic class.

A third significant price control mechanism is generic substitution laws. Competition laws may be used to police the market, though the impact of such laws tends to be felt "after-the-fact".

Pharmaceuticals are supplied to the public through a wide variety of mechanisms that vary from country to country. There is typically private sector purchasing. In the OECD countries, this is usually through private insurance schemes. For many developing countries, private-sector purchases are "out of pocket". In addition to private sector purchasing, many governments operate programs for the supply of medicines from public budgets. These are effectively government subsidization programs paid for by tax revenues. For lesser-developed countries, there is also contribution from multilateral financing institutions, such as the Global Fund, PEPFAR, the World Bank, and so forth.

For developing countries, one of the most important programs in terms of financial resources was the development by the WHO of the "essential medicines" concept.[61] This calls upon public health authorities to assure the availability of a relatively low number of medicines that will address the preponderance of public health issues at affordable prices. By using an essential medicines approach, developing country public health authorities should be able to conserve their financial resources. There are certain important exceptions, such as in providing treatment for HIV-AIDS, where newer more expensive medicines may be needed, and where even low-priced generic medicines (because of the quantities needed) become unaffordable. For this reason, there is virtually no "market-based"

mechanism that will assure affordable access to medicines for all countries and populations. Some countries and some populations simply lack the resources to effectively participate in the global market economy and require multilateral subsidization for the purchase of medicines.

The financing of AERs/MTs and medicines appears to raise similar issues and potential solutions. A good deal of the purchasing of AERs/MTs may be done by private-sector consumers with their own funds, such as for the installation of solar panels and/or the purchase of cleaner-energy transportation. Some government support, such as through tax incentives, may be needed to encourage such purchases until pricing comes down. But, private-sector consumption expenditure may not be possible for a significant part of the global population. In that regard, governments will be required to subsidize and/or provide AERs/MTs financial resources to producers and consumers. Price controls have long played an important role in energy production and distribution, and it seems likely that governments will likewise need to exercise control over providers of AERs/MTs solutions, just as they do over producers of energy using hydrocarbon-based fuels.

As with pharmaceuticals, it may be useful to limit the number of technologies employed in countries with limited resources so as to promote purchasing efficiency. However, it is not clear that an "essential medicines" approach is transposable to the energy sector where continuing improvements in technology may rapidly to bring down costs and prices.

It will undoubtedly be important for competition authorities to police AERs/MTs markets against abusive conduct. This is an area in which technology and expertise from the developed countries may be useful for developing country authorities. Because developing countries face considerable obstacles in pursuing legal claims against major multinational corporations, this is also an area where cooperation among policing authorities will add value.

As with pharmaceuticals, there will remain among lesser-developed countries and among less affluent populations the need to receive multilateral subsidization for AERs/MTs. Where resource bases are sufficiently low, participation in market-based solutions may not be feasible.

9. A DECLARATION ON IPRS AND CLIMATE CHANGE?

As noted at the outset of this paper, there has been considerable discussion by developing country delegations and NGOs regarding the possibility of adopting a declaration on IPRs and climate change comparable to the Doha Declaration on the TRIPS Agreement and Public Health.[62]

Among experts familiar with the TRIPS Agreement, the availability of flexibilities such as compulsory and government use patent licensing, limited exceptions to patent rights, variability in patentability standards and possibilities for liability regimes (as enforcement mechanisms) may be seen as adequate to address potential transfer of technology constraints presented by IPRs. Moreover, the TRIPS Agreement provides considerable leeway for the application of competition law. The Article 31*bis* amendment applies only to predominant exports of pharmaceutical products, and in that context a constraint imposed by Article 31(f) of the TRIPS Agreement does exist, although further work (as discussed below) is needed to determine its importance to the AERs/MTs context.

Assuming that TRIPS Agreement flexibilities are well understood among experts, negotiations regarding a Declaration on IPRs and Climate Change arguably would be time-consuming and disruptive in the absence of significant foreseeable "payoff". Some have argued that the Doha Declaration was the product of a specific set of concrete circumstances requiring redress, and that there is no comparable set of circumstances evident in the climate change arena.

Although TRIPS Agreement flexibilities may be well understood by experts, governments that have attempted to implement and use these flexibilities have confronted serious political obstacles. Industry groups from OECD countries strongly object to any perceived weakening of IPRs protection and enlist the aid of their governments to prevent such erosion. The recent experience of the government of Thailand in issuing several compulsory licenses for essential medicines is illustrative. Bilateral and regional trade agreements have been used by OECD governments to limit the use of TRIPS flexibilities and to create possibilities for withdrawal of trade concessions. From the standpoint of developing countries, a declaration might provide political support for the use of TRIPS flexibilities, acknowledging that flexibilities are already built into the system. Recent controversy at the WTO and WHO arising out of the seizure of generic pharmaceutical products in transit (based on patents locally granted in a transit country) suggests that new issues may arise under the TRIPS Agreement the resolution of which will benefit from a decisive interpretation comparable to the Doha Declaration.[63]

It may, of course, be pointed out that the Doha Declaration was adopted more than seven years ago and that governments have continued to face political constraints in using flexibilities. While this is true, the adoption of the Doha Declaration was followed by a number of positive developments in terms of access to medicines, as discussed in previous sections of this paper. The negotiating environment at the WTO, WHO and WIPO have all improved from the standpoint of access to medicines.

Pedro Roffe reminded us at the Poznan COP 14 in December 2008 that international legal rules develop slowly. The most important impact of the Doha Declaration may be long-term as it provides concrete evidence of changing attitudes at the international level regarding the intended policy impact of TRIPS Agreement rules. That change and evolution will be felt as the WTO Appellate Body takes the Declaration into account in future decision-making processes. A comparable Declaration on IPRs and Climate Change would reinforce the trend toward balancing innovation and access at the international level.

If a Declaration on IPRs and Climate Change is desirable from the standpoint of the progressive development of international law, a next step is to determine what body should issue such Declaration and what its contents should be.

The Doha Declaration was adopted within the framework of the WTO and expressly applied to the TRIPS Agreement. However, because negotiations with respect to climate change are taking place in the UN framework, and because the WTO is not a UN institution, it appears more appropriate to situate an IPRs and Climate Change Declaration in the forum of the United Nations Framework Convention on Climate Change, or even more broadly in the United Nations General Assembly.

In principle, because all of the members of the UNFCCC will also be members of the WTO and other multilateral organizations, there should be coherence among the rules of the institutions on the theory that the IPRs and Climate Change Declaration would be a "later in time" interpretation or agreement.[64] However, in practice this process might well give rise to a rather complex legal situation, particularly if the new Declaration is in the form of an interpretation or understanding. In order to avoid any possible lack of coherence among multilateral rule-making institutions, it would be important to make clear that the Declaration is intended to bind all of its participants across the entire range of multilateral institutions and rules. To this end, it may be useful from a practical standpoint to draft and adopt a multi-institutional Declaration, with the participating member states to be constituted as the decision-making body of each of the relevant forums. Thus, for example, governments sitting as the UNFCCC governing body might also constitute themselves as the WTO Ministerial Conference, as well as the Paris Convention Union and the Bern Convention Union, for the purpose of adopting the IPRs and Climate Change Declaration. Such a cross-institutional arrangement would avoid prolonged debate within each institution regarding the extent to which rules are compatible.

There is at least one specific rule that developing country governments and NGOs have argued should receive particular treatment within the framework of TRIPS, and that is the same Article 31(f) that was the subject of Paragraph 6 of the Doha Declaration, and the Article 31*bis* Amendment to the TRIPS Agreement. Article 31(f) limits exports under compulsory license to the non-predominant part of production. The Article 31*bis* Amendment to the TRIPS Agreement, which provides an exception to the Article 31(f) rule, is specifically designed for and expressly applies to the pharmaceutical sector. Even assuming *arguendo* that developing countries would support its transposition to the climate change arena, it would not seem adequate simply to declare such Amendment to apply *mutatis mutandis* to AERs/MTs. Does Article 31(f) constitute a material impediment to compulsory licensing to address climate change? Further analysis of the industry and relevant technologies is needed to come to an informed conclusion. This would appear to be a logical next step.[65]

Another important question concerns the extent to which a Declaration will be considered legally binding and, equally importantly, whether and what dispute settlement mechanisms would be used to resolve issues of interpretation or compliance. The UNFCCC provides for dispute settlement by the International Court of Justice, or alternatively by an arbitration body to be established by the Conference of the Parties. If these dispute settlement procedures are to be used in connection with a Declaration, what remedial measures would be contemplated? For example, would trade-based remedies be available? If so, how would coherence with WTO and (regional trade arrangement) rules be achieved?

All of the foregoing begs the question, what would a Declaration on IPRs and Climate Change say? Recall that the core of the Doha Declaration is the agreement by WTO Members that the TRIPS Agreement "does not and should not prevent Members from taking measures to protect public health". Most of the remainder is an affirmation of pre-existing TRIPS flexibilities. Would such commitment transposed to the climate change context be sufficient to alleviate concerns of developing countries that intellectual property rules would otherwise be used to impede their access to essential technologies? Are more specific affirmative obligations required? This

paper does not propose even tentative answers to these questions. Answering them will entail gathering and refining input from many interested stakeholders.

The main reason arguing against seeking a Declaration on IPRs and Climate Change is the capacity for the negotiations to divert governmental attention away from concrete solutions and toward political debate and discord. There is no way to assure against that other than through very careful and good diplomacy that lays the groundwork for reaching a consensus. If a consensus can be reached with some degree of cooperation and mutual concession, the resulting Declaration may be useful in the longer-term development of international law balancing innovation and access.

CONCLUSION

There has been a protracted struggle to reconcile the public interest in development of and access to essential medicines, on one side, with the interests of the business community in profiting through the development of new medicines and protection of related intellectual property, on the other. This struggle has yielded benefits by focusing the attention of government policymakers on the need to proactively address the needs of the less economically fortunate, and resulted in large-scale funding of medicines aid programs, as well as the development of new public-private R & D partnerships.

The international community is at a relatively early stage in seeking to reconcile the public interest in ameliorating and mitigating the effects of climate change through the development and application of improved technologies, on one side, and the interests of the private sector in profitably developing and implementing technical solutions protected by IPRs, on the other. The struggle on the issue of public health and technology reveals a compelling need to find solutions that simultaneously benefit the public and the private sectors in developed and developing countries.

The 2008-2009 global economic crisis has led governments of a number of economically powerful developed and developing countries to adopt stimulus programs focusing on innovation, with emphasis on increasing the use of renewable energy resources. New government involvement in R&D programs may prove beneficial in the sense that climate change negotiators representing governments should be better able to influence the direction of industry. The private sector may be encouraged to extend the benefits of new technologies by entering into mutually beneficial arrangements with foreign joint venture partners. Keeping an optimistic frame of mind, the present winds of creative destruction may encourage a stronger and more collective approach to addressing climate change through the development and transfer of technology.

ENDNOTES

1 See, e.g., IPCC: *Summary for Policymakers,* in Climate Change 2007: The Physical Science Basis, Contribution of Working Group I to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change (Solomon, S.D., et al. eds.) Cambridge Univ. Press 2007.

2 *See, e.g.,* Keith E. Maskus and Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, in International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime, 3-45 K.E. Maskus and J.H. Reichman (eds.),Cambridge Univ. Press 2005.

3 *See, e.g.,* Susan Sell, Private Power, and Public Law: the Globalization of Intellectual Property Rights, Cambridge Univ. Press 2003.

4 TRIPS Agreement, Article 27.1 requires that patents be granted without "discrimination" as to all fields of technology based on the criteria of novelty, inventive step and utility. A key holding of the WTO dispute settlement panel in the *Canada - Generic Pharmaceuticals case* (Canada—Patent Protection of Pharmaceutical Products, Report of the Panel, WTO Doc. WT/DS1141R, adopted 7 April 2000) was that the prohibition on "discrimination" in Article 27.1 does not preclude differences in patent legislation and implementation based on legitimate policy grounds, but rather precludes only unjustified distinctions. See, e.g., Frederick M. Abbott, *Bob Hudec as Chair of the Canada - Generic Pharmaceuticals Panel - The WTO Gets Something Right*, 6 J. Int'l Econ. L. 733-37 (2003).

5 A specific provision in the U.S. Patent Act establishes a broad exemption for research regarding pharmaceutical products that does not, by its terms, apply to other fields of technology. U.S Patent Act, 35 USC§ 271(e)(1), as interpreted by the U.S. Supreme Court in *Merck v. Integra Lifesciences,* 545 U.S. 193 (2005).

6 The European Patent Convention, at Article 52(2), expressly excludes computer programs from the subject matter scope of patent protection as distinguished, for example, from patent practice in the United States.

7 It appears that the Japanese Patent Office does not recognize so-called "business methods" as patentable subject matter. At least until recently, business methods have been considered patentable subject matter in the United States. See Jinseok Park, *Has Patentable Subject Matter Been Expanded? - A Comparative Study on Software Patent Practices in the European Patent Office, the United States Patent and Trademark Office and the Japanese Patent Office*, 13 Int'l J. L. & Info. Tech. 336, 366 (2005).

8 Detailed treatment of the various forms of intellectual property and the mechanisms by which they are regulated at the international level can be found in Frederick M. Abbott, Thomas Cottier and Francis Gurry, International Intellectual Property in an Integrated World Economy, Aspen Publishers 2007.

9 Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention,* in The Rate and Direction of Inventive Activity: Economic and Social Factors 609, 617 (Richard R. Nelson ed., 1962).

10 Frederick M. Abbott, *Patent Licensing, Competition Law and the draft Substantive Patent Law Treaty*, presented at Open Forum on the draft Substantive Patent Law Treaty, World Intellectual Property Organization, Geneva, March 2, 2006, available at http://www.wipo.int.

11 It is worth considering whether awarding a monopoly position to one of several persons crossing the innovation finish line at approximately the same time is the best policy.

12 See generally, Frederick M. Abbott and Graham Dukes, Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World, Edward Elgar Publishing, forthcoming 2009, at Chapter 2 (hereinafter "Abbott & Dukes").

13 WTO TRIPS Agreement, art. 39.3.

14 See John H. Barton, *IP and Climate Technology*, unpublished manuscript, October 19, 2007 (in author's files).

15 See Abbott & Dukes, supra note 12, at ch. 2.

16 See, e.g., UNCTAD/ICTSD, Resource Book on TRIPS and Development, Cambridge Univ. Press 2005, at 25-27 (hereinafter "TRIPS Resource Book").

17 See, e.g., Batting HIV/AIDS: A Decision Maker's Guide to the Procurement of Medecines and Related Supplies (ed. Y. Tayler), World Bank 2004, at Annex B.

18 Private holders of IPRs are often (though not invariably) hostile to the use by governments of exceptions and limitations to IPRs because this represents an intrusion upon their capacity to exercise exclusive rights. In cases involving large multinational enterprises, the economic effect of intrusion may be substantial. For this reason, industrial lobbies expend significant financial resources seeking to limit the use of exceptions and limitations. Lobbying efforts include approaches to legislatures, as well as the financing of media campaigns. Such efforts may include distortion of the rules in an effort to convince the public and the legislature that governments are not permitted to undertake various activities. As a consequence, there is considerable confusion among non-experts regarding the nature and scope of intellectual property rights. See generally Ellen 't Hoen, The Global Politics of Pharmaceutical Monopoly Power, Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health, AMB Publishers 2009.

19 By way of illustration, UPOV 1991 establishes specific flexibility authorizing governments to enable farmers to replant seed (so-called "farmers' rights")(Article15(2)), and more general recognition that exceptions may be authorized to protect the public interest (Article 17(1)).

20 See, e.g., William Nordhaus, Invention, Growth and Welfare: A Theoretical Treatment of Technological Change, MIT 1969.

21 See James Love and Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, The Ruby Hutchison Memorial Address, KEI Research Paper 2007:1 Presented November 14, 2006, Revised 26 March 2007, and; Joseph Stiglitz, *Scrooge and intellectual property rights*, BMJ 2006; 333:1279-1280 (Dec. 23, 2006).

22 See generally, Abbott & Dukes, supra note 12, at ch. 2.

23 See Kendall Haven, 100 Greatest Science Inventions of All Time, 69-71, Libraries Unlimited 2006.

24 See, e.g., Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Management Science (1986) 175, and Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, July 2002 manuscript, available atwww.econ.duke.edu/Papers/Other/Grabowski/Patents.pdf.

25 *Definition of Biotechnology for the Bioeconomy to 2030.* Draft, Organization for Economic Cooperation and Development, Paris, June 2008.

26 See US Government Accountability Office, *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts*, GAO-07-49, Nov. 2006.

27 See Abbott & Dukes, supra note 12, at chs. 2-3.

28 See European Commission, Competition Staff Working Paper, Pharmaceutical Sector Inquiry, Preliminary Report, 28 Nov. 2008, at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.

29 See, e.g., John H. Barton, *Intellectual Property and Access to Clean Energy Technologies in Developing Countries: An Analysis of Solar Photovoltaic, Biofuel and Wind Technologies*, ICTSD Trade and Sustainable Energy Series, Issue Paper No. 2, Dec. 2007, and John H. Barton, *International Diffusion of Climate Change Technologies in the Transport Sector*, manuscript of April 2008 (in author's files).

30 This contrasts with the pharmaceuticals market. If a pharmaceutical enterprise holds a patent on a novel therapy, and that therapy is the most successful at treating a disease (and, in some cases is the only means to treat a disease), end-users may not switch to alternate sources of supply. The demand for a new pharmaceutical treament may be highly price-inelastic. Thus, the originator pharmaceuticals market may be quite different than the AERs/MTs market. See also Barton, *Diffusion in the Transport Sector*, id.

31 The foregoing observation regarding AERs/MTs is a generalization and cannot anticipate the future. We do not and cannot know what inventions are on the horizon. There may be a patent examiner in Switzerland close to revolutionizing our collective understanding of energy generation, just as an earlier Swiss patent examiner revolutionized our understanding of space and time. He or she might be able to patent the revolutionary technology (recognizing that $e=mc^2$ is often used as an illustration of what is not patentable). In other words, it is difficult to plan and make policy around an unknown path of technological development. What we can do is extrapolate from what we do know. What we know now seems to suggest that innovation in AERs/MTs is less likely than in the pharmaceutical field to block market entry because incremental innovations are more likely than foundational innovations to leave room for alternative technological pathways.

32 This reflects the nature of the pharmaceutical product; typically tablets, capsules and injectables. Such products are comparatively cost-effective to transport across long distances, particularly when high prices are paid for them.

33 Because capital costs of producing energy generation equipment may be higher than for producing pharmaceuticals, and because energy generation facilities may be more closely linked to physical presence on land, AERs/MTs owners may be less capable of serving distant markets by export, and therefore may be more inclined to license their technology to foreign third parties. Or, it might be that as energy generation technologies become more sophisticated, the energy industries will begin to emulate the originator pharmaceutical industry and rely to a greater extent on strong patent protection.

34 See Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 Harv. J. L. & Tech. 389, 407-09 (2002).

35 The TRIPS Agreement included the requirement to provide pharmaceutical product patent protection, for developing countries by the end of a 10-year transition period. Brazil, which had fought against the product patent requirement, almost immediately adopted pharmaceutical product patent protection -- a political decision that remains highly controversial within Brazil today. India made full use of the transition period.

36 The World Health Organization did not play any meaningful role in the TRIPS negotiations.

37 Following the inauguration of Nelson Mandela as president of South Africa, the country adopted a new medicines policy intended to facilitate access among the less affluent. That policy was manifested in legislation -- the Medicines and Related Substances Control Amendments Act of 1997 – that included provisions regarding parallel importation, price controls and generic substitution. All of those provisions were designed to reduce prices of newer medicines. The TRIPS Agreement did not prevent South Africa from authorizing parallel importation of medicines, and it did not address price controls or generic substitution. Notwithstanding this, the major originator pharmaceutical companies backed by their home governments (the European Union and United States), threatened South Africa with trade sanctions and civil litigation based upon alleged TRIPS Agreement inconsistencies.

The United States eventually conceded that the TRIPS Agreement did not prevent the measures adopted by South Africa, but the pharmaceutical companies pursued litigation. These events coincided with the mushrooming of the HIV-AIDS pandemic in South Africa. Thus, the pharmaceutical companies were essentially suing to block access to generic versions of antiretroviral and other medicines necessary to address the pandemic. While the TRIPS Agreement did not directly preclude South Africa from addressing the pandemic, the abuse of the TRIPS Agreement by the pharmaceutical companies as the basis for their actions certainly made it appear to the media and public that it did. Ultimately, the pharmaceutical companies were forced to withdraw their legal action and pay the legal fees of the South African government in defending its legislation. Nonetheless, the series of events had the unfortunate effect of paralyzing the government of South Africa in the midst of the pandemic (though the attitude of President Mbeki almost certainly played a role in the unfolding of events).

38 See discussion of role of September 11, 2001 attack in Frederick M Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. Int'l Econ. L. 469 (2002). First, in response to an anthrax bio-weapon threat, the United States threatened to issue a compulsory patent license for the antibiotic Cipro. Second, because of the weakening of the global financial system and economy, the United States was forced to offer concessions at Doha to assure a successful conclusion of the meeting as a whole.

39 The Doha Declaration mainly clarified existing rules in favor of access to medicines. Only in paragraphs 6 and 7 was there evidence of a roll-back of previously existing rules. Paragraph 7 allowed least developed countries additional flexibility in implementing commitments. Paragraph 6 authorized further negotiations on a recommendation to expand exports under compulsory license beyond those already permitted under the TRIPS Agreement.

40 See Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 Am. J. Int'l L. 31 (2005).

41 *Inter alia*, UNITAID is endeavoring to form a patent pool.

42 See generally, and Frederick M. Abbott and Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. Int'l Econ. L. 921 (2007).

43 As noted earlier, the negotiations resulting in adoption of the Doha Declaration on the TRIPS Agreement and Public Health in November 2001 succeeded in significant measure because of a unique set of external circumstances. The OECD countries were at that juncture economically vulnerable and needed the cooperation of developing countries to move the comprehensive WTO agenda forward. This necessitated concessions on public health from the OECD side. The subsequent negotiations based upon Paragraph 6 of the Doha Declaration reflected to a greater extent the traditional exercise of power by the United States and European Union, although developing countries had by this time absorbed from the Doha Declaration negotiations the importance of coalition building and cooperation, even when certain intra-group concessions were required.

44 The heavy involvement of NGOs in multilateral IP discussions perhaps first manifested itself during negotiation of the Doha Declaration on the TRIPS Agreement and Public Health, and was a key element of the Paragraph 6 negotiations leading to the TRIPS Article 31*bis* amendment and August 30, 2003 waiver. More recently, the active participation of NGOs was instrumental in adoption by the WHO of the Global Strategy and Plan of Action on Public Health, Innovation, Intellectual Property.

45 An industry group NGO seeking to block carbon emission restrictions would not name itself "Corporations for Global Warming". It would instead call itself "Citizens for a Green Planet".

46 "Transfer of technology" – that is, the conveyance from one party to another of information, know-how and performance skills, technical materials and equipment -- takes place in a variety of settings and ways. Educators and educational resources (books, Internet access, and so on) transfer technology to students. Scientific journals, patents (and patent databases) and other technical information resources transfer technology among the scientific community. Enterprise investors transfer technology in the form of materials, equipment and training among institutions and employees. Public and private patent and know-how licensors transfer technical information, implementing skills and, in some circumstances, materials and equipment. All of these activities may take place in a variety of configurations, whether public or private, institutional or individual, through partnerships or joint ventures, and within or across national borders.

47 US Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July 2002.

48 European Commission, Competition Staff Working Paper, *Pharmaceutical Sector Inquiry, Preliminary Report*, 28 Nov. 2008, at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.

49 See Frederick M. Abbott, *Are the Competition Rules in the WTO TRIPS Agreement Adequate?,* 7 J. Int'l Econ L. 687 (2004).

50 See, e.g., Barton, *Intellectual Property and Access to Clean Energy Technologies in Developing Countries*, supra note 29, and J. Reichman, A. Rai, R. Newell & J. Wiener, *Intellectual Property and Alternatives: Strategies for Green Innovation*, December 2008 draft (Chatham House). But, compare South Centre, Analytical Note, *Accelerating Climate-Relevant Technology Innovation and Transfer to Developing Countries: Using TRIPS Flexibilities Under the UNFCCC*, SC/IAKP/AN/ENV/1, SC/GGDP/AN/ENV/8, Mar. 2009 ("South Centre Note"), and; Cameron Hutchison, *Does TRIPS Facilitate or Impede Climate Change Technology Transfer into Developing Countries?,* U. Ottawa L. & Tech. J. 517 (2006).

51 See, e.g., the draft paper presented by Nick Johnson on behalf of the OECD at the ICTSD Dialogue on Climate Change, Transfer of Technology and IPRs in Geneva on March 27, 2009.

52 See 35 USC §§ 204 & 209(b). See also Barton, *IP and Climate Technology*, supra note 14.

53 The New International Economic Order movement of the 1970s may have generated some interesting United Nations resolutions, but it did not result in concrete transfers of technology.

54 See, e.g,, Barton, *IP and Climate Technology*, supra note 14.

55 U.S. Department of Justice/Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property (1995), and; European Commission Regulation No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements and Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements (2004/C/ 101/02).

56 See Abbott, *Are the Competition Rules of the TRIPS Agreement Adequate?* , supra note 49.

57 See Barton, *IP and Climate Technology*, supra note 14.

58 As quoted from Patrick Avato and Jonathan Coony, *Accelerating Clean Energy Technology Research, Development, and Deployment, Lessons from Non-energy Sectors*, World Bank Working Paper No. 138 (2008), "UNEP's 2007 report Global Trends in Sustainable Energy Investment 2007 estimates that R&D spending by renewable energy and energy efficiency by governments and corporations rose from $13 billion in 2005 to $16.3 billion in 2006," at p. 10.

59 *Id.*, at p. 11.

60 See Abbott & Dukes, supra note 12, ch. 2.

61 See Abbott & Dukes, supra note 12, ch. 5.

62 See, e.g., South Centre Note, supra note 50, and; Third World Network, *Some Key Points on*

Climate Change, Access to Technology and Intellectual Property Rights, Oct. 2008. See also, Matthew Littleton, *The TRIPS Agreement and Transfer of Climate-Change-Related Technologies to Developing Countries*, UN/DESA Working Paper No. 71, ST/ESA/2008/DWP/71, Oct. 2008. It should be noted that the European Parliament adopted a resolution, in November 2007, recommending launching a study on possible amendments to the TRIPS Agreement in order to allow for the compulsory licensing of environmentally necessary technologies (available at http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2007-0576&language=EN)

63 See Frederick M. Abbott, *Worst Fears Realised: The Dutch Confiscation of Medicines Bound from India to Brazil*, 13 Bridges No. 1, Feb.-Mar. 2009, at 13-14.

64 The rules of the Vienna Convention on the Law of Treaties provides that as between the same parties to successive treaties, the later in time rule prevails . Article 30(3) of the VCLT states: "When all the parties to the earlier treaty are parties also to the later treaty but the earlier treaty is not terminated or suspended in operation under article 59, the earlier treaty applies only to the extent that its provisions are compatible with those of the later treaty."

65 Even a casual observer of UNFCCC negotiations will be aware that a comparable level of stakeholder intensity will be present in negotiations for a solution to the Article 31(f) problem. The energy generation industries will substitute for the pharmaceutical industries, and environmental NGOs will substitute for public health NGOs. Governments will be influenced by industry and political interests. We might anticipate a replay of the Article 30/Article 31 debates concerning the appropriate mechanism for a solution. Taking this into account, it is critical that the practical side of the Article 31(f) problem be given serious attention prior to engaging in negotiations for a change.

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