SEMINAR ON THE RIGHT TO ENJOY THE BENEFITS OF SCIENTIFIC PROGRESS AND ITS APPLICATIONS

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Remarks
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1. Today there is strong effort underway to push public health regulation out of the WHO and bodies such as the UN Human Rights Bodies, and into WTO and other trade-related forums such as bilateral and plurilateral trade negotiations. Tobacco lobbies are fighting a furious battle to prevent governments from bringing dangerous products under control. Tobacco trademarks are argued to trump the value of human life and health. Investment chapters of trade agreements are now being invoked to prevent governments from protecting public health, including through challenges to judicial limitations on patents. What I would like to emphasize is that the groups promoting human rights and the groups promoting the protection of public health and other public values must be prepared to defend their policy space, and reject the idea that the WTO or other trade agreements or institutions have jurisdiction or priority over the UN Human Rights regime, the WHO and related rules. If a government purports to give up the right to determine how to protect the health of its citizens under a bilateral trade agreement that decision may well be inconsistent with fundamental human rights. The Universal Declaration of Human Rights is not subordinate to trading rules or intellectual property rules.
2. A substantial amount of background work, including by the Special Rapporteur, already has been presented regarding the source of a human right to share in the benefits of scientific advancement and enjoy the benefits of scientific progress and application. I will not try to elaborate on the source of human rights, or the resource limitations that give rise to subsidiary doctrines of progressive realization.
3. I was asked to address the question whether states may be under an obligation to adopt and use IP flexibilities in order to assure the realization of those rights. At the request of UNDP, I had recently co-authored a working paper addressing related subject matter in the context of assuring realization of the rights to life and health, and benefits of scientific progress, in the

context of promoting R&D and access to medicines -- principally in that case in the context of HIV-AIDS, malaria and tuberculosis. My work on that paper was primarily directed at practical mechanisms for achieving the objectives, including automatic compulsory licensing, including fair compensation; delinkage between R&D and production more generally -- a concept which is being considered at the WHO, and; establishment of a stabilization fund for procurement, potentially including the involvement of the World Bank, as well as funding for carrying out delinkage. In this context, the human rights side of the paper (developed with a co-author) suggested the emergence of a norm requiring that states use IP flexibilities to address public health requirements in appropriate circumstances. The paper suggested that the main question was not so much whether states are obligated to use IP flexibilities, but rather in more concretely specifying the circumstances or more specific content of the norm.

4. It is self-evident that governments are under an international human rights legal obligation to make use of IP flexibilities in appropriate circumstances. The source of that obligation may be found in a number of human rights, and more than one such right can be applicable in a given situation. For example, the right to life and the right to benefit from scientific advancement may apply to the same situation, or the right to health and the right to benefit from scientific advancement. There is no international legal doctrine to suggest that a particular situation generally must be assessed under an exclusive or single rule.
5. The obligation or necessity as self-evident can be illustrated without much difficulty. Consider the circumstances which there is an outbreak of pandemic influenza, and consider (though this may not be the current situation) that there is a medicine that is known to “cure” the condition, and that the medicine is under patent throughout the world. You are the Prime Minister of a country with the capacity to manufacture the referenced medicine. Under existing circumstances, there is insufficient supply from the originator patent holder to cover the large population in your country. The holder of the patent has refused to grant your manufacturers a license to produce the product. Without the product, millions of individuals within your country will die. There is no question but that you are under an international human rights obligation to use an IP flexibility, such as a government use or compulsory license, so as to allow your producers to manufacture and distribute the medicine.
6. The Same type of exigent scenarios can be used, by way of illustration for other subject matter areas. There may be farming communities in least developed countries experiencing severe drought where there is a technical solution under patent for use of a particular type of

genetically modified seed, or a patented rapid water desalination process, that could be used to provide drought relief. You are the Prime Minister of the least developed country facing the possibility that hundreds of thousands of citizens of your country will perish from malnutrition unless there is a solution to the drought problem. The international community has not or cannot contribute sufficient surplus agricultural products to provide relief. The patent holders refuse to authorize your farmers to make use of the patented seeds at low cost, or your water supply system to make use of the patented desalinization process. You would be under an international human rights obligation to use IP flexibilities to address that exigency.

7. Taken at the level of exigency, it is evident that there are international human rights obligations to exercise IP flexibilities under appropriate circumstances. The issues that require more deliberation and development concern whether it is necessary or appropriate to further elaborate circumstances under which the international human rights obligations arise, and how those obligations can and should be used in a practical way.
8. There is a well-known critique of international human rights law suggesting that obligations are sometimes framed in an overbroad manner so as to become effectively nonjusticiable, or difficult to invoke in concrete circumstances. There is also a generally recognized attention to the lack of sufficient resources, whether financial, human, technical or otherwise, to immediately give effect to the panoply of human rights, and that some are subject to a doctrine of progressive realization.
9. The first critique gives rise to the notion that in order to make international human rights obligations more effective, it is necessary to provide more detailed context or rules regarding the scope of the obligation, such as more specifically elaborating circumstances under which the obligations can or must be invoked.
    a. Is specificity necessary? One of the core arguments that have taken place in the field of IP is the extent to which governments can or should be able to exercise discretion or flexibility in the manner in which IP rules are implemented. Much of the argument coming from the developmental side of the debate is that developing countries, in particular, but countries more generally, should be entitled to exercise a substantial level of discretion to take into account their particular circumstances, and to give effect to their own policy preferences. Similarly, in the field of human rights, it is worthwhile to ask whether it may not be better for governments to preserve discretion or flexibility regarding the circumstances under which human rights-based actions are undertaken.

The answer is, perhaps not, because of the circumstances in which human rights are invoked.

b. Human rights typically flow to individuals (or communities), and are frequently invoked as a protection against an abuse of governmental authority, or to demand that a government take steps that it has been unwilling to take. Human rights are protective of the individual person. IP rights have a component of individual entitlement -- as recognized in human rights law -- but are primarily an instrument of industrial policy. The vast majority of IP in commercial use is owned by large industrial corporations (and today large digital enterprises) using that IP instrument to generate wealth.

c. If international human rights in favor of sharing the benefits of science and technology are going to be successfully used to push governments to promote and protect the interests of individuals, it is probably necessary to provide additional specificity to the norms or, to put another way, to circumscribe the degree of flexibility governments have to implement those rights. Successfully invoking rights as against the government requires that the government not be given an open ended interpretative space.

10. It is important to keep in mind that IP flexibilities cover all IP subject matter, and in doing so, encompass a great portion of human activity. The subject matter area that has received the most attention over the past 15 years, and for good reason, has been public health. However, the various forms of IP affect agriculture, climate change, education, energy generation, traditional knowledge, communications, entertainment, and so on. The balance or context under which there are international human rights obligations to exercise IP flexibilities must be assessed in all of these subject matter areas. It is possible to envisage an effort to elaborate more specific norms on a field-specific step-by step basis, and/or an effort to elaborate a more specific set of norms that would be applicable across the fields.
11. In the elaboration of specificity there are two main sets of principal considerations:
    a. The circumstances under which a government is obligated to make use of IP flexibilities;
    b. The nature of the IP flexibility that a government is obligated to use and, as a subsidiary question, whether there are positive or negative constraints on the manner in which the flexibility must be used
12. In terms of the elaboration of norms, there has recently been a publication of a set of principles regarding protection of privacy in the digital environment against governmental surveillance by a wide-ranging group of NGOs. This particular set of principles is primarily grounded in the well-

known legal doctrine of proportionality, and further provides more detailed elaboration of circumstances in which actions might be appropriate or inappropriate.

a. It would seem that this type of approach may be the most useful in the sense that setting up concrete hypothetical circumstances may be problematic, at least in terms of first-order rules. It is difficult to anticipate with precision the circumstances in which norms must be invoked. But, in terms of guidance, it is certainly possible to present scenarios in which it would be necessary to invoke an IP flexibility.
b. This type of legal approach is not uncommon. A good illustration can be found in competition law, both in the European Union and the USA, where the legislature has enacted rules at a fairly high level of generality, the regulatory authorities have promulgated specific rules implementing those higher-level norms, and additionally have promulgated guidance documents that include specific hypotheticals or scenarios that layout the circumstances in which the rules will be applied in a particular way.
c. The international human rights field has the same type of process in which the higher-level norms are Incorporated in treaties or the binding Universal Declaration, and then further elaborated in Comments developed by the treaty bodies.

13. Has a very preliminary way to begin thinking about this, a generalized norm relating to the international human rights obligation to use IP flexibilities might take the following approach:

    There is an obligation to make use of a legal mechanism to prevent the exercise of an intellectual property-based exclusive right to control a technology or expression when:

    (a) there is a substantial risk to human life or health, and such risk is not adequately addressed by existing governmental resources; or
    (b) exclusive control of the technology or expression is substantially impairing human development, including educational development; and
    (c) the holder of the intellectual property-based exclusive right has not offered or provided a satisfactory solution, recognizing that in exigent circumstances it may not be appropriate or feasible to offer an opportunity for the holder to provide such a solution.

14. A more specific set of concrete circumstances would then require some significant attention, and developing a set of proposals will require some additional time and effort. But, it is probably a reasonable assumption that we have the most well-developed analytic and data resources with respect to public health, and in particular access to medicines and vaccines. In

that regard, an approach that relied on step-by step elaboration of more specific scenarios might best be addressed to that subject matter. In some recent cases, and I will note for illustrative purposes the decision by the Indian Appellate Board in the matter of the compulsory license for Nexavar, there was reference to the need to protect the public health interests of Indian citizens in terms of analyzing the pricing and access considerations. An analysis which takes into account the scale of the public health problem, the existing level of access to a medicine based, inter alia, on pricing considerations, and the prospective alternatives, is one that might be more broadly developed into a more specific set of rules.

15. We could continue along the public health track. Assume there is a new patented type of diagnostic equipment that can determine whether an individual has a greater than 60% chance of developing a coronary disease within the next 5 years. That diagnostic equipment is developed and sold by a German medical equipment company, and cost $1 million. A number of issues are raised. How important on a relative scale is the diagnostic information? Presumably there is some benefit in terms of prescribing preventatives, but how much? Expensive medical equipment such as this is beyond the budget of most health departments, at least when referring to a theoretically modest benefit. Do individuals in countries with limited budgets have a right to that equipment as part of the benefit of scientific advance? Should a government be required to exercise IP flexibilities to get it? (That assumes the potential existence of a lower cost non-patented version.)
16. The results of clinical trials may be quite important to understanding the potential adverse effects of medicines. The originator companies that finance these trials may have rights under certain arguable IP laws to protect clinical data from disclosure. Is not clinical trial data a type of scientific advance? How can the maintenance of secrecy regarding such data be justified if it can benefit researchers in understanding adverse effects, or if it can provide a significant boost to future research? The TRIPS Agreement at article 39.3 may obligate WTO Members to protect the confidentiality of a limited type of regulatory data, but at the same time allows governments to disclose such data [to address public health requirements. Should governments have an obligation to disclose clinical trial data because it benefits the public?
17. In terms of the right to share the benefits of scientific advancement, it is well recognized that scientific advancement in many circumstances requires the expenditure of significant financial resources, and that the necessity for protecting the life and health of individuals should give due account to demands for improvements in the treatments that are available. This is part of the

balancing equation that needs to be considered, and the suggestions here are not predicated on the idea that the interests of promoting R&D are unimportant. They are important, but it is possible to address those interests without ignoring the fundamental objective of R&D in the field of public health, which is to improve the human condition.

18. As discussed above, the circumstances can be defined both in terms of broad principles and in terms of more concrete cases, and the rules may well vary depending upon the subject matter field of application.
19. Marco Aleman already will have laid out some details regarding the nature and characteristics of IP flexibilities, and in this presentation I will not cover that ground. Each form of IP has its own legal characteristics and incorporates a set of flexibilities that are defined at the multilateral level and that the level of national legislation. To be clear at the outset, there might be circumstances under which there is a conflict of multilateral norms, and a national government may need to determine the relative intensity of the obligation is facing. For example, it is possible that there are WTO norms that are inconsistent with fundamental human rights and which a government may determine should not be applied in an exigent case. I have an example. At the end of the so-called Paragraph 6 negotiations and the adoption of the 30 August 2003 decision enabling the use of compulsory licensing for predominantly exporting, a number of OECD and other countries opted out of using the system as importers with a specific reference in the decision. That opt-out is reflected in the Amendment to the TRIPS Agreement not yet entered into force, article 31bis. Imagine there is a pandemic affecting my home country, the USA, and there are inadequate supplies of a patented treatment. Imagine further that Canadian manufacturers would be in a position to supply the treatment, but that the treatment is patented in Canada, and even if a compulsory license were ordinarily issued in Canada, the quantities needed for the United States would constitute the preponderant production. Article 31 of the TRIPS Agreement, without the Paragraph 6 solution, would tell us that Canadian manufacturers would violate multilateral norms by exporting to the United States. In my view, by failing to import from Canada, the United States would be violating the fundamental rights to life and health of its citizens. In such circumstances, international human rights obligations of the United States would take precedence over WTO rules concerning IP flexibilities. Moreover, I cannot even imagine the circumstances in which a US President or Secretary of Health would announce that because of WTO rules millions of fellow citizens would

be left to die. Without doubt, the United States would make a decision that the human rights of its citizens take precedence over a specific IP flexibility constraint.

20. Putting aside that issue of the relative intensity of norms, if we take patents as an example, there is a panoply of IP flexibilities, including discretion in the way in which the criterion of patentability are framed (India's Section 3(d), by way of illustration), the option for parallel importation, limited exceptions to patent rights, compulsory licensing and government use, the means to provide protection for plant varieties and others. The TRIPS Agreement, as an example of multilateral norms, is drafted at a moderate degree of specificity, leaving substantial room for national government discretion. However, such discretion is not unbounded, even if the boundaries are often blurry.
21. The same set of circumstances that may trigger an obligation to use an IP flexibility might be addressed by more than one legal means, depending on the nature of the solution the government seeks to implement. For example, it might be the case that the government discovers that there is a sufficient supply of low-cost medicines on a foreign market that could be parallel imported and solve a particular problem. Or, in the same case, the government may find that parallel importation would not solve the problem, and that it is necessary to issue a compulsory license for import or local production. The type of flexibility that is used may give rise to different conditions or limitations. For example, parallel importation does not entail remuneration to a right holder. Government use and compulsory licensing do entail a remuneration obligation, but one that is variable depending on the specific conditions. Not only is it important to consider the circumstances under which an obligation to use an IP flexibility arise, but also what are the operational constraints regarding that usage?
22. This is not a subject matter that can be addressed in 15 minutes, nor would I be prepared to lay out a detailed set of rules and conditions from a human rights perspective. But, this is where a work program might well be directed. Thank you