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Re-Evaluating the Freedom of Scientific Inquiry Through Biotechnology and Human Rights

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BIOTECHNOLOGY, HUMAN RIGHTS, AND INTELLECTUAL PROPERTY

The panel was convened at 12:30 P.M., Thursday, March 14, by its co-chairs, Allyn L. Taylor and Frederick Abbott, of Florida State University College of Law. Allyn Taylor introduced the panelists: George P. Smith, Catholic University School of Law, and Jensine Andresen, Boston University.

OPENING REMARKS BY ALLYN L. TAYLOR*

The globalization of public health has been described as posing new threats and important opportunities for international health.¹ Perhaps nowhere else is this phenomenon more evident than in the realm of biotechnology.

Research into the genetic basis of life is creating a plethora of new possibilities to diagnose, treat, and prevent illness. Advances in biotechnology promise to revolutionize medicine in identifying and treating illnesses that exact an enormous toll on people throughout the world. Although few promising interventions currently exist, the potential global public health implications of the promised treatments and cures based on genetics technologies are profound. Tools and treatments generated by genetics research may have an extraordinary effect on diseases and illnesses that afflict industrialized nations, as well as those that are the curse of developing states. Genetics technologies may affect the health of billions to the extent that they become affordable and accessible worldwide.

Potential applications of genetic science, such as germ-line therapy and human reproductive cloning, raise controversial global issues about the manipulation of the human species, in particular how to promote the biosocial potential of humans in a manner consonant with the integrity of the individual and the entire species. Even though they raise no new issues in medicine, human rights, or public health, many of the potential applications of genetic science exacerbate old issues, especially those related to equity, privacy, disclosure of genetic information, and freedom of reproductive choices and of scientific inquiry.

The distinguished scholars on this panel will consider critical issues of resource allocation and human rights. The potential inequity in the global distribution of health care interventions generated by biotechnology may well widen the gaps in health standards that already exist between and within rich and poor states. To what extent is intellectual property law consistent with the human right to health in this era of genetic advances? What types of collective action and partnerships can advance universal access to the benefits of genetic science? Can the codification of international law contribute to ensuring that the results of scientific inquiry are made available to individuals in both rich and poor states and that advances in biotechnology fulfill their promise of improving the health of billions?

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¹ Derek Yach & Douglas Bettcher, *The Globalization of Public Health I: Threats and Opportunities*, 88 AM. J. PUB. HEALTH 735 (1998).

RE-EVALUATING THE FREEDOM OF SCIENTIFIC INQUIRY THROUGH BIOTECHNOLOGY AND HUMAN RIGHTS

by George P. Smith, II*

From 1633 and Pope Urban VIII's censure of Galileo for averring Copernicanism¹ to July 31, 2001, when the U.S. House of Representatives voted, on bipartisan lines, to ban human cloning for reproduction as well as for therapeutic medical research purposes,² the quest to validate the freedom of scientific inquiry is both seen and questioned. While the mandate for progress has been unclear, one conclusion is inescapable: The freedom of scientific freedom, shaped by a spirit of social responsibility, must be ensured, and indeed promoted, if biotechnology is to be utilized fully in the development of human rights.³

Much as with structuring a regime for the law of the seas in the 1970s,⁴ now—in matters of biotechnology—and more especially the Convention on Biological Diversity adopted on May 22, 1992⁵—the split is predictable between developed and less-developed countries over the use of products derived from plant genetic resources.⁶ In developing countries, products derived from plant genetic resources become major sources of potential wealth. Indeed, with the phenomenal growth of knowledge-based industries, the intellectual property regime assumes a greater vitality in assuring the development of human rights in developing countries.⁷

The challenge is to find a balance between conservation and the reasonable exploitation of national resources. With the proper balance in place, opportunities for economic development become a base on which to engraft human rights to growth and sustainability and to human development. Regrettably, the present international regime and the amendments proffered to it are defective in accommodating both innovation and conservation.⁸

One intriguing proposal for meeting the international problems associated with biotechnology is the establishment, by treaty, of an international biotechnology patent office, to which would be referred all end-products derived from plant genetic resources. Such a system would not only advance conservation and preserve biodiversity, at the same time it would foster a spirit of innovation leading to new end-products.⁹

The globalization of international relations has given rise to complex issues in geopolitics—with no problem more central than that of conferring equal status on all human rights. To achieve this equality, economic and social rights must be factored into efforts to define and then recognize a rapprochement, indeed an interdependency between, development and human rights policy. In other words, recognition and use of a human rights approach to development elevates economic, social, and cultural rights to a co-equal ranking with political and civil rights.¹⁰

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¹ See GEORGE P. SMITH, II, HUMAN RIGHTS AND BIOMEDICINE 20–24 (2000).

² H.R. 2505, 107th Cong. (2001).

³ See generally, GEORGE P. SMITH, II, THE NEW BIOLOGY: LAW, ETHICS AND BIOTECHNOLOGY (1989).

⁴ See GEORGE P. SMITH, II, RESTRICTING THE CONCEPT OF FREE SEAS: MODERN MARITIME LAW RE-EVALUATED (1980).

⁵ Convention on Biological Diversity, June 5, 1992, 31 ILM 822 (1992).

⁶ See David J. Schnier, *Genetically Modified Organisms and the Cartagena Protocol*, 12 FORDHAM ENVTL. L.J. 377 (2001).

⁷ Chetan Gulati, *The Tragedy of the Commons in Plant Genetic Resources: The Need for a New International Regime Centered Around an International Biotechnology Patent Office*, 4 YALE HUM. RTS. & DEV. L.J. 63 (2001).

⁸ *Id.* at 84.

⁹ *Id.* at 63.

¹⁰ Brigitte I. Hamm, *A Human Rights Approach to Development*, 23 HUM. RTS. Q. 1005 (2001).

It has been suggested that lawyers and scientists have a shared “moral authority” in defending life and justice and, further, that both professional groups have “special obligations to humanity.”¹¹ Ideally, both should work together for social and distributive justice—seeking to promote adequate health care, for example, for all members of society.¹²

Medical science and biotechnology should seek, through the spirit of scientific inquiry, to achieve global implementation of the health-related provisions of the Universal Declaration of Human Rights, the Covenant on Civil and Political Rights, and the Covenant on Economic, Social and Cultural Rights, with a special concern for health care ethics, patient rights, medical research, and human experimentation.¹³

Efforts to abridge or destroy the most basic of all human rights—the right to be different—must be restrained by international and national structures, such as a proposed international biotechnology patent office and enhanced policy-making bodies, such as the United Nations Educational, Scientific and Cultural Organization (UNESCO), the United Nations International Children’s Emergency Fund (UNICEF), the World Health Organization (WHO), and the president’s Bioethics Advisory Counsel, as well as the National Academy of Sciences. A new ethic of deliberative democracy must be nurtured—one that sets and then translates standards of normative conduct for the new Age of Biotechnology that are practical, reasonable, humane, and understandable to the world community.¹⁴

REMARKS BY JENSINE ANDRESEN*

We welcome the intervention of people with resources who can develop a vaccine for HIV. But we must make certain that that guidelines are in place to ensure that AIDS vaccines will be affordable by the poorest of the poor.¹

—Nelson Mandela

The staggering statistics on the AIDS pandemic help put into perspective the deep and profound humanitarian significance of this issue and the critical need for a vaccine. However, many obstacles stand in the way of the development of an AIDS vaccine; intellectual property considerations, for example, have considerable impact on the vaccine development scenario. Some proposed solutions to the impasse include tiered pricing, licensing agreements, purchase commitments, and vaccine development partnerships.

Over forty million people worldwide are infected with HIV, the precursor to AIDS, and more than fourteen thousand new infections are estimated to occur each day. In sixteen African countries, between 10 and 20 percent of the adult population has HIV. AIDS now kills more people than any other infectious disease, and it has orphaned more than thirteen million children worldwide.² In fact, some people believe the number of AIDS orphans will reach forty million in the next decade—a number that represents, simply, the darkest face of the world’s humanitarian failure.

¹¹ GEORGE J. ANNAS, *SOME CHOICE: LAW, MEDICINE AND THE MARKET* 257 (1998).

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.* at 257. See also George P. Smith, II, *Setting Limits: Medical Technology and the Law*, 23 SYDNEY L. REV. 283 (2001); George P. Smith, II, *Judicial Decisionmaking in the Age of Biotechnology*, 13 NOTRE DAME J.L. ETHICS & PUB. POL’Y 93 (1999).

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¹ See IAVI Web site, at <http://www.iavi.org/globalmobil_z_economics.html>.

² Statistics provided by the International AIDS Vaccine Initiative (IAVI), available at <<http://www.iavi.org>> (internal link: need for a VACCINE/the world needs an aids vaccine) [hereinafter IAVI, Need for a vaccine].

The AIDS crisis also exerts a significant economic drain on the world's economy, both in wealthy countries, where healthcare costs were increased, for example, by an estimated \$7 billion in the United States in 1996,³ and in developing countries, where the drain on sub-Saharan GNP is estimated at 11.7 percent for 1999 alone.⁴ The United Nations estimates that AIDS-related costs have reversed social and economic development in twenty countries already.⁵

Given these grim statistics, it is no wonder that more people have begun to place their hopes in a vaccine.⁶ Nevertheless, there are many obstacles to the AIDS vaccine. First, a rather macabre reality is that private companies that produce drugs to *treat* AIDS accrue significantly greater amounts of money than would those who might offer a preventive vaccine. The annual global market for vaccines is estimated at \$4 billion, whereas the global drug treatment market is one hundred times this size (\$400 billion). Second, the costs associated with developing a vaccine are high, estimated at \$250–\$500 million, while the payoff may be low relative to more profitable drugs.⁷ These discrepancies are further compounded by the fact that “those countries with the greatest potential demand for a vaccine have the least ability to pay”.⁸

Dr. Seth Berkley, the president of the International AIDS Vaccine Institute, speaks out strongly against “[t]he current paradigm” for vaccine development, wherein companies develop and sell vaccines, often exclusively and at very high prices, in order to recover their research and development costs. As he argues, “Developing countries should not be forced to wait 10 to 15 years for an AIDS vaccine to trickle down to them.”⁹ Still, it would be naïve to attempt to develop an AIDS vaccine without the large-scale manufacturing facilities and quality control procedures of private industry.¹⁰

Thus far, comparatively little money has been directed towards AIDS vaccine development: In 2001, the combined public and private total was \$430–\$470 million, less than 1 percent of global health research and development spending. Furthermore, less than one-third of this sum actually went toward producing vaccine candidates; the rest went into basic and applied research or trials infrastructure.¹¹

According to the International AIDS Vaccine Initiative (IAVI), intellectual property can be defined most broadly as:

intangible property based on creations of the mind. Mechanisms such as patents, copyrights and trademarks all provide legal protection for these rights. Patent rights, for example, enable the owner to exclude others from exploiting the protected invention for a specific period of time in exchange for full disclosure to the public. Licensing of intellectual property allows a party to use such rights without obtaining ownership. Payment for these rights is called a licensing or royalty fee.¹²

³ Message 51, Media-AIDS (Aug. 17, 2000), available at <<http://www.hivnet.ch:8000/global/media-aids/viewR?51>>.

⁴ IAVI World Economic Forum (WEF), 1/2002 [hereinafter IAVI WEF]; cf. Jeffery D. Sachs et al., *Macroeconomics and Health: Investing in Health for Economic Development*, World Health Org. (Dec. 2001), at <http://www3.who.int/whosis/cmh/cmh_report/e/pdf/021-128.pdf>.

⁵ IAVI Need for a vaccine, *supra* note 1.

⁶ IAVI WEF, *supra* note 3, at 1.

⁷ *Id.* at 2.

⁸ *Id.*

⁹ IAVI, at <http://www.iavi.org/programs_z_science_4-1-2.html> [hereinafter IAVI Programs].

¹⁰ Denise Brehm, *TLO's Nelsen Helps in Fight for AIDS Vaccine*, MIT TECH TALK (May 9, 2001) (on file with author).

¹¹ IAVI WEF, *supra* note 3, at 3.

¹² IAVI Programs, *supra* note 8.

The United States has resisted compulsory licensing of intellectual property; according to one study, the United States “is pushing hard in several forums to ban or severely limit compulsory licensing of pharmaceuticals patents or related property rights,”¹³ and “consumer groups and others are concerned that international rules for intellectual property are biased toward the interests of a handful of large firms capable of lobbying national and international governments.”¹⁴

The General Agreement on Tariffs and Trade (GATT), the North American Free Trade Agreement (NAFTA), and the proposed Multilateral Agreement on Investments (MAI) tend toward price controls but severely limit compulsory licensing. Price controls are preferred because they are harder to estimate, so tend to result in greater company profits. However, licensing is not only easier for countries to administer (it can be a simple net sales percentage), it also promotes a local, competitive generic drug industry, driving down drug prices and generating additional local economies and technology transfer. Compulsory licensing also sidesteps many problems, such as failure of price controls, refusals by companies to import drugs, and multipart products. Finally, compulsory licensing avoids potential price discrimination by companies seeking to charge higher prices in higher-income countries that employ price controls. These countries often look at foreign prices to set price caps, so the incentive is for companies to price their drugs as high as possible in lower-income countries to avoid losing potential profits from the higher-income countries. One example is the AIDS drug Crixivan®,¹⁵ which ended up being priced higher in South Africa than in the United States.¹⁶

In plain words, without incentives private companies are unlikely to invest in developing a vaccine that compromises their intellectual property rights.¹⁷ However, there is precedent for collaboration between the private sector and local communities or governments. The anti-HIV compound prostratin (from a hepatitis tree bark remedy) was developed in Samoa with the cooperation of village chiefs in exchange for a portion of future profits; 20 percent of the profits from any future drug will now be split between the Samoan government, this particular village, and the two village healers who helped develop the drug.¹⁸

One possible incentive is voluntary agreements that “allow the company to retain intellectual property rights in wealthier markets but which reserve limited rights for marketing of the vaccine in developing countries.”¹⁹

Alternative tax regimes and venture capital tax incentives may also encourage private industry to invest in a vaccine by lowering the financial risks.²⁰ Tiered pricing is also important, because affordability is essential for global access to a vaccine while still allowing companies to achieve reasonable returns on their research and production investments.²¹ Purchase agreements may also be essential to ensure a market once the

¹³ James Packard Love, *A Free Trade Area for the Americas: A Consumer Perspective on Proposals as they Relate to Rules Regarding Intellectual Property*, Third Trade Ministerial and Americas Business Forum, May 13–16, 1997, at <<http://www.cptech.org/pharm/belopaper.html#trade>>.

¹⁴ *Id.* at 10–11.

¹⁵ Crixivan is a registered trademark of Merck & Co., Inc.

¹⁶ Love, *supra* note 12, at 8.

¹⁷ IAVI, available at <<http://www.iavi.org>> (internal link: iavi’s PROGRAMS/encouraging industrial participation [hereinafter IAVI, Industrial Participation]).

¹⁸ *Landmark Deal Reached Between AIDS Research Group, Samoans on HIV Drug*, REUTERS HEALTH (New York) Dec. 13, 2001 (on file with author).

¹⁹ IAVI WEF, *supra* note 3, at 4.

²⁰ Anatole F. Krattiger, *Public-Private Partnerships for Efficient Proprietary Biotech Management and Transfer, and Increased Private Sector Investments*, in IP STRATEGY TODAY 22 (2002) (on file with author).

²¹ IAVI WEF, *supra* note 3, at 4.

vaccine has been developed; this type of agreement secures private investments by generating governmental planning and infrastructures for drug delivery.²²

Finally, IAVI has invested \$15 million to create vaccine development partnerships to ensure that AIDS vaccines reach developing countries.²³ For example, IAVI invested \$9.1 million in U.K.-Kenya and U.S.-South Africa vaccine research teams, with funding coming from Crusaid, the Elton John AIDS Foundation, the United Kingdom's National AIDS Trust, and the government of the United Kingdom. In the U.S.-South African collaboration, two scientists at AlphaVax Human Vaccines Inc., a private company based in Durham, North Carolina, will join with collaborators from the University of Cape-town in South Africa to "develop a vaccine based on VEE alphavirus replicon particles."²⁴ What is unique about these two partnerships is that, "[u]ntil now, most AIDS vaccine candidates have been produced from HIV strains prevalent in North America and Europe," while this project will use African strains of the virus and hence will be more directly relevant to Africans.

Vaccine development partnerships enable IAVI "to help make the fruits of weighty intellectual property rights available to the public sector of developing countries." In one example, "IAVI has secured rights to ensure that a successful vaccine will be distributed in developing countries at a reasonable price. Under the terms of the agreement, should the company decline to produce the vaccine for developing countries in reasonable quantity at reasonable price, IAVI will have certain rights to obtain licenses in order to contract with other manufacturers to make the vaccine available in those countries."²⁵ Exclusive intellectual property gives control over manufacturing, tiered pricing, etc.—but developing partnerships require giving up some intellectual property rights. The partnerships also address other important bioethical issues associated with human testing, regulatory oversight of pharmaceutical companies, risk-benefit analyses, and sufficient supply and distribution of vaccines.

To conclude, the AIDS vaccine conundrum will not be solved unilaterally. We cannot rely on private companies to be either philanthropic or humanitarian organizations—but we can expect that they will do their part when offered the proper incentives, in the form of partnerships with philanthropic organizations, governments, and in some cases even local communities. Only by working together, and by working smart, will we be able to surmount the obstacles to AIDS vaccine research and development and begin to make an impact on alleviating the tremendous burden of human suffering engendered by this tenacious disease.

CLOSING REMARKS BY ALLYN L. TAYLOR

The presentations by Professors Abbott, Smith, and Andresen point to the need to advance global intersectoral action, including innovative mechanisms for cooperation with the private sector both nationally and internationally, to promote universal access to interventions based on increased knowledge of the molecular basis of disease processes.

One important approach, described by Professor Andresen in her review of the International AIDS Vaccine Initiative, is the global public-private partnership. Although formal collaboration with the private sector on health matters was virtually unheard of a decade

²² *Id.*

²³ IAVI, Industrial Participation, *supra* note 16.

²⁴ IAVI, *Two Innovative AIDS Vaccine Development Partnerships Launched* (Nov. 26, 1998), at <http://www.iavi.org/press/22/events_z_press_archives_12.html>.

²⁵ IAVI Programs, *supra* note 8.

ago, in the last ten years public international organizations have entered into a remarkably diverse array of partnerships with the commercial sector, which vary according to function, legal status, governance, management, and participants. A large variety of such partnerships have been formed to strengthen product development and product donation or distribution, or to strengthen and coordinate health services generally.

There is a clearly a wide diversity of associations encompassed within the generic expression "public-private partnership." While such ventures hold important promise in promoting global public health and human rights, there has generally been little systematic evaluation of how these partnerships function and what constitutes good practice. Professor Andresen's remarks provide important insight on how such partnerships can further the development of vaccines and other pharmacological interventions in light of the structure of intellectual property rights.

Finally, I would ask everyone to consider what meaningful contribution international law can make to protecting human rights and public health in this era of genetic advances. What are the strengths and limitations of international law as a tool to protect human rights and public health? As a number of scholars have noted, a plethora of international texts, principally the International Bill of Human Rights, contain core axioms of international human rights law that apply broadly to the protection of global public health and human rights in regard to genetic science. However, most of the rights enumerated at the global level are highly general principles that are not specific to genetics and technology.

An important effort of the global community to address the human rights implications of genetic science through conventional international lawmaking has just begun. In December 2001, the UN General Assembly established an ad hoc working group of the Sixth Committee to consider an international instrument to ban the reproductive cloning of human beings. This initiative, which was sponsored by France and Germany, was motivated by public announcements from certain laboratories of impending attempts to begin reproductive cloning of humans. It is reported that the venue of the Sixth Committee was sought, in part, because the sponsors of the initiative believed that a convention narrowly tailored to prohibit human reproductive cloning could be achieved relatively expeditiously in the Legal Committee.

The Ad Hoc Committee met at the end of February in its first of two scheduled sessions to elaborate a mandate for the proposed treaty. I attended this closed session on behalf of WHO, but most of what occurred has already been publicly reported. Most notably, controversy has already swelled at the first session. The majority of delegations that took the floor supported the original proposal of France and Germany to limit the convention to the reproductive cloning of human beings. However, a small but vocal minority of states supported extending the proposed prohibition to cover therapeutic cloning. One of their principal arguments is that therapeutic cloning and embryonic stem cell research involve the destruction of human life, since cloned embryos are destroyed in the process.

The controversy in the first session of the Ad Hoc Committee has the potential to significantly slow down and perhaps completely derail the codification effort. Those interested in the role of international law in regulating genetic science should carefully watch this current treaty initiative. It raises important questions about the capacity of the international community to respond to developments in technology and science rapidly and effectively. It also raises questions about the capacity of international law to effectively address global issues raised by scientific advances that closely border the politically explosive question of when life begins.