

The Responsibility of Research Universities to Promote Access to Essential Medicines

Ellen F.M. 't Hoen, LL.M.*

INTRODUCTION

One-third of the world's population lacks access to essential medicines. In the poorest parts of Africa and Asia, this figure climbs to one-half. This global health and medicines crisis is the result of increased microbial resistance to older medicines, discontinued production of unprofitable existing medicines, and the prohibitive price of many drugs. In addition, very few new drugs are being developed to tackle major diseases affecting people in poor countries. Many other factors also contribute to the problem of limited access to essential medicines, including logistical supply and storage problems, substandard drug quality, and the inappropriate selection and use of drugs.¹

This piece focuses on the role universities can play in helping to improve access to medicines in developing countries. Most basic medical research in the United States takes place at universities. Universities can take steps to increase the amount of research relevant to health in the developing world. Universities also hold patents on many important medicines. By managing this intellectual property (IP) responsibly, universities can do much to ensure access to medical innovations in developing countries.

SUSTAINABLE ACCESS TO MEDICINES: A LONG WAY OFF

Infectious diseases kill over ten million people each year, with the majority of these deaths occurring in the developing world.² The leading causes of illness and death in Africa, Asia, and South America—regions

* Ellen 't Hoen is the Policy Advocacy and Research Coordinator of the Campaign for Access to Essential Medicines of Médecins Sans Frontières.

1. Bernard Pécoul et al., *Access to Essential Drugs in Poor Countries: A Lost Battle?*, 281 JAMA 361- 67 (1999).

2. WHO, THE WORLD HEALTH REPORT 2002, at 186-87 (2002).

that account for four-fifths of the world's population—are HIV/AIDS, respiratory infections, malaria, and tuberculosis.

In particular, the magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat disease or alleviate suffering. Each day, nearly eight thousand people die of AIDS in the developing world.³ One key factor preventing access to medicines in poor countries is the high price of new drugs. Prohibitive drug prices are often the result of IP protection, which usually takes the form of a patent. The owners of IP have a responsibility to consider measures to ensure that IP does not become an unacceptable barrier to appropriate health care in developing countries.

The high price of antiretrovirals—the class of drugs prescribed to treat HIV/AIDS—prevents many in developing countries from using these drugs. While in recent years, some pharmaceutical companies have responded to growing public pressure to lower the prices of certain AIDS medicines for developing countries, their efforts have been neither systematic nor sufficient. For example, until January 2003, more than three years after the need for access to medicines made world headlines at the World Trade Organization's (WTO) Seattle conference, one pharmaceutical company was charging \$2,000 a year more in Guatemala than in Switzerland for its AIDS drug. Only after months of public pressure did the price of the drug come down in Guatemala.⁴

The pharmaceutical industry usually justifies high prices for medicines by pointing to the high costs of drug research and development (R&D). But many antiretroviral medicines were initially developed by public research institutes—including universities—and not by pharmaceutical companies. Public research institutes have heavily contributed to the development of many of the most important AIDS drugs, including zidovudine, stavudine, zalcitabine, abacavir, and a number of protease inhibitors.⁵

Stavudine (also known as d4T) is an important nucleoside reverse

3. UNAIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC, at 125, 129, 133 (2000), http://www.unaids.org/epidemic_update/report/Epi_report.pdf (Mar. 24, 2002). This document outlines the statistics utilized to reach the generally recognized figure of eight thousand deaths per day due to AIDS in the developing world.

4. Associated Press, *Roche Cuts Price of AIDS Drug to Nations* (Feb. 13, 2003), available at <http://www.aegis.com/news/ap/2003/AP030220.html> (last visited May 14, 2003).

5. Pierre Chirac et al., *AIDS: Patent Rights Versus Patient's Rights*, 356 THE LANCET 502 (2000).

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transcriptase inhibitor used in antiretroviral combination therapy to treat HIV/AIDS. Stavudine was developed by researchers at Yale University, which holds the patent on the drug. Yale licensed the stavudine patent to Bristol-Myers Squibb (BMS), which currently sells stavudine under the brand name Zerit. Zerit has been a great commercial success for both BMS and Yale. In 2000 Yale earned over \$40 million in royalties from the stavudine license.⁶

In March 2001, researchers and students campaigned on the Yale campus, demanding that Yale not enforce its stavudine patent in South Africa so that generic versions of the drug could be used. In South Africa at that time, the price of the generic version of stavudine was thirty-four times less than the price of BMS' brand name Zerit. Yale professor Dr. William Prusoff, who, with the late Dr. Tai-Shun Lin, demonstrated the value of stavudine in treating AIDS, stated publicly, "People shouldn't die for economic reasons, because they can't afford the drug."⁷

Under pressure from researchers, students, and access advocates, Yale renegotiated its license with BMS to ensure the availability of generic versions of stavudine (d4T) in developing countries.⁸ This action showed that research institutions like Yale can play a central role in improving access to their innovations. In light of this power, it is imperative that universities and other research institutions be aware of the global implications of their patent and licensing policies.

DRUG ACCESS AND R&D: TWO SIDES OF THE SAME COIN

Developing countries account for four-fifths of the world's population, but less than ten percent of the global pharmaceutical market. Because the development of medicines is almost entirely profit-driven, investment in R&D related to the health needs of people in developing countries has come to a near standstill.⁹

6. YALE UNIVERSITY OFFICE OF COOPERATIVE RESEARCH, 1999-2000 ANNUAL REPORT (2000), http://www.yale.edu/ocr/images/docs/ocr_report_99-00.pdf (last visited July 16, 2003).

7. Philippe Demenet, *The High Cost of Living: Yale Shares Profits from AIDS Drugs*, *Le Monde Diplomatique*, Feb. 2002, <http://mondediplo.com/2002/02/04stavudine> (last visited May 13, 2003). For further details see the Consumer Project on Technology page on stavudine at <http://www.cptech.org/ip/health/d4T.html>.

8. Julian Borger & Sarah Boseley, *Campus Revolt Challenges Yale over \$40m AIDS Drug*, *THE GUARDIAN* (Manchester, U.K.), Mar. 13, 2001.

9. Patrice Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 *THE LANCET* 2188 (2002).

As a result, many of the diseases common in the developing world remain difficult to treat, while others are completely untreatable. For example, there is a growing need for new medicines to combat resistant strains of malaria and tuberculosis, to replace the ineffective and toxic drugs for sleeping sickness and Chagas disease, and to find treatments for diseases like dengue fever and Buruli ulcer that are currently almost untreatable.

The rationale of the patent system is to stimulate R&D by offering a temporary monopoly in exchange for beneficial innovation. Medical research aims to contribute to the advancement of human health, but in reality, it is primarily people in wealthy countries who benefit from medical progress. Ninety-seven percent of the patents held worldwide are in the hands of individuals and companies in industrialized countries, and eighty percent of the patents granted in developing countries belong to residents of industrial countries.¹⁰

World Bank estimates suggest that developing countries will be the net losers in an increasingly global patent system.¹¹ The implementation of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights is expected to further inflate drug prices, while increased R&D investment, despite higher levels of IP protection, is not expected.¹² Certainly, strict IP laws are unlikely to stimulate investment in non-profitable areas such as tropical diseases.

Market forces will not solve the access and R&D crisis. Therefore, the public sector, including universities and public research institutes, must step in where the market fails. The activities of the public sector should be guided by global health needs, and IP should be managed with the intent of increasing access to medicines and stimulating further research.

MARKET PROSPECTS DO NOT EQUAL HEALTH NEEDS

Investments in health-related R&D tends to gravitate towards illnesses

10. U. N. DEVELOPMENT PROGRAMME, HUMAN DEVELOPMENT REPORT 68 (1999), *available at* <http://hdr.undp.org/reports/global/1999/en/> (last visited May 13, 2003).

11. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 21 (2002), *available at* http://www.iprcommission.org/graphic/documents/final_report.htm (last visited May 13, 2003).

12. Access to Essential Medicines Campaign and the Drugs for Neglected Diseases Working Group, Médecins Sans Frontières, Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases 10-18 (2001), *available at* <http://www.msf.org/source/access/2001/fatal/fatal.pdf> (last visited Mar. 24, 2002).

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or symptoms that offer the greatest potential return on investment, regardless of actual health needs. When it comes to priority-setting for R&D in the health field, money talks louder than needs. Pharmaceutical innovation does not necessarily equal therapeutic innovation. An assessment of 2,257 new products that were brought to the health market in France between 1981 and 2000 shows that sixty-three percent of new products were “me-too” drugs (those that offer no therapeutic gain over existing drugs). Only seven products (0.13%) represented real therapeutic breakthroughs.¹³ In the United States, less than five percent of the drugs introduced by the top twenty-five pharmaceutical companies were therapeutic advances. Of these, seventy percent were developed with government involvement.¹⁴ While sixty-eight percent of the 1,393 new chemical entities registered world wide for marketing over the last twenty-five years were classified as “me-too” drugs, only one percent were for tropical diseases and tuberculosis, diseases that together account for over eleven percent of the worldwide disease burden.¹⁵

Almost all R&D activities are currently undertaken in the industrialized world. Ensuring R&D for neglected diseases in the developing world will require a strong commitment by all actors involved, including research institutions and universities in wealthy countries.

However, academic research is increasingly guided towards avenues that may yield profitable returns. Moreover, those activities that do result in progress in the field of neglected disease are often not taken up by the private sector and translated into products useful to patients in developing countries. This is shown most strikingly in the cases of sleeping sickness and leishmaniasis. These parasitic diseases cause significant illness and death in the developing world and urgent health tools are needed. Scientists have long studied these parasites and know a great deal about their molecular biology, immunology, and genetics. Yet, despite an urgent need for new medical tools, many pharmaceutical companies are not working to develop new diagnostics, medicines, or vaccines for these diseases.¹⁶

A PUBLIC RESPONSIBILITY BEYOND BORDERS: THE ROLE OF UNIVERSITIES

A Yale initiative to bring together a group of experts in public health,

13. *A Look Back at 2000*, 10 *PRESCRIBE INTERNATIONAL* 52, 52-54 (2001).

14. U. N. DEVELOPMENT PROGRAMME, *supra* note 9, at 69.

15. Trouiller et al., *supra* note 8, at 2189.

16. *Id.* at 2190.

IP management, and university policy on September 25, 2002, signaled a willingness to address the role of universities in promoting access to essential medicines. The group discussed what universities as IP holders can do to promote access to essential medicines and medical technologies in developing countries. The report from that meeting identified the crucial role that universities can play in the development of new medicines and medical technologies, stressing the need to create and implement best practices in this area.¹⁷

The decisions universities make when patenting and licensing their technologies can help determine whether individuals in developing countries have access to the end products of university research. University research is “upstream” in the development process, meaning that universities have potential early leverage, though they rarely know in advance whether or not a product will result in a marketable technology useful in developing countries. This suggests the importance of establishing a policy framework upfront and then ensuring its consistent application.

Those attending the Yale meeting generally agreed upon the following principles to guide universities in establishing a framework for making patenting and licensing decisions:

- University research is intended to advance the common public good, a primary element of which is the advancement of health;
- Global public health concerns need to be an important part of patenting and licensing decisions;
- The success of patenting and licensing programs should be measured according to their impact upon public health;
- University IP policies should be implemented in a manner supportive of developing countries’ rights to protect public health and, in particular, to promote access to medicines for all; and
- Technology transfer to develop capacity in developing countries is an important part of universities’ mandate to advance knowledge and the social good.

Universities should consider different strategies to implement these principles, including not patenting or allowing their licensees to patent in developing countries, and issuing non-exclusive licenses for developing country markets.

17. Yale Ctr. for Interdisciplinary Research on AIDS, *Access to Essential Medicines and University Research: Building Best Practices* (2002), http://cira.med.yale.edu/whats_new/Essential%20meds,%20final%20report.doc (last visited July 16, 2003).

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Universities must also be aware of the effect that an IP strategy will have on innovation. In some cases, exclusive rights to sell a drug in the developing world may be the only way to encourage research because no other market exists for the drug. However, because developing country markets are small and provide limited financial incentive for research, there is cause to think such cases will be rare.

Changes in university practice will require collective action and leadership. Participants at the Yale meeting were clear that where universities act together they can successfully establish norms and implement best practices. In a recent positive step, an assembly of the American Medical Students Association (AMSA) adopted a resolution urging universities to follow the principles discussed at the Yale meeting when making patenting and licensing decisions that potentially impact access to essential medicines and medical technologies worldwide.

It is encouraging to see that universities and researchers in wealthy countries are increasingly aware of global health needs and are working to ensure that the fruits of medical progress are not withheld from people in developing countries. Biomedical research in university laboratories should indeed be guided by policies that take global health needs into account.

Universities should also review their existing research incentives. For example, researchers should not be rewarded solely for publication or patenting, but also for ensuring that innovations actually reach the people who need access to them. Western universities have an obligation to take a global perspective and look beyond market opportunities in the United States and Europe when considering research priorities.

CONCLUSION

The Yale initiative on “Access to Essential Medicines and University Research: Building Best Practices” deserves follow-up within the public research sector. The meeting concluded that changes in university practice will require collective action and leadership and acknowledged that universities can act together to successfully establish norms and implement best practices. This enterprise must also take an international dimension. Increasingly, research activities are becoming global, as are the initiatives to tackle the R&D divide.

John Barton, Professor of Law at Stanford University and Chair of the U.K. Commission in Intellectual Property Rights, has proposed a treaty to

preserve the global scientific and technology commons.¹⁸ He argues that science and technology require a commons of data, ideas, and insight, and that all scientists will benefit from having access to the work of their predecessors. Such a commons should be global. Existing restrictions to creating a commons—such as licensing regulations that favor nationals and the global trend to expand the scope of IP protection to include basic ideas, procedures, methodologies, and research tools—need to be overcome. This requires an international treaty to create a global scientific and technology commons. This treaty could include a commitment ensuring that the benefits of publicly funded research are made available to all and not just to nationals of a few wealthy countries.

Médecins Sans Frontières (known in the U.S. as Doctors Without Borders), together with other organizations, is exploring the feasibility of a new Essential Health Technology R&D Convention to address international R&D priorities, and to ensure the development of and access to new essential medicines, vaccines, diagnostics, and equipment. Such a convention would:

- Define a needs-driven international R&D priority agenda;
- Secure commitments from all countries to contribute to R&D for health;
- Establish a financing system for sharing the burden of the cost of this R&D;
- Define appropriate funding and incentive mechanisms for governments to fulfill their commitments to essential health technology R&D.
- Establish and strengthen international mechanisms for exchanging and transferring research results, knowledge, and technology; and
- Ensure that developing countries play a central role in public R&D, through North-South and South-South collaboration, and through the conduct of R&D in disease-endemic countries.

It is crucial that universities and other research institutions engage in these international debates and developments. The increasing awareness among researchers that millions are not reaping the benefits of medical and scientific progress must be translated into concrete action and benefits for those in greatest need.

18. John H. Barton, Preserving the Global Scientific and Technological Commons, Address at the International Centre for Trade and Sustainable Development, U.N. Conference on Trade and Development Policy Dialogue on a Proposal for an International Science and Technology Treaty (Apr. 11, 2003) (transcript available at http://www.ictsd.org/dlogue/docs/tech_transfer_dialogue.pdf).