

# The Development of Medicines for Developing Country Diseases: The Role of Intellectual Property

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## I. Introduction

Former President Jimmy Carter urged the last World Health Assembly to demonstrate its commitment to improving the health of the world's poor, a commitment that would serve to bring broadly-shared economic benefits, advance human rights and reduce violence.<sup>1</sup> To this end, he recalled the words of Edmund Burke that “[t]he public interest requires doing today those things that men of intelligence and good will would wish, five or ten years hence, had been done.”<sup>2</sup>

What is proposed here is a practical, results-oriented way to deal with the intellectual property issues related to development of medicines<sup>3</sup> for the treatment of neglected diseases<sup>4</sup> in developing countries.<sup>5</sup> In short, in the words of Burke, we explore what men and women of intelligence and good will must do today in order to satisfy the public interest. Our suggestions – based on our experience and recent work in the field – are directed at managing intellectual property in connection with specific agreements or research projects to ensure the development

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<sup>1</sup> Remarks of Mr. Jimmy Carter, former President of the United States of America, at the World Health Assembly, Fifty-seventh World Health Assembly, 19 May 2004, WHO/Geneva, <http://www.who.int/mediacentre/events/2004/wha57/carter/en/>.

<sup>2</sup> *Id.*

<sup>3</sup> We use the term “medicine” here to encompass drugs, vaccines and diagnostics. This broad definition is imperfect at best as the technical, commercial, and legal realities pertaining to drugs, vaccines, and diagnostics vary widely. That said, the basic principles being discussed herein as to the management of intellectual property are broadly applicable.

<sup>4</sup> For the purpose of this paper, the term “neglected diseases” is taken to include both “neglected diseases” and “most neglected diseases” where the former includes diseases, such as malaria and tuberculosis, where there may be small market in developed countries and the latter are diseases that almost exclusively affect poor people in developing countries. For further information, see the web site for the Drugs for Neglected Diseases Initiative (DNDi) at [www.dndi.org](http://www.dndi.org).

<sup>5</sup> The term “developing country” does not have an authoritative definition in connection with the issues discussed in this paper. The World Bank maintains lists of low-income and lower middle-income countries (reported at: <http://www.worldbank.org/data/countryclass/classgroups.htm>) and the list of Least Developed Countries (which currently includes 50 such countries) is maintained by the United Nations Office for the High Representative of Least Developed Countries (reported at: <http://www.un.org/special-rep/ohrlls/ldc/list.htm>). For the purposes of this paper, however, the term “developing country” is taken to mean the low-income and lower middle-income countries as includes on the World Bank lists identified above.

of new medicines for the treatment of diseases that particularly affect people in developing countries.

Ensuring such development is perhaps the most important need of our time. It is clear that millions of people in developing countries are suffering and dying needlessly from diseases that are either treatable or preventable. HIV/AIDS, for example, has been called “one of the most urgent public health issues humanity has ever faced”, with estimates of over 100 million people infected by 2005.<sup>6</sup> AIDS kills 3-4 million people each year (about 2.3 million of them in Africa), and malaria kills over 1 million people with 300-500 million new cases each year. It is often children – the most vulnerable members of society – that bear the greatest burden.

In addition to causing human suffering, these diseases place a tremendous burden on economies that are already in trouble<sup>7</sup>, contributing to a vicious cycle of poverty and disease. Breaking this cycle was the point of Mr. Carter’s remarks to the World Health Assembly, and the point of many others before him.<sup>8</sup>

The level of resources needed to break this cycle is well known – both qualitatively and quantitatively.<sup>9</sup> This knowledge, and the very appropriate political impetus it has generated, has led to the mobilization of governments, private industry, non-governmental institutions, international organizations, and public-private partnerships to provide desperately needed leadership and direction. But more needs to be done. According to a joint study of the WHO and IFPMA, in 2001, the two major diseases requiring additional research and development are malaria and tuberculosis.<sup>10</sup> Despite this manifest need, it has been estimated that only 10% of

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<sup>6</sup> Jimmy Carter and Bill Gates Sr., *Los Angeles Times* (7 April 2002).

<sup>7</sup> It was recently estimated that in South Africa, the Gross Domestic Product will be perhaps 17 percent lower in 2010 than it would be without HIV/AIDS, reducing economic output by perhaps 22 billion dollars. Keith Maskus, *Ensuring Access to Essential Medicines: Some Economic Considerations*, 20 *Wis. Int’l L. J.* 563, 563 (Summer 2002).

<sup>8</sup> Perhaps the most cogent statement on this point was made by the Commission on Macroeconomics and Health. Its report made the following points about the relationship between health and security for individuals, families and societies:

For individuals and families, health brings the capacity for personal development and economic security in the future. Health is the basis for job productivity, the capacity to learn in school, and the capability to grow intellectually, physically, and emotionally. . . . As with the economic well-being of individual households, good population health is a critical input into poverty reduction, economic growth, and long term economic development at the scale of whole societies.

*Macroeconomics and Health: Investing in Health for Economic Development*, Report of the Commission on Macroeconomics and Health, December 2001, p. 21.

<sup>9</sup> The Commission on Macroeconomics and Health has estimated that the achievement of broad essential health coverage for developing countries would require around \$27 billion per year by 2007 (with the upper limit determined based on the amount that could be effectively distributed), to be increased to \$38 billion by 2015. This would cover the cost of procurement of additional research & development, infrastructure, and currently available medicines. See Report of the Commission on Macroeconomics and Health, p. 92.

<sup>10</sup> Working Paper on Priority Infectious Diseases Requiring Additional R&D, WHO-IFPMA Round Table (July 2001), <http://www.who.int/intellectualproperty/documents/en/IFPMA.pdf>.

health research is devoted to conditions accounting for 90% of the diseases that afflict humans around the world.<sup>11</sup>

Many studies have already been performed, papers written, and speeches presented to address the roots of the global health crisis, but they all too often focus their attention on trying to apportion blame for those institutions and policies responsible for the current state of affairs. As with other crises, papers exploring creative and practical solutions have unfortunately been few and far between. The rhetoric regarding the relationship between intellectual property, on the one hand, and access to and development of medicines, on the other hand, is no exception, with some presenting intellectual property (and patents, in particular) as the root of all evil that benefits only the right holders, and others arguing that stronger intellectual property protection is the answer to many of the problems faced by the developing countries. The former camp seems to hold that if any aspect of intellectual property protection is problematic, then no protection is the ideal, while the latter camp holds that if intellectual property protection is good, more *must* always be better.

This paper grounds the discussion in a practical, results-oriented approach to intellectual property management – in particular in the context of the development of new medicines for developing country diseases. The key issue is not one of resolving a **conflict** between intellectual property and the issues surrounding the development of new medicines, but how to identify ways to utilize intellectual property protection to **promote** the development of needed new medicines. In short, intellectual property is a critical tool to manage public-private partnerships to develop medicines for the treatment of neglected diseases.

## II. Development of New Medicines

Patent systems are intended to facilitate the introduction of new pharmaceutical products by stimulating the climate for private investment and encouraging research by pharmaceutical manufacturers – but their role is complex in the case of neglected diseases.<sup>12</sup> The development of medicines is a complex and expensive process with one study estimating that the average cost of bringing a new medicine to market is up to \$800 million, reflecting in part the fact that the vast majority of products never reach the marketplace.<sup>13</sup> In a different context, and based on

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<sup>11</sup> *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases*, Drugs for Neglected Diseases Working Group, Médecins Sans Frontières (September 2001) (“Fatal Imbalance”), p. 10, citing Global Forum for Health Research, The 10/90 Report on Health Research (2000).

<sup>12</sup> “There is a strong global public interest in providing sufficient incentives for the continual development of new medical treatments for diseases that afflict the poor. Within the intellectual property system, these incentives stem largely from exclusive production and distribution rights provided by EMRs [Exclusive Marketing Rights] and patents. However, such rights may be inadequate for meeting the needs of extremely poor patients, who do not have enough income to purchase new medical treatments, even at low prices.” M. Ganslandt, K. Maskus, and E. Wong, *Developing and Delivering Essential Medicines to Poor Countries: The DEFEND Proposal*, reprinted in *Intellectual Property and Development: Lessons from Recent Economic Research*, the World Bank (2005), p. 209. This conclusion is consistent with the well-known 1988 study by Edwin Mansfield of 12 industries that found that 65 percent of medicine products would not have been introduced without adequate patent protection. See E. Mansfield, *Patents and Innovation: An Empirical Study*, 32 *Management Science* (1986) 175. It is also consistent with position we take here that patents alone (and the private-sector investment they are intended to incentivise) are not alone sufficient to attract investment in medicines for neglected diseases.

<sup>13</sup> See Joseph A. DiMasi, Ronald W. Hansen and Henry G. Grabowski, “The Price of Innovation: New

different assumptions, the Global Alliance for TB Drug Development published a report that made a “rough estimate” of “a total cost of between \$115 million and \$240 million to discover and develop a new anti-TB drug (including the costs of failure).”<sup>14</sup> There is no need for the purposes of this paper to resolve these and other estimates to a single estimate of the costs of medicine research and development. For present purposes, it is sufficient to say that the costs are significant, and without assurances that they can make a return on their investment, it is unlikely that private-sector entities will initiate such research and development on their own.

While it is clear that the possibility for patent protection provides an impetus to innovation, it is also equally clear, however, that strong intellectual property systems are not a *sufficient* condition for the development of new medicines for neglected diseases, especially in the short term.<sup>15</sup> If the purchasing power of those in need is not sufficient to justify an investment in a new medicine, then private industry will generally not invest the funds on its own unless such investment is considered as part of a charitable effort outside of their traditional business model. Companies acting pursuant to market considerations logically invest where they have the greatest opportunity for financial return. Thus, when diseases afflict only patients in developing countries, but few in developed countries, the free market may not support the development of a new medicine, even with patent and data protection.

It has often been reported that of the 1393 new medicines approved between 1975 and 1999, only 13 medicines were for the treatment of neglected diseases that most impact developing countries.<sup>16</sup> Although this number does not provide the whole picture (because it ignores medicines that were being developed but which were not yet approved) it is, nevertheless, revealing. There are a number of factors that account for this disparity, but the greatest single factor is a lack of resources. Thus, involvement of the public sector – including charitable foundations and charitable activities of the private sector – is required to fill the gap in research.

As detailed below, creative use and effective management of intellectual property can facilitate development, even for diseases that largely affect developing countries. Indeed, a study currently underway by the Wellcome Trust/London School of Economics has found that the numbers cited at the beginning of this paragraph are rapidly changing. Currently, that study found that 63 drugs for the treatment of neglected diseases have been registered or in development since 2000 – with 14 of those drugs under development by industry alone and the remaining 49 through public-private partnerships.<sup>17</sup> Indeed, as will be discussed in this paper –

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Estimates of Drug Development Costs” (Boston: Tufts University Center for the Study of Drug Development, 2002).

<sup>14</sup> The Economics of TB Drug Development, Global Alliance for TB Drug Development, October 2001, p. 38.

<sup>15</sup> See generally Fatal Imbalance.

<sup>16</sup> *Id.* at 11, citing Dyann F. Wirth, survey for the Drugs for Neglected Diseases Working Group, Switzerland, May 2001; See also *Drug Development for neglected diseases: a deficient market and public-health policy failure*, Public Health, The Lancet, Vol. 359 (June 22, 2002).

<sup>17</sup> See *New Approaches to Funding Drug R&D for Neglected Diseases*, Pharmaceutical R&D Policy Project, Wellcome Trust/London School of Economics, Jan. 2005 (summary reproduced at <http://www.who.int/intellectualproperty/submissions/en.mary.moran.pdf> (accessed April 20, 2005));

and as concluded in the Wellcome Trust/LSE study – this rapid growth is being driven by public-private partnerships. As we develop in the following sections, intellectual property is an important and essential part of the contracts entered into by the public and private sectors when they work together on research and development for developing countries.

### A. Gaps in Medicine Development Process

Before examining the specific gaps in the medicine development process for neglected diseases, we note that this paper does not address the very important gap in research capacity in developing countries. Efforts to narrow that gap have been the subject of study, intense debate, and work.<sup>18</sup>

To better understand the role of public-private partnerships to increase research and development targeted at neglected diseases, it is important to briefly outline the different phases of medicine development in order to clarify the important gaps that require filling. There are essentially four different phases in medicine development –

- (1) **Basic research**, conducted mostly by universities and public institutions, driven primarily by curiosity and leading to identification of candidate medicine targets and lead compounds;
- (2) **Pre-clinical research**, which applies basic research to validate candidate medicines, including lead-optimization, synthesis, dosage and stability studies, and toxicology-safety studies;
- (3) **Clinical research**, including Phase I, II, and III clinical studies, scaling up of production, and regulatory review; and
- (4) **Post-marketing**, including surveillance of effects after wide distribution of medicines, marketing, etc.<sup>19</sup>

Between each of these phases, gaps in the development process must be filled, either through private investments that are induced by incentives from patents or data protection, public and charitable support, or a combination of the two. The most important gap is that between basic research and pre-clinical research, as this generally requires investment by private companies to continue where the public sector left off. The public sector generally does not have the capability to do this on its own. It is for this reason that regimes such as that enacted by the Bayh-Dole Act in the United States have been important.<sup>20</sup> The Bayh-Dole Act has been

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private communication from Dr. Mary Moran, London School of Economics, April 22, 2005)

<sup>18</sup> The Global Forum for Health Research in its study last year on the “10/90 gap” found that despite decades of effort, the hoped-for large numbers of trained scientists needed in developing countries have not materialized and that “[b]uilding and retaining indigenous capacity for health research must move centre stage, as this is vital for sustainable development.” *The 10/90 Report on Health Research, 2003-2004*, The Global Forum for Health Research (2004), page xxiii.

<sup>19</sup> See *Fatal Imbalance* at p. 18.

<sup>20</sup> Bayh-Dole Act, P.L. 96-517 (Dec. 12, 1980). The Bayh-Dole Act created a uniform patent policy among the many U.S.-agencies that fund research. It enabled small businesses and non-profit organizations, including

successful in allowing universities, not-for-profit corporations, and businesses to patent and commercialize federally funded inventions for their own financial benefit, while at the same time providing incentives to shift from the research phase to the development phase of projects in a manner that benefits the general public.<sup>21</sup>

Starting at the level of basic research, governments and universities generally spend taxpayer money for development of medicines that will most benefit their taxpayers. Of course, the public sector in developed countries spends, in absolute terms, far more resources on public health than the public sector in developing countries.<sup>22</sup> International funds and organizations targeting specific diseases – such as the Medicines for Malaria Venture<sup>23</sup> and the Global Alliance for TB Drug Development<sup>24</sup> – serve the important purpose of providing a central fund in which governments, foundations and companies in the private sector can pool their resources for common goals.

Where the market supports it, intellectual property protection, if available, encourages private investment to fill all three of the gaps. When the gaps remain unfilled, largely due to demand by a patient population with little purchasing power, the result is scarcity of new medicines for diseases. This situation predominately afflicts developing countries. A variety of approaches have been taken to address these gaps, with public-private partnerships providing some of the more creative and effective solutions. Purely philanthropic organizations – such as the Bill and Melinda Gates Foundation – have been major contributors to funding research and development for neglected diseases, especially through public-private partnerships.<sup>25</sup> Governments are also contributing some of the much-needed funds and support for new medicine development. For example, the European Communities has developed a program for

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universities, to retain title to inventions made under federally-funded research programs.

<sup>21</sup> See Technology Transfer, Administration of the Bayh-Dole Act by Research Universities, Report to Congress of the United States General Accounting Office (May 1998). The leading association of university technology-transfer offices that manage rights that arise under Bayh-Dole and otherwise is the Association of University Technology Managers (AUTM). AUTM has recently established a Special Interest Group called the “Technology Managers for Global Health” to facilitate the efforts of AUTM members to pursue global health goals by serving as a professional resource and a network among AUTM members. (Private communication from Usha R. Balakrishnan, Director, Office of Corporate Partnerships, The University of Iowa and Founder, Technology Managers for Global Health in possession of author.)

<sup>22</sup> See Report of the Commission on Macroeconomics and Health, p. 56.

<sup>23</sup> The Medicines for Malaria Venture is a nonprofit foundation under Swiss law created to discover, develop and deliver new affordable antimalarial medicines through effective public-private partnerships. More information may be found about MMV at [www.mmv.org](http://www.mmv.org).

<sup>24</sup> The Global Alliance for TB Drug Development is a nonprofit corporation that has as its mission to accelerate the discovery and/or development of cost-effective new medicines that 1) shorten or otherwise simplify treatment of tuberculosis (“TB”), 2) provide a more effective treatment of multi-drug-resistant TB, 3) improve the treatment of latent TB infection and 4) to ensure that such medicines are subsequently commercialized in a manner, including price considerations, that facilitates their widespread use. More information about the Alliance may be found at [www.tballiance.org](http://www.tballiance.org).

<sup>25</sup> Fatal Imbalance at p. 22. For example, as of August 2004, the Gates Foundation has granted \$65 million to the Medicines for Malaria Venture, and \$25 million to the Global Alliance for TB Drug Development. <http://www.gatesfoundation.org>. The Rockefeller Foundation has also been a major contributor to medicine development, granting \$8 million to the Global Alliance for TB Drug Development, as of August 2004. Global Alliance for TB Drug Development, 2002-2003 Annual Report, p. 23.

“accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction”.<sup>26</sup> The EC has committed to (1) increase support for basic and strategic research; (2) assist developing countries with building capacity; (3) provide incentives for research and development for new medicines; and (4) participate in global initiatives targeting the major communicable diseases.<sup>27</sup>

## **B. Public-Private Partnerships for Development and Achieving Public Health Goals Through Management of Intellectual Property Rights**

Public-private partnerships for the development of new medicines attempt to combine the strengths of the private and public sector in order to simultaneously satisfy both public interests (increased research & development) and private interests (profit potential where markets exist, proof of technology concept (in particular for small companies) and improved corporate profiles (in particular for larger companies)). They act as providers of “social venture capital” that invest in development of new medicines for the public good that would not be developed pursuant to natural forces of the free market alone.<sup>28</sup> Such activities are better suited to small flexible organizations with low overhead costs, rather than as divisions of larger multilateral agencies.<sup>29</sup> They generally participate in expensive high-risk projects that convert results of basic research into new products. Once developed, the partners commit to sell the new medicines at prices that promote maximum access for people in the developing world.

As demonstrated above, the private sector has advantages and skills that are not ordinarily found in the public sector. In particular, the private sector is experienced in converting basic research into a medicine approved for distribution. Public sector involvement provides taxpayer- or charity-supported funding and access to government and university laboratories and researchers.

Public-private partnerships have evolved from ad-hoc arrangements, such as the collaboration between industry and the U.S. Walter Reed Army Institute of Research to develop medicines, including antimalarial medicines in the 1990s, to more structured independent legal entities based on product-based partnerships that often focus on neglected diseases.<sup>30</sup> Some of the more prominent partnerships include the Drugs for Neglected Diseases Initiative (DNDi), Medicines for Malaria Venture (MMV), the Malaria Vaccine Initiative (MVI), the International AIDS Vaccine Initiative (IAVI), the Institute for One World Health (IOWH) and the Global Alliance for TB Drug Development (GATB).<sup>31</sup> Donors to and founders of such public-private

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<sup>26</sup> Programme for Action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction, Communication from the Commission to the Council and the European Parliament (21 February 2001).

<sup>27</sup> *Id.* at Section 3.3.

<sup>28</sup> See Craig Wheeler & Seth Berkley, Initial Lessons From Public-private Partnerships in Drug and Vaccine Development, Bulletin of the World Health Organization, 79(8) (2001), at 729.

<sup>29</sup> *Id.* at 730.

<sup>30</sup> *Drug Development for neglected diseases: a deficient market and a public-health policy failure*, The Lancet, Vol. 359, June 22, 2002, p. 2192.

<sup>31</sup> Hannah Kettler & Karen White, Valuing Industry Contributions to Public-Private Partnerships for Health Product Development, Initiative on Public-Private Partnerships for Health (May 2003), at 5,

partnerships have included the Gates Foundation, the Rockefeller Foundation, the World Health Organization, the International Federation of Pharmaceutical Manufacturers Associations, the World Bank, Médecins Sans Frontières and governments (including, the United States of America, the United Kingdom, and the Netherlands).<sup>32</sup>

In order to succeed, public-private partnerships must be seen as a proposition that will benefit all collaborators, including private industry. For the public sector and charitable foundations, the benefit is clear – taking advantage of the expertise of the private sector in order to achieve the goal of developing a medicine for neglected diseases. For example, the public sector can take advantage of the experience of the private enterprises in conducting clinical trials and in performing the final steps required for marketing approval.

Once the product is developed and approved, contractual arrangements in public-private partnerships generally provide that it will be distributed and sold in developing countries at prices low enough to greatly promote access.<sup>33</sup> This type of distribution may be mandated by contractual clauses that specifically set the conditions of pricing in developing countries, or allow for exclusive licenses in developed countries but multiple suppliers in developing countries.

The benefits are less tangible, but no less important, for private industry, which operates in a market economy to generate profits and returns for investors. Private industry benefits from a public-private partnership through positive public relations, proof of technology, data, training and know-how, and introduction to new markets.<sup>34</sup> In the short term, private sector companies generally receive funds from the public-private partnership that, in addition to providing resources with which to conduct the research related to the specific project, also serves to educate their own employees through additional experience. It is also important to recognize that private sector companies may be bringing technologies to the partnership that they had developed for other applications. Intellectual property plays a role in recognizing rights in such previously-developed technologies and making it possible for companies to make the rights available to the partnership, without compromising their legitimate, pre-existing commercial interests.

In the long term, and depending on how intellectual property rights ownership and licensing are worked out in structuring a particular agreement or partnership, the private sector company may obtain rights in for-profit markets (such as the so-called “travelers market” for antimalarials) that form part of the inducement for their participation in a particular partnership.

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<http://www.eldis.org/static/DOC13088.htm>.

<sup>32</sup> *Id.* at 5.

<sup>33</sup> See generally Antony Taubman, *Public-private management of intellectual property for public health outcomes in the developing world: the lessons of access conditions in research and development* (2004 draft on file with author), at pp. 25-26.

<sup>34</sup> Kettler & White, at p. 7. There are differences between what large companies seek and obtain from public-private partnerships versus small companies. For example, small companies may be thinly capitalized and look to public-private partnerships to provide needed investments to move early stage technologies from the discovery phase to proof of concept. Larger companies may not need capital, but are looking for ways to make their intellectual and human capital available to a charitable enterprise, but without threatening their commercial interests.

For example, when private industry is granted exclusive rights to market a medicine that has a market in developed countries, they will often be willing to contribute more to a partnership (or will be willing to accept fewer resources from the funding entity) than would otherwise be the case. By tying together funds for medicine development with commitments to further access to these medicines in developing countries by providing them at low cost and in sufficient volume, public-private partnerships are able to address the issues of medicine development and access simultaneously. Intellectual property can provide value to public-private partnerships in two ways. First, intellectual property may provide leverage to obtain desired public health goals. For example, the exercise of intellectual property rights in high-income markets<sup>35</sup> can subsidize the cost of medicines for poor people in developing countries.<sup>36</sup> Intellectual property rights in developing countries may also be leveraged to obtain public-health goals – such as requiring concessionary prices on medicines in exchange for data generated through having access to hospitals, laboratories, clinical investigators, and patient populations in the development of the medicines. Second, intellectual property that has broad applicability – such as outside the “field” of the treatment of neglected diseases – may have value when incorporated into products or when licensed for use outside the field. Such value may be harnessed to subsidize cost of existing medicines or may be channeled into the furtherance of other public health goals.<sup>37</sup>

It is imperative that all of the foregoing is carefully negotiated at the outset in public-private partnership agreements. No party in a public-private partnership – whether a government laboratory, private sector company (large or small), university or foundation – will lightly give up existing intellectual property rights, nor relinquish future rights. This is as it should be – not for ideological reasons, but for reasons of good management of the rights and of the partnership. That said, it is also true that intellectual property protection for a given technology may not be necessary or even desirable in connection with the development of a given medicine for developing countries. For example, if no further investment is required to bring a given technology to market and intellectual property rights in that technology may not otherwise generate revenue, then intellectual property protection may not be necessary.<sup>38</sup> For example, it is the policy of the Public Health Service in the United States of America to generally not seek

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<sup>35</sup> Such “high-income markets” may be wholly within developed countries, but could also be found in some developing countries where there are markets served at private market rates and markets served by public-sector procurement. Separating and serving such mixed markets would be complex and would likely require not only physically different products in the two markets, but effective and distinct channels of distribution for each.

<sup>36</sup> The BIO Ventures for Global Health (BVGH) has posted market assessments for interventions for several neglected diseases: pediatric dengue vaccine, microbicides, and tuberculosis drugs. See, <http://www.bvgh.org/resources/market/>. BVGH is also developing a series of business cases for specific developing-world medicines. Certainly as these business cases are developed – by BVGH and others – and as the markets for such medicines improve, then the role of intellectual property as potential leverage to obtain public health goals will also improve. Those goals, as explained in this paper, include specific price and volume commitments pertaining to medicines intended for poor people in developing countries and the goal of generating sustainable sources of financing for future public-health oriented research.

<sup>37</sup> This last point warrants further study. In particular, to determine the extent to which intellectual property rights may form a basis for generating income that may be aggregated in a general fund to be used to further public-health goals.

<sup>38</sup> There are instances, however, where intellectual property protection can be used as a tool to control use or distribution of a medicine or diagnostic product. Such control can be used, to control who can distribute or use a given product to achieve public health goals and not necessarily private or profit-oriented goals.

patent protection for research tools, such as transgenic mice, receptors, or cell lines.<sup>39</sup> The point of raising this example is not to indicate that intellectual property protection may not be appropriate to use to pursue public health goals generally or in specific areas of technology. Rather, it is to emphasize that the starting point for the discussion must be the public health goal to be achieved and that the necessary agreements are put in place and managed to achieve that goal. When intellectual property issues arise, their purpose must be appreciated and intellectual property rights should be sought – as appropriate – and managed to ensure that the public health goal can be achieved.

From the foregoing, three principles can be elucidated:

First, the starting point for public-private partnership and any ensuing agreements has to be the public health goal that is being sought – typically the development of a medicine for a neglected disease that will be available at the lowest possible cost to poor patients in developing countries.

Second, intellectual property rights clauses in such agreements enable all parties (including for-profit companies, universities, and government research organizations) to bring their pre-existing background rights to a given project and manage them as well as rights to technologies developed under the project to achieve the public health goal.

Third, the remedies for failure to meet terms in the agreement have to be clear and suitable to achieving the public health goal. These remedies fall into two categories. First, if any of the parties to the agreement determine that they will not or cannot continue with the development of the medicine, then the other parties have to have the rights necessary to do so – including all background intellectual property as well as rights that arise during the project that is the subject of the agreement. Second, if the parties have made commitments to manufacture medicines, then the provisions regarding price and quantity must have clear parameters as to how they are met. Again, if these commitments are not met, provision must be made to allow the project to continue with another party.<sup>40</sup>

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<sup>39</sup> See United States Public Health Service Technology Transfer Manual Chapter No. 300, PHS Licensing Policy (accessible at: <http://www.nih.gov/news/researchtools/appendd2.htm> (accessed April 21, 2005)) (“For example, PHS will generally not seek patent protection for research tools, such as transgenic mice, receptors, or cell lines. Such materials can be licensed effectively in the absence of patent protection, under royalty-bearing biological materials licenses, or distributed to the research community through non royalty-bearing material transfer agreements. For research tools, the public interest is served primarily by ensuring that the tool is widely available to both academic and commercial scientists to advance further scientific discovery. Secondly, a financial return to the public is obtained through royalties on the rare research tool that has significant commercial value.”)

<sup>40</sup> Continuation with another party where price and quantity commitments are not met may require an aggregation of all intellectual property rights in both developed and developing countries. Such an aggregation of rights may be necessary where price concessions in developing countries are contingent upon being able to sell the medicine at full market prices in developed countries.

### III. Conclusion

Intellectual property can be managed by private and public entities in order to promote the development of new medicines for neglected diseases.<sup>41</sup> Intellectual property – in particular patents – is intended to provide incentives for investments into innovation, including the development of new medicines. Yet, when the primary consumers of a potential new product, even when they number in the millions, lack the buying power to guarantee a return on investment regardless of market exclusivity, the public sector and charitable foundations must step in to fill this gap in purchasing power. However, it is the private sector that has the experience, laboratories, and human capital to bring a medicine from the phase of basic research to the shelves and clinics. Moreover, medicine development often depends and builds upon technology that has already been developed, and often patented.

Thus, public/charitable funding, together with creative and effective use of intellectual property, can be instrumental in bringing a new medicine to market in developing countries.

There is now a track record on how intellectual property rights may be properly managed in connection with such development. Certainly not all questions have been asked – let alone answered – as to how intellectual property rights should be managed in connection with all projects for the development of new medicines or for the treatment of neglected diseases. None of these matters is susceptible to a “cookbook” or “one-size-fits-all” approach. We do believe, however, that the time has arrived to shift from a question of *whether* intellectual property has a productive role to play in the development of medicines to treat neglected diseases to *how* intellectual property can be put to the service of such development.

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<sup>41</sup> This conclusion has been found specifically to apply in the case of vaccines, namely “that public sector vaccine development groups have to manage IP because the priorities that private sector partners set for choosing among potential new vaccines and the prices at which the future vaccines will be available to the poor are determined in very large part by IP considerations.” R. Mahoney, A. Pablos-Mendez, S. Ramachandran, *The Introduction of New Vaccines into Developing Countries, III. The Role of Intellectual Property*, Vaccine 22 (2004), 788.