

**From:** Ethan Guillen [redacted]  
**Sent:** Friday, November 19, 2010 1:09 PM  
**To:** HumanitarianProgram  
**Subject:** Comments of Universities Allied for Essential Medicines

To Whom It May Concern:

Please find attached UAEM's comments and related attachments in response to the Federal Register Doc. 2010-23395, Docket No. PTO-P-2010-0066 filed by the United States Patent and Trademark Office on September 17, 2010.

We appreciate the opportunity to participate in this process and would gladly contribute any further information required or offer clarifications.

Kind regards,  
Ethan Guillen

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**MEMORANDUM IN RESPONSE TO USPTO REQUEST FOR COMMENTS  
ON INCENTIVIZING HUMANITARIAN TECHNOLOGIES AND LICENSING  
THROUGH THE INTELLECTUAL PROPERTY SYSTEM**

The following is a memorandum responding to Federal Register Doc. 2010-23395, Docket No. PTO-P-2010-0066 filed by the United States Patent and Trademark Office on September 17, 2010. Universities Allied for Essential Medicines welcomes the opportunity to participate in the process of creating the framework for humanitarian access licensing, an issue core to our mission.

**INTERESTED PARTY**

Universities Allied for Essential Medicines (“UAEM”) is a coalition of students at 70 top research institutions across the United States, United Kingdom, Canada, Brazil, Germany, and Norway. UAEM’s mission is to promote access to medicines for people in developing countries by changing norms and practices surrounding university and public research institution patenting and licensing. We also work to ensure that university medical research meets the needs of the majority of the world’s population.

UAEM plays a distinct role in the access to medicines movement because of its unique position in promoting the use of socially responsible patenting and licensing practices, including global access license terms at universities and public research institutions.

**LICENSING IN THE PUBLIC INTEREST**

According to the World Health Organization, ten million people—most of them in developing countries—die needlessly every year because they do not have access to existing medicines and vaccines. While price is not the only factor, the need for better access to affordable medicines is clearly great. Industry plays a critical role in developing medicines and should, as good global citizens, participate in efforts to improve affordable access to medicines

under their control. At the same time, universities and public research institutions remain major powerhouses for drug discovery,<sup>1</sup> but unfortunately, often license out drugs to pharmaceutical companies with no provisions for affordable access in developing countries. This is true despite their public-interest missions.

Our comments to the USPTO are made from the perspective of promoting equitable access to essential medicines, vaccines, diagnostics, and other health-related technologies.

### **I. Defining Humanitarian Licensing**

The humanitarian purposes hoped to be encouraged by the USPTO program will clearly require the licensing of patents in particular ways to meet humanitarian ends. Having standards for such licenses will be critical to evaluating the merits of any application to the program. For this reason, we begin with a discussion of humanitarian licensing trends that may aid USPTO in setting criteria for the program. The issue of humanitarian licensing, (we typically refer to this issue as “global access licensing”), particularly of patented discoveries emanating from universities or brought about with public funding, has gained greater prominence in the past decade. UAEM’s early work at Yale University highlighted the importance of global access licensing. In 2001, the price of the HIV/AIDS drug, Stavudine (d4T) remained too costly for those in South Africa (and much of the rest of the developing world). UAEM worked with Doctors Without Borders/Médecins Sans Frontières (MSF) to reduce the medicine’s price from \$1,600 per patient per year to less than \$55 per year in South Africa. This drastic price reduction helped trigger radical price reductions of the drug across the African continent. Today, the price of anti-retroviral treatment has dropped from over \$10,000 in 2000 to less than \$100 today.<sup>2</sup> The

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<sup>1</sup> For instance, between 1987 and 2007, university patents have been included in 30% of anti-retroviral medicines. Chokshi, Dave, et al. 1934, JAMA, October 24/31, 2007—Vol 298, No. 16.

<sup>2</sup> Médecins sans Frontières, *Untangling the Web of Antiretroviral Price Reductions*, (13th ed. July 9, 2010) *available*



drop in prices brought about by generic competition has been fundamental to the success of the President's Emergency Plan for AIDS Relief (PEPFAR) program.

In response to the Stavudine price reductions, in 2002, Yale UAEM students and academics organized a symposium on equitable licensing which included representatives from universities and civil society to start a discussion on best licensing practices for universities. The hope was to ensure that universities would systematically work to ensure access to their discoveries. This symposium laid the groundwork for the Equitable Access License, discussed below, devised by academics and students as a first attempt to examine licensing terms that universities could use to ensure access to medicines emanating from their labs.

There are a number of models focused on equitable dissemination of medicines that USPTO may look to in creating the current program. UAEM, in conjunction with academics, civil society and others through the years, has created both the Equitable Access License (Attachment 1) and Global Access Licensing Framework (Attachment 2). Various advocacy efforts also led to the adoption of related statements over the years including the Nine Points to Consider in Licensing University Technology ("Nine Points") (Attachment 3), and Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies (SPS) (Attachment 4), which grew out of UAEM's work on the Global Access Licensing Framework. Principles to inform a humanitarian access policy are also included in the World Health Assembly Resolution 61.21, adopted in 2008. Each of these policies is briefly discussed below to offer background to USPTO on potential terms and strategies that might qualify for the proposed voucher program.

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at [http://www.msfacecess.org/fileadmin/user\\_upload/diseases/hiv-aids/Untangling\\_the\\_Web/MSF\\_Access\\_Report\\_13th\\_edition.pdf](http://www.msfacecess.org/fileadmin/user_upload/diseases/hiv-aids/Untangling_the_Web/MSF_Access_Report_13th_edition.pdf).

### **A. Equitable Access License**

The Equitable Access License was the first attempt to create licensing terms for use by university and government patent holders that ensured access to medicines discovered at an institution while minimizing abuse of the system. Through easy-to-use mechanisms such as open licensing, grant-back, and reach-through, access would be effectively increased should a patent be included in a registered medicine. Under the approach set forth in the Equitable Access Licensing framework:

- All patent and data rights necessary for the production of the end product are made available in low- to middle-income countries in exchange for a reasonable royalty, and
- A university's access provision reaches any end product that relies even in part on the university's patented innovation through contractual agreement.

This approach is particularly beneficial because it does not place any ongoing demands or administrative burdens on universities or pharmaceutical companies. It also recognizes that intellectual property rights may be used to promote open and closed access while protecting the public good as well a private property.

### **B. Global Access Licensing Framework**

Building upon the Equitable Access License, UAEM developed the Global Access Licensing Framework, a strategy for universities to implement Global Access Policies in their licenses that will make their technologies more affordable and available in resource-limited countries. The Global Access Licensing Framework encourages universities to follow six principles in licensing:

- *Create licenses* with the idea that access to medicines and health-related technologies as the primary purpose of technology transfer,
- *Preserve future research and development* by ensuring that intellectual property does not act as a barrier to further research,



- *Promote generic competition*, which remains the most efficient method of facilitating affordable access to medicines in developing countries, by removing legal barriers to generic production,
- *Prevent follow-on patents, data exclusivity or other methods* that may be used to block generic production,
- *Facilitate future research and development by patenting only when truly necessary* to promote commercialization, use non-exclusive licensing, and reserve broad rights to use the licensed technology for future research, and
- *Maintain a transparent process with metrics* that measure the success of technology transfer on its impact on access and further research and development

By following the principles set forth in the Equitable Access License and Global Access Licensing Framework, universities can create licenses that address the health needs of developing nations through reductions in intellectual property barriers, as well as promote future research and development, while minimizing the administrative burden on the university and the licensee. Principles contained in UAEM policies have contributed to policies later adopted by universities.

### **C. Nine Points to Consider**

It is worth noting that the policies espoused in the Equitable Access License and Global Access Licensing Framework have become norms in the university community. Significantly, the final point in the Nine Points to Consider explicitly encourages universities to construct licenses to ensure that underserved, underprivileged populations can access adequate quantities of innovations—with particular attention given to improved therapeutics, diagnostics and agricultural technologies—at a low- or no-cost basis. The Nine Points to Consider now has 75 signatories<sup>3</sup> including major research universities and the Biotechnology Industry Organization.

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<sup>3</sup> A full list of signatories of Nine Points is available at:  
[http://www.autm.net/source/NinePoints/ninepoints\\_endorsement.cfm](http://www.autm.net/source/NinePoints/ninepoints_endorsement.cfm).

We should note that while the Nine Points represents a positive normative statement, actual implementation varies and we believe needs to be improved at many signatory institutions. Nonetheless, the principles espoused in the ninth point lay a positive backdrop for positive action.

#### **D. Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies**

In an effort to provide a more concrete statement of goals and licensing practices with respect to promoting global access to university developed technologies, the SPS was developed. The SPS recognizes that university intellectual property should not become a barrier to access for patients in the developing world and announces strategies such as not patenting in developing countries or reserving rights for mandatory sublicenses. While committing signatories to support neglected disease research, the SPS also recognizes that signatory institution policies should cover all therapeutics and vaccines and commits to the development of meaningful metrics to monitor implementation. The SPS, a much newer statement than the Nine Points to Consider, has 27 signatories including top research universities, such as Harvard and Yale, and government institutions such as the National Institutes of Health and the Centers for Disease Control and Prevention.<sup>4</sup>

Although SPS sets out a number of goals and strategies for improving global access to university created technologies, it also possesses a number of shortcomings. Specifically, SPS:

- Does not address nations such as China, India and Brazil and other similarly situated countries, where a small portion of these countries' populations may be able to afford to pay monopoly prices while the vast majority cannot. These countries also serve as key providers of generic medicines to the developing world; failure to include them in global access licensing strategies will diminish the accessibility of critical drugs worldwide.

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<sup>4</sup> A full list of signatories of SPS is available at:  
<http://www.autm.net/source/Endorsement/endorsement.cfm?section=endorsement>.

- Fails to fully recognize the value and importance of generic competition as the most effective means of reducing drug prices.
- Does not prioritize its strategies for improving access in poor countries and does not consider that some strategies are more effective than others and does not list open licensing as one of its valuable strategies.
- Neglects to ensure that university licensees' intellectual property does not become a barrier to access

In practice, signatory institutions have taken different approaches. Harvard University has worked to include China and India in its policy which we see as a first positive step. The licensing terms Harvard is currently negotiating into licenses are also novel and worthy of examination.

Though we believe that Nine Points to Consider offers positive normative statements that should be taken into account, we believe the more concrete statements developed by UAEM as well as SPS should be considered carefully by USPTO in crafting the humanitarian access program. We strongly caution, however, that SPS has shortcomings that must be taken into account as well that are discussed in UAEM's response to the document (Attachment 5). The Equitable Access License and Global Access Licensing Framework, we believe, provide the best models for improving access to medicines through humanitarian licensing provisions.

#### **E. Movement Towards Global (Humanitarian) Access Licensing**

Beyond the joint statements arising from advocacy, UAEM's work with individual institutions has resulted in policies on global access at University of California, Berkeley, University of British Columbia, University of Washington, University of Edinburgh, Emory University and, most recently, at Charité - Universitätsmedizin Berlin. Together, the adopted individual policies, positive group policies such as SPS, and norms at public research institutions have demonstrated eagerness to promote global access by way of licensing practices. As a part

of these changing norms in the public sector, industry institutions such as BIO have gone beyond their initial signature to Nine Points to Consider, and have issued their own statement that demonstrates a new willingness to explore innovative mechanisms that ensure access.<sup>5</sup> BIO's Policy Statement: Options for Increasing Access to Medicines in the Developing World recommends, *inter alia*, that companies explore humanitarian pricing that includes at-cost or low-cost medicines, engage in capacity building with local partners, or license to generic companies and other alternative partners for the production and distribution of essential drugs in developing countries.

Similar principles of humanitarian licensing have been widespread and numerous organizations have emphasized the importance of access to medicines and global health concerns. For example, the World Health Assembly's Resolution 61.21 (also known as WHO's Global Strategy and Plan of Action; Attachment 6) explicitly encourages the "further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies" to improve access to innovations relevant "to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms."<sup>6</sup>

Also discussed in the Global Strategy and Plan of Action is the concept of patent pools for medicines. As is further discussed below, the U.S. government recently licensed the first patent for an anti-retroviral to the UNITAID-supported Medicines Patent Pool. This initiative also demonstrates a concrete measure to improve access to medicines that we believe should be considered by USPTO.

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<sup>5</sup> Biotechnology Industry Organization, BIO Announces New Policy on Options for Increasing Access to Medicines in the Developing World (May 3, 2010), [http://www.bio.org/news/pressreleases/newsitem.asp?id=2010\\_0503\\_04](http://www.bio.org/news/pressreleases/newsitem.asp?id=2010_0503_04).

<sup>6</sup> World Health Assembly, Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHA § 61.21 (May 24, 2008), available at [http://apps.who.int/gb/ebwha/pdf\\_files/A61/A61\\_R21-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf); see also Universities Allied for Essential Medicines, Elements of IGWG Global Strategy Particularly Relevant to UAEM § 2.4(d), available at <http://essentialmedicine.org/projects/international-agreements> (last visited Nov. 18, 2010).



Principles of humanitarian licensing have also found their way into the U.S. Congress when Senator Leahy (VT) proposed the Public Research in the Public Interest Act of 2006 (S.4040) (Attachment 7). S.4040 proposed mandated humanitarian licensing terms that would allow generic manufacturers to supply drugs developed at federally-funded institutions in eligible developing countries at affordable prices. Proposals to ensure licensing provisions that will benefit the developing world have been espoused in a wide range of fora. We believe that in crafting the proposed program, the USPTO will be aided by considering the goals and strategies espoused in the aforementioned documents. In particular, we hope that USPTO will use lessons from the various policies on the types of definitive terms that can improve access to ensure that licenses qualifying for the program have more than simply cosmetic effect.

#### **F. USPTO's Role**

The USPTO may address the shortcomings contained in Nine Points to Consider or SPS (and other documents) by providing greater humanitarian licensing incentives to all types of patent applicants, not just public institutions. While UAEM may achieve its objective of promoting the adoption of the Global Access Licensing Framework by working with universities at the grassroots level to ensure socially responsible, global access licensing, USPTO has the power to expand upon our foundational frameworks with a humanitarian licensing incentives program for all patent owners. Using the Equitable Access License or Global Access Licensing Framework may provide an excellent model for the USPTO program.

## Preventing Abuse and Gaming of the System

As USPTO recognizes, there is the strong potential for abuse of the system that must be addressed. As with any system, bad-faith actors will seek to find loopholes that allow for receipt of the program's benefits by merely acting to technically fulfill the requirements of the system without actually having significant impact on affordable access or other humanitarian considerations. The careful crafting of rules by USPTO will lessen the risk of potential abuse of the system.

There are several examples we highlight as potentially presenting suboptimal outcomes if vouchers were available for the noted actions. We would view these examples as gaming of the system, and hope that the USPTO program will be designed to avoid these pitfalls:

- *Reward of a USPTO voucher based on the Food and Drug Administration award of a priority review voucher for Coartem*: As discussed in greater detail below, the reward of a PRV for Coartem is recognized as failing to create a pull for incentive but rather Novartis benefiting for a medicine already on the market that simply fit the requirements to receive a PRV. USPTO rules should ensure that simply registering a “humanitarian license” or other qualifying action that took place in the past should not qualify.
- *Reward of voucher for inclusion of patent in ill-defined “patent pools”*: The EcoPatent Commons<sup>7</sup> is a project of the World Business Council for Sustainable Development. While a laudable program, any sort of sharing of patents in pool or commons type mechanisms should demonstrate the utility of a patent and likeliness to actually be used. An initiative such as the EcoPatent Commons should not qualify as it does neither of these things.<sup>8</sup> While such endeavors on a large scale can be helpful, having a random assortment of technologies only vaguely focused on an undefined problem would be ripe for abuse, allowing participants in the USPTO program to, for instance, receive vouchers for including patents they no longer considered valuable. If the barriers to the program are too low by allowing vouchers for participation in programs such as this, the vouchers could quickly become meaningless, given low barriers to entry. The Glaxo Smith Kline patent pool presents a difficult case but likely should not qualify unless there are additional criteria showing specific usefulness or potential for a patent included in the GSK pool. The program should also consider access considerations in connection to any potential discovery that could come from the pool. If patents are made available for research but any resulting discovery is still unaffordable do to licensing terms of the pool, this would not be a positive outcome and would go against the purpose of the USPTO program. By way of contrast, we believe the UNITAID-supported

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<sup>7</sup> World Business Council for Sustainable Development, Eco-Patents Database (2010), <http://www.wbcd.org/plugins/GENERICDB/result.asp?DBID=8&type=p&MenuId=MTU2MQ&doOpen=1&ClickMenu=LeftMenu&DBEntityTitle=&DBEntityText=&cbo68=&cbo69=> (last visited Nov. 18, 2010).

<sup>8</sup> World Business Council for Sustainable Development, Eco-Patent Commons: Joining or Submitting Additional Patents to the Commons, available at <http://www.wbcd.org/web/projects/ecopatent/EcoPatentGroundRules.pdf> (last visited Nov. 18, 2010).

MODEL PROVISIONS FOR AN  
“EQUITABLE ACCESS and NEGLECTED DISEASE LICENSE”  
**Version 1.0<sup>1</sup>**

1. Definitions

- a. “Licensed Technology” means the rights licensed by the University to the Licensee pursuant to [Main Agreement].
- b. “Associated Licensee Rights” means all rights in data, information, know-how, methods, procedures and processes, including patent and marketing rights, possessed by Licensee during the term of this Agreement that are necessary to make, use, sell, offer to sell, import or export an End Product or to perform Neglected Research, including but not limited to biological, chemical, biochemical, toxicological, pharmacological, metabolic, formulation, clinical, analytical and stability information and data.
- c. “Associated Notifier Rights” means all rights in data, information, know-how, methods, procedures and processes, including patent and marketing rights, possessed by a Notifier during the term of the Open License granted to such Notifier that are necessary to make, use, sell, offer to sell, import or export an End Product or to perform Neglected Research, including but not limited to biological, chemical, biochemical, toxicological, pharmacological, metabolic, formulation, clinical, analytical and stability information and data.
- d. “Eligible Country” means any country classified by the World Bank as “Low-income” or “Middle-income” at the time a Notification is made.
- e. “End Product” means any product whose manufacture or use relies upon or is covered by the Licensed Technology.
- f. “Fair Royalty” means:
  - i. For countries classified by the World Bank as “Low-income” at the time of the sales on which royalties are due, 2% of Notifier’s Net Sales of End Products in the Notified Country of Net Sales;
  - ii. For countries classified by the World Bank as “Middle-income” at the time of the sales on which royalties are due, 5% of Notifier’s the Net Sales of the End Products by the Notifier in the Notified Country in question.
- g. “Licensed Technology” means the rights licensed by University to the Licensee pursuant to [Main Agreement].

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<sup>1</sup> This license is the product of an independent working group, based at Yale University, convened by Universities Allied for Essential Medicines.

- h. “Neglected Disease” means any disease, condition, or affliction that, at the time Notification under Section 3.a. is made, either affects less than 200,000 persons in the United States or for which there is no reasonable expectation that the cost of developing and making available in the United States a treatment, prophylaxis, or device for such disease, condition, or affliction can be recovered from sales in the United States of such treatment, prophylaxis, or device.
  - i. “Neglected Research” means any use of the Licensed Technology or Associated Licensee Rights in an effort to develop treatments, prophylaxis, or devices for a Neglected Disease.
  - j. “Notification” means a writing that announces the intention of a party to receive an Open License.
  - k. “Notification Fee” means:
    - i. For Notification to receive an Open License to supply End Products to an Eligible Country that is classified by the World Bank as “Low-income” at the time of Notification, \$5,000;
    - ii. For Notification to receive an Open License to supply End Products to an Eligible Country that is classified by the World Bank as “Middle-income” at the time of Notification, \$50,000;
    - iii. For Notification to receive an Open License to perform Neglected Research, \$500.]
  - l. “Notified Country” means an Eligible Country indicated by a Notifier in a Notification.
  - m. “Notifier” means a party that has submitted a Notification to the University and Licensee[along with an appropriate Notification Fee]. [University or Licensee acceptance of the Notification and Notification Fee are not required for a party to be a Notifier or for a Notifier to receive an Open License.]
  - n. “Open License” means a non-exclusive license to the Licensed Technology, Associated Licensee Rights, and Associated Notifier Rights granted by the University to a Notifier from University upon Notification. There are no limitations on the number of Open Licenses that may be received or the parties whom may receive an Open License.
2. Licensee Grant: Licensee hereby grants University a license to the Associated Licensee Rights for the sole purpose of granting Open Licenses either to Supply in accordance with Section 3.a. or for Neglected Research in accordance with Section 4.a.. [The licensee also agrees to include, in any patent application for a Licensee Improvement, a sentence reading: “This patent is subject to the provisions of the Equitable Access and Neglected Disease License.”]

3. Notification to Supply
  - a. Grant of Open License to Supply: Upon providing to University and Licensee Notification to receive an Open License to supply End Products to an Eligible Country, a Notifier automatically receives an Open License from the University permitting the making, using, selling, offering to sell, importing, and exporting of End Products in the Notified Country and the making and exporting of End Products in any country other than the Notified Country for the sole purpose of supplying End Products to the Notified Country. If Notifier exercises its right to make and export an End Product in any country other than a Notified Country for the sole purpose of export to a Notified Country, then Notifier shall use reasonable efforts to visibly distinguish the End Product it manufactures from the End Product sold distributed by the Licensee in the country of manufacture, but such reasonable efforts do not require Notifier to expend significant expense.
  - b. Fair Royalties: The Open License to supply End Products received by Notifier shall be irrevocable and perpetual so long as Notifier submits to University and Licensee payment of a Fair Royalty on sales of End Products covered by the Licensed Technology or Associated Licensee Rights within 90 days of such sales, such Fair Royalty to be divided equally between University and Licensee. [Failure or refusal of University or Licensee to accept the Fair Royalty shall not terminate or affect in any way the Open License.]
  - c. Notifier Grant: In exchange for receipt of an Open License to Supply, Notifier grants University a license to its Associated Notifier Rights for the sole purpose of granting Open Licenses either to Supply in accordance with Section 3.a. or for Neglected Research in accordance with Section 4.a..
  
4. Notification for Neglected Research
  - a. Grant of Open License for Neglected Research: Upon providing to University and Licensee Notification to receive an Open License to perform Neglected Research, a Notifier automatically receives a worldwide, irrevocable, and perpetual Open License from the University to perform Neglected Research.
  - b. No Royalty: No royalty shall be payable to either the University or the Licensee for the Open License for Neglected Research.
  - c. Notifier Grant: In exchange for receipt of an Open License for Neglected Research, Notifier grants University a license to its Associated Notifier Rights for the sole purpose of granting Open Licenses either to Supply in accordance with

Section 3.a. or for Neglected Research in accordance with Section 4.a..

5. Assurance of Freedom to Operate: No license or other transfer of the Licensed Technology or Associated Licensee Rights by the University or Licensee shall be valid unless the terms of this Equitable Access and Neglected Disease License are incorporated therein.
6. Transparency: Notwithstanding any other agreement or provision between the parties, either party may publicize the fact that the Licensed Technology and Associated Licensee Rights are subject to a license that includes this Equitable Access License.



## GLOBAL ACCESS LICENSING FRAMEWORK

Every university-developed technology with potential for further development into a drug, vaccine, or medical diagnostic should be licensed with a concrete and transparent strategy to make affordable versions available in resource-limited countries for medical care. Licenses are complex and each will be unique. Universities should therefore implement Global Access Policies that adhere to the following six principles:

### Goals

1. Access to medicines and health-related technologies for all is the primary purpose of technology transfer of health-related innovations. This includes protecting access to the final end product needed by patients (e.g. formulated pills or vaccines).
2. Technology transfer should preserve future innovation by ensuring that intellectual property does not act as a barrier to further research.

### Strategies

3. Generic competition is the most efficient method of facilitating affordable access to medicines in resource-limited countries. Legal barriers to generic production of these products for use in resource-limited countries should therefore be removed. In the cases of biologic compounds or other drugs where generic provision is forecast to be technically or economically infeasible, “at-cost” or other provisioning requirements should be used as a supplement to generic provisioning terms but should never replace those terms.
4. Proactive licensing provisions are essential to ensure that follow-on patents and data exclusivity cannot be used to block generic production. Other barriers may need to be addressed for the licensing of biologics.
5. University technology transfer programs should facilitate future innovation by patenting only when truly necessary to promote commercialization, utilizing non-exclusive licensing, creating streamlined processes for materials transfer, and reserving broad rights to use licensed technology in future research.
6. A global access licensing policy should be systematic in its approach, sufficiently transparent to verify its effectiveness, and based on explicit metrics that measure the success of technology transfer by its impact on access and continued innovation.

## GLOBAL ACCESS LICENSING FRAMEWORK EXPLANATORY NOTES

**Licenses for *all* drugs with actual or potential global health applications should contain global access provisions.**

Access concerns are not limited to diseases such as HIV/AIDS, tuberculosis, malaria, and other communicable diseases. The World Health Organization reports that chronic diseases such as cardiovascular disease, chronic respiratory diseases, cancer, and diabetes made up 60% of the 58 million annual worldwide deaths, 80% of which occur in low and middle income countries.<sup>1</sup> Over three times as many people die annually from cardiovascular diseases as from HIV/AIDS, tuberculosis, and malaria combined.<sup>2</sup> To ensure access for all essential medicines, it is important that every drug, vaccine, and medical diagnostic license contains access provisions.

Universities Allied for Essential Medicines (UAEM) is sensitive to the opinion that generic production is not essential for medicines indicated for “lifestyle” conditions such as hair loss, acne, or erectile dysfunction. However, because it is difficult to know at licensing time whether a product will have an essential medical use, even products that are originally licensed for lifestyle indications should have global access provisions in their license. These provisions should automatically allow for generic production in the event that any new, non-lifestyle use is demonstrated to be effective, for example via a meta-analysis published in a peer-reviewed journal. Lifestyle uses should be defined narrowly.

**The Global Access Licensing Framework should apply to all low and middle income countries.**

The decision to include or exclude particular countries in a license has grave human consequences. One key concern remains the treatment of lower-middle income countries like China, Brazil and India. More than a billion poor people live in those three countries. Although a small portion of these countries’ population may be technically able to afford to pay monopoly prices for medicines and vaccines, the vast majority cannot. Coverage is doubly important because these countries, particularly India, serve as the pharmacies for the rest of the world’s developing countries. China, India, and other countries in similar situations must be covered by universities’ global access licensing policies. Resource-limited countries should be defined to include those countries not ranked as high income on the World Bank's List of Economies (<http://go.worldbank.org/K2CKM78CC0>).

**Generic provision is the best way to facilitate access.**

Market competition generated by generic provision of drugs is recognized as the most effective means of driving down prices and increasing access.<sup>3</sup> There are several reasons that generic provisions should be required in all licenses:

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<sup>1</sup> *Preventing Chronic Disease: A Vital Investment*, World Health Organization (2005), [http://www.who.int/chp/chronic\\_disease\\_report/en/](http://www.who.int/chp/chronic_disease_report/en/).

<sup>2</sup> *The World Health Report 2003—Shaping the Future*, Geneva: WHO, 2003

<sup>3</sup> *Report to Congress by the U.S. Global AIDS Coordinator on the Use of Generic Drugs in the President's Emergency Plan for AIDS Relief*, PEPFAR (May 2008), <http://www.pepfar.gov/documents/organization/105842.pdf>.



1. Generic provision enlists competitive market forces to develop the most affordable, most efficient ways to get drugs to patients and providers. Generic companies sustainably supply large volumes of drugs as cheaply as possible. In contrast, pharmaceutical companies' drug donation programs do not provide an effective long-term solution—charitable providers have fewer incentives to drive down costs and are not sustainable options for meeting continuous demand.<sup>4</sup>
2. Generic provision eliminates the measurement and enforcement problems inherent in “at-cost” approaches.<sup>5</sup>
3. Approaches that foster generic access, such as open licensing, can also foster important innovations specific to the developing-world. For example, such approaches could allow generic companies to create pediatric and heat-stable formulations of new drugs.<sup>6</sup>

### **Generic provisions for resource-limited countries will have a negligible financial impact on the pharmaceutical industry.**

The financial impact to pharmaceutical companies of allowing generic competition in resource-limited countries is negligible, especially when the global access license offers licensees revenues from reasonable royalties on the generics. Drugs with a global market generate only a tiny fraction of their revenue in resource-limited countries. The Pharmaceutical Research and Manufacturers of America (PhRMA) estimated that between 2002 and 2007, Africa accounted for only 0.4% of the global pharmaceutical market for PhRMA members, China accounted for only 0.4%, and India only 0.2%.<sup>7</sup> Sales in the United States, European Union, and Japan accounted for 93.2% of all pharmaceutical revenues for PhRMA members during that same period.<sup>8</sup>

To ensure a fully competitive market, production of generics should be allowed in any country, so long as the products are sold only in resource-limited countries, as defined above. This approach is consistent with the framework adopted in the World Trade Organization's Doha Declaration.<sup>9</sup> Differential appearance and packaging requirements can be used to ensure that products destined for developing world market are not illegally sold elsewhere.<sup>10</sup>

A subset of the pharmaceutical industry is increasingly hospitable to controlled licensing of their drugs for generic use in developing world settings. For example, Gilead recently provided an open voluntary

<sup>4</sup> E-mail from Daniel Berman et al., MSF, to Robert Lefebvre, Bristol-Myers Squibb (Feb. 8, 2002), <http://www.essentialdrugs.org/edrug/archive/200202/msg00055.php>.

<sup>5</sup> Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, Berkeley Tech. L.J., 20, 1031 (2005).

<sup>6</sup> *UNITAID and CHAI Announce Lower Prices for AIDS Drugs and Affordable Formulations for Children*, UNITAID (Apr. 28, 2008), <http://www.unitaid.eu/index.php/en/NEWS/UNITAID-and-CHAI-announce-Lower-Prices-for-AIDS-Drugs-and-Affordable-Formulations-for-Children.html>.

<sup>7</sup> *Industry Profile 2008*, PhRMA, <http://www.phrma.org/files/2008%20Profile.pdf>.

<sup>8</sup> *The Pharmaceutical Industry in Figures*, European Federation of Pharmaceutical Industries and Associations (2008), p. 5, <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=4883>.

<sup>9</sup> *Ministerial Declaration*, World Trade Organization (Nov. 14, 2001), [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm).

<sup>10</sup> Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 Yale J. Health Pol'y L. & Ethics 193, 261-265 (2005).



license of its important AIDS medication tenofovir to generic producers in India,<sup>11</sup> and both Gilead and Johnson & Johnson announced at the 2008 World AIDS conference that they would be willing to put intellectual property into a new patent pool being created by UNITAID to allow further generic production of AIDS medications.<sup>12</sup> Even where pharmaceutical companies are initially resistant to a generic production arrangement, universities can and should insist on such terms as critical to the overall licensing goal of getting innovations to patients, just as they now insist on due diligence terms and measurable development milestones to ensure licensed innovations reach wealthier patients in primary markets.

### **Additional legal barriers that prevent access to the end product needed by patients must be removed.**

Some universities have argued that simply not patenting their own discoveries in resource-limited countries constitutes a sufficient access policy. However, if a university does **not** include specific access provisions in its license, there are still several ways licensees could block a generic company from producing the drug for use in resource-limited countries:

**Follow-On Patents:** Licensees can patent many of the incremental developments inherent in turning the basic licensed compound into a finished marketable drug, creating barriers to access. Several kinds of “follow-on” patents exist:

- *Product patents* cover modifications to, or new formulations of the original compound, such as those permitting increased solubility.
- *Process patents* cover the techniques, paths, and intermediates that producers use to synthesize the chemical compound at scale.
- *Use patents* cover the use of the drug for a particular indication.

**Data Exclusivity:** It currently takes years for a generic company to gain the right to refer to the clinical trial data of drugs that are “bioequivalent” to its own, delaying its ability to provide these drugs in developing countries. In order to sell its drugs to the public, an originator pharmaceutical company must show that the drug is safe and effective by performing clinical trials. A generic company, in contrast, can sell a drug without performing such trials by proving that its drug is bioequivalent to a previously approved drug. In order to do so, it must make reference to the originator pharmaceutical company’s clinical trial data. This “right of reference” is limited by law; in the United States, for example, generic companies must wait five years before referring to clinical trials already registered with the FDA. This delay is particularly problematic for drugs that treat diseases like HIV, where resistance to first- and second-line therapies develops rapidly.

There are a number of strategies to address the issues of follow-on patents and data exclusivity, including non-assert clauses, sublicensing agreements, patent pools, data waivers, and grantback provisions.<sup>13</sup>

<sup>11</sup> *Gilead Announces Licensing Agreements*, Gilead (Sep. 22, 2006), [http://www.gilead.com/pr\\_908393](http://www.gilead.com/pr_908393).

<sup>12</sup> James Love, *The Health Impact Fund and product monopolies*, Knowledge Ecology International (Nov. 17, 2008), <http://www.keionline.org/blogs/2008/11/17/health-impact-fund-monopolies/>.

<sup>13</sup> April E. Effort and Ashley J. Stevens, *The Critical Role of Academic Licensing in Promoting Global Social Responsibility* (2008); Kapczynski et al., *supra*; UNITAID Mission (2005), <http://www.unitaid.eu/index.php/en/UNITAID-Mission.html>.



## **At-cost or other access provisions are sometimes necessary, but they should never replace generic provisions.**

At-cost provisions, which require the licensee to sell the licensed technology in resource-limited countries for no profit, may be necessary:

1. When the drug, process, technology, diagnostic, or other component of the licensed product is too complex to be feasible for replication and generic production. For example, many biologics may require at-cost provisions.
2. When the demand for the product in resource-limited countries is too small to induce a generic company to enter into production. Causes of a small demand could include a very small affected patient population as in rare genetic diseases, or an isolated or constrained geographic distribution.

## **Additional barriers to access must be overcome for biologics.**

While there is a clear paradigm for the production of small molecule generics, there are a number of important issues related to the production of biosimilar vaccines and other biologics that this framework does not address; there are multiple additional barriers—many of which are non-proprietary—that need to be addressed in order to ensure efficient, cost-effective generic development.

Still, universities that license biologics should follow the same basic principle: generic provision is the best method for ensuring access, and biologic licenses should do as much to facilitate generic provision as possible. In particular, universities should seek commitments from licensees to transfer materials and know-how to follow-on producers when necessary.<sup>14</sup> Where such agreements are impractical or impossible; when they may be insufficient to ensure follow-on provision; and while there remains no established legal pathway for follow-on biologics, at-cost provisioning commitments should be required.

## **Intellectual property barriers to innovation should be minimized**

While patents and other forms of intellectual property are commonly justified on the grounds that they promote innovation, such property rights can also have the unintended consequence of discouraging future innovation.<sup>15</sup> Costly licensing fees, as well as “reach through” provisions that call for royalties on products developed from upstream technologies, place taxes on downstream research that discourages commercialization and use of future technologies. Patenting also raises concerns about patent thickets, blockages that result when numerous patents on a product lead to bargaining breakdowns that can prevent downstream research and development from taking place. Exclusively held patents may also block useful follow-on innovation that can result in combination products that magnify the impact of a technology, or in products that are tailored to serve the needs of people in developing countries.

<sup>14</sup> Sara E. Crager, Ethan Guillen, and Matt Price, *University contributions to HPV vaccines and implications for access in developing countries: Potential models for improving access to university discovered vaccines*, American Journal of Law & Medicine 110-132 (forthcoming, 2009).

<sup>15</sup> See generally, Anthony D. So, et. al, *Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience*, PLoS Biol 6(10): e262.



Finally, the practices of patenting and licensing can have a negative impact on longstanding academic norms regarding the open, swift, and disinterested scientific exchange of knowledge.

To avoid these unnecessary barriers to innovation, universities should craft policies that allow for patenting only those inventions that would fail to be commercialized in absence of the patent incentive. For example, universities need not seek patents on research platforms, diagnostic tests, and other technologies that can be adapted for commercial use in a short period with little additional investment. Such patents hinder innovation while providing no social benefits beyond enrichment to the patent-holding institution. Where patents are acquired, such technologies should be licensed non-exclusively to encourage the broadest possible dissemination of university research. Universities should reserve rights to grant future researchers the right to work with products in order to make improvements and modify them for uses particular to developing countries. Finally, universities should work to foster the scientific exchange of knowledge by adopting streamlined processes for materials transfer and providing internal incentives for the exchange of knowledge among researchers.

### **Implementation requires effective governance: policies must be systematic, transparent, and utilize explicit access metrics**

The dynamic nature of the technology transfer process means that no single set of mechanisms, policies, or commitments is likely to be sufficient to ensure the greatest possible access to university technologies in the long term. For this reason, universities must strive to continuously improve on existing licensing practices, evolving policies and practices in order to improve access to medicines for all people, regardless of income. Effective governance is essential to ensure the implementation of global access licensing policies and to help guide this evolution. Transparency and accountability are essential features to ensuring effective governance.

One way to ensure transparency and accountability is to make redacted licenses available through publication. Where such publication is not practicable, governance may be accomplished by committees that, like institutional review boards, have public stewardship and review responsibilities. Governance mechanisms should be accountable to the broader university community, for example by including faculty with expertise in medical research and global health, as well as students and administrators.

Each university should develop and implement metrics to account for their own access-oriented licensing strategies. These metrics should include operational or process measures of university licensing activities in order to support and further develop technology transfer strategies that prioritize access. Metrics should measure not only university implementation of access licensing strategies through concrete licensing terms and provisions, but also the frequency of implementation of such terms for all health-related invention disclosures. The indicators should be clear and publicly-available.

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**In the Public Interest:  
Nine Points to Consider in Licensing University Technology**

Licensing approaches, even for comparable technologies, can vary considerably from case to case and from institution to institution based on circumstances particular to each specific invention, business opportunity, licensee and university. In spite of this uniqueness, universities share certain core values that can and should be maintained to the fullest extent possible in all technology transfer agreements.

In the summer of 2006, Stanford University's then Dean of Research Arthur Bienenstock convened a small meeting of research officers, licensing directors and a representative from the Association of American Medical Colleges to brainstorm about important societal, policy, legislative and other issues in university technology transfer.

Representatives of the participating institutions, listed below, have tried to capture in this document certain shared perspectives that emerged from that meeting. Recognizing that each license is subject to unique influences that render 'cookie-cutter' solutions insufficient, it is our aim in releasing this paper to encourage our colleagues in the academic technology transfer profession to analyze each licensing opportunity individually in a manner that reflects the business needs and values of their institution, but at the same time, to the extent appropriate, also to bear in mind the concepts articulated herein when crafting agreements with industry. We recognize that many of these points are already being practiced. In the end, we hope to foster thoughtful approaches and encourage creative solutions to complex problems that may arise when universities license technologies in the public interest and for society's benefit.

California Institute of Technology  
Cornell University  
Harvard University  
Massachusetts Institute of Technology  
Stanford University  
University of California  
University of Illinois, Chicago  
University of Illinois, Urbana-Champaign  
University of Washington  
Wisconsin Alumni Research Foundation  
Yale University  
and  
Association of American Medical Colleges (AAMC)

### **Point 1**

#### **Universities should reserve the right to practice licensed inventions and to allow other non-profit and governmental organizations to do so**

In the spirit of preserving the ability of all universities to perform research, ensuring that researchers are able to publish the results of their research in dissertations and peer-reviewed journals and that other scholars are able to verify published results without concern for patents, universities should consider reserving rights in all fields of use, even if the invention is licensed exclusively to a commercial entity, for themselves and other non-profit and governmental organizations:

- to practice inventions and to use associated information and data for research and educational purposes, including research sponsored by commercial entities; and
- to transfer tangible research materials (e.g., biological materials and chemical compounds) and intangible materials (e.g., computer software, databases and know-how) to others in the non-profit and governmental sectors.

Clear articulation of the scope of reserved rights is critical. Recent examples of such “retained rights” clauses are included in the Appendix for reference.

### **Point 2**

#### **Exclusive licenses should be structured in a manner that encourages technology development and use**

When significant investment of time and resources in a technology are needed in order to achieve its broad implementation, an exclusive license often is necessary and appropriate. However, it is important that technology transfer offices be aware of the potential impact that the exclusive license might have on further research, unanticipated uses, future commercialization efforts and markets. Universities need to be mindful of the impact of granting overly broad exclusive rights and should strive to grant just those rights necessary to encourage development of the technology.

Special consideration should be given to the impact of an exclusive license on uses of a technology that may not be appreciated at the time of initial licensing. A license grant that encompasses all fields of use for the life of the licensed patent(s) may have negative consequences if the subject technology is found to have unanticipated utility. This possibility is particularly troublesome if the licensee is not able or willing to develop the technology in fields outside of its core business. Universities are encouraged to use approaches that balance a licensee’s legitimate commercial needs against the university’s goal (based on its educational and charitable mission and the public interest) of ensuring broad practical application of the fruits of its research programs. There are many alternatives to strict exclusive licensing, several of which are described in the Appendix.

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In situations where an exclusive license is warranted, it is important that licensees commit to diligently develop the technology to protect against a licensee that is unable or unwilling to move an innovation forward. In long-term exclusive licenses, diligent development should be well-defined and regularly monitored during the exclusive term of the agreement and should promote the development and broad dissemination of the licensed technology. Ideally, objective, time-limited performance milestones are set, with termination or non-exclusivity (subject to limited, but reasonable, cure provisions) as the penalty for breach of the diligence obligation. Examples of diligence requirements (also known as performance milestones) are described in the Appendix.

Another means of ensuring diligent development, often used in conjunction with milestones, is to require exclusive licensees to grant sublicenses to third parties to address unmet market or public health needs (“mandatory sublicensing”) and/or to diligently commercialize new applications of the licensed rights. Such a requirement could also be implemented through a reserved right of the licensor to grant direct licenses within the scope of the exclusive grant to third parties based on unmet need. In such situations, it is important to ensure that the parties have a common understanding of what constitutes a new application or unmet need for the purpose of implementing such a provision. An example of mandatory sublicensing language is provided in the Appendix.

Absent the need for a significant investment - such as to optimize a technology for wide use - broad, non-exclusive licensing of tools such as genomic and proteomic inventions can help maximize the benefits derived from those technologies, in part by removing obstacles to further innovation. Unlike most research tools or manufacturing methods, diagnostic tests often must go through the regulatory approval process, and so may warrant exclusive licensing when the costs of test development, approval or diffusion require substantial investment of capital. Nevertheless, licensing of diagnostic tests based on broadly applicable genomics or proteomics methods should strive to preserve sufficient flexibility to permit testing for multiple indications (i.e., not an exclusive licensee’s single disease of interest) perhaps through multiple field-restricted or non-exclusive licenses. Exclusive licensing of a single gene for a diagnostic may be counterproductive in a multi-gene pathology where only a panel of genes can yield an adequate diagnosis, unless the licensee has access to the other genes of the panel. Such licenses can also be limited in other ways. For example, a university might license a genomics method exclusively for a company to optimize and sell licensed products for diagnostic use. The drafting of the exclusive grant could make it clear that the license is exclusive for the sale, but not use, of such products; in doing so, the university ensures that it is free to license non-exclusively to others the right (or may simply not assert its rights) to use the patented technology, which they may do either using products purchased from the exclusive licensee or those that they make in-house for their own use.

In general, when no alternative testing strategy is available for a given indication, consideration should be given to means of ensuring reasonable access for patients and shielding individual healthcare providers from the risk of suit for patent infringement. As with any medical technology, licenses should not hinder clinical research, professional

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education and training, use by public health authorities, independent validation of test results or quality verification and/or control.

**Point 3**  
**Strive to minimize the licensing of “future improvements”**

Although licensees often seek guaranteed access to future improvements on licensed inventions, the obligation of such future inventions may effectively enslave a faculty member’s research program to the company, thereby exerting a chilling effect on their ability to receive corporate and other research funding and to engage in productive collaborations with scientists employed by companies other than the licensee – perhaps even to collaborate with other academic scientists. In particular, if such future rights reach to inventions made elsewhere in the university, researchers who did not benefit from the licensing of the original invention may have their opportunities restricted as well, and may be disadvantaged economically relative to the original inventors if the licensing office has pre-committed their inventions to a licensee.

For these reasons, exclusive licensees should not automatically receive rights to “improvement” or “follow-on” inventions. Instead, as a matter of course, licensed rights should be limited to existing patent applications and patents, and only to those claims in any continuing patent applications that are (i) fully supported by information in an identified, existing patent application or patent and (ii) entitled to the priority date of that application or patent.

In the rare case where a licensee is granted rights to improvement patents, it is critical to limit the scope of the grant so that it does not impact uninvolved researchers and does not extend indefinitely into the future. It is important to further restrict the grant of improvements to inventions that are owned and controlled by the licensor institution - i.e., (i) not made by the inventor at another institution, should they move on or (ii) co-owned with, or controlled by, another party. One refinement to this strategy would be to limit the license to inventions that are dominated by the original licensed patents, as these could not be meaningfully licensed to a third party, at least within the first licensee’s exclusive field. As was discussed earlier, appropriate field restrictions enable the licensing not only of the background technology, but also of improvements, to third parties for use outside the initial licensee’s core business. In all cases, a license to improvements should be subject to appropriate diligent development requirements.

It should be recognized, however, that not all “improvements” have commercial potential (for example, they may not confer sufficient additional benefit over the existing technology to merit the expense of the development of new or modified products), in which case a licensee might not wish to develop them. In general, it may be best simply not to patent such improvements.

**Point 4**  
**Universities should anticipate and help to manage  
technology transfer related conflicts of interest**

Technology transfer offices should be particularly conscious and sensitive about their roles in the identification, review and management of conflicts of interest, both at the investigator and institutional levels. Licensing to a start-up founded by faculty, student or other university inventors raises the potential for conflicts of interest; these conflicts should be properly reviewed and managed by academic and administrative officers and committees outside of the technology transfer office. A technology licensing professional ideally works in an open and collegial manner with those directly responsible for oversight of conflicts of interest so as to ensure that potential conflicts arising from licensing arrangements are reviewed and managed in a way that reflects well on their university and its community. Ideally, the university has an administrative channel and reporting point whereby potential conflicts can be non-punitively reported and discussed, and through which consistent decisions are made in a timely manner.

**Point 5**  
**Ensure broad access to research tools**

Consistent with the NIH Guidelines on Research Tools, principles set forth by various charitable foundations that sponsor academic research programs and by the mission of the typical university to advance scientific research, universities are expected to make research tools as broadly available as possible. Such an approach is in keeping with the policies of numerous peer-reviewed scientific journals, on which the scientific enterprise depends as much as it does on the receipt of funding: in order to publish research results, scientists must agree to make unique resources (e.g., novel antibodies, cell lines, animal models, chemical compounds) available to others for verification of their published data and conclusions.

Through a blend of field-exclusive and non-exclusive licenses, research tools may be licensed appropriately, depending on the resources needed to develop each particular invention, the licensee's needs and the public good. As suggested with respect to genomics and proteomics method patents in Point 2 above, a university might license a research reagent, kit or device exclusively to a company to optimize and sell licensed products and services for research, diagnostic or other end uses. The drafting of such an exclusive grant should make clear that the license is exclusive for the sale, but not use, of such products and services; in doing so, the university ensures that it is free to license non-exclusively to others the right to use the patented technology, which they may do either using products purchased from the exclusive licensee or those that they make in-house for their own use.

**Point 6**  
**Enforcement action should be carefully considered**

In considering enforcement of their intellectual property, it is important that universities be mindful of their primary mission to use patents to promote technology development for the benefit of society. All efforts should be made to reach a resolution that benefits both sides and promotes the continuing expansion and adoption of new technologies. Litigation is seldom the preferred option for resolving disputes.

However, after serious consideration, if a university still decides to initiate an infringement lawsuit, it should be with a clear, mission-oriented rationale for doing so—one that can be clearly articulated both to its internal constituencies and to the public. Ideally, the university’s decision to litigate is based on factors that closely track the reasons for which universities obtain and license patents in the first place, as set out elsewhere in this paper. Examples might include:

- Contractual or ethical obligation to protect the rights of existing licensees to enjoy the benefits conferred by their licenses; and
- Blatant disregard on the part of the infringer for the university’s legitimate rights in availing itself of patent protection, as evidenced by refusal on the part of the infringer to negotiate with or otherwise entertain a reasonable offer of license terms.

Under all circumstances, it reflects poorly on universities to be involved in “nuisance suits.” Exclusive licensees should be encouraged to approach patent enforcement in a manner that is consistent with the philosophy described in this Point 6.

**Point 7**  
**Be mindful of export regulations**

University technology transfer offices should have a heightened sensitivity about export laws and regulations and how these bodies of law could affect university licensing practices. Licensing “proprietary information” or “confidential information” can affect the “fundamental research exclusion” (enunciated by the various export regulations) enjoyed by most university research, so the use of appropriate language is particularly important. Diligence in ensuring that technology license transactions comply with federal export control laws helps to safeguard the continued ability of technology transfer offices to serve the public interest.

### **Point 8**

#### **Be mindful of the implications of working with patent aggregators**

As is true of patents generally, the majority of university-owned patents are unlicensed. With increasing frequency, university technology transfer offices are approached by parties who wish to acquire rights in such ‘overstock’ in order to commercialize it through further licenses. These patent aggregators typically work under one of two models: the ‘added value’ model and the so-called ‘patent troll’ model.

Under the added value model, the primary licensee assembles a portfolio of patents related to a particular technology. In doing so, they are able to offer secondary licensees a complete package that affords them freedom to operate under patents perhaps obtained from multiple sources. As universities do not normally have the resources to identify and in-license relevant patents of importance, they cannot offer others all of the rights that may control practice (and, consequently, commercialization) of university inventions. By consolidating rights in patents that cover foundational technologies and later improvements, patent aggregators serve an important translational function in the successful development of new technologies and so exert a positive force toward commercialization. For example, aggregation of patents by venture capital groups regularly results in the establishment of corporate entities that focus on the development of new technologies, including those that arise from university research programs. To ensure that the potential benefits of patent aggregation actually are realized, however, license agreements, both primary and secondary, should contain terms (for example, time-limited diligence requirements) that are consistent with the university’s overarching goal of delivering useful products to the public.

In contrast to patent aggregators who add value through technology-appropriate bundling of intellectual property rights, there are also aggregators (the ‘patent trolls’) who acquire rights that cut broadly across one or more technological fields with no real intention of commercializing the technologies. In the extreme case, this kind of aggregator approaches companies with a large bundle of patent rights with the expectation that they license the entire package on the theory that any company that operates in the relevant field(s) must be infringing at least one of the hundreds, or even thousands, of included patents. Daunted by the prospect of committing the human and financial resources needed to perform due diligence sufficient to establish their freedom to operate under each of the bundled patents, many companies in this situation will conclude that they must pay for a license that they may not need. Unlike the original patent owner, who has created the technology and so is reasonably entitled to some economic benefit in recognition for its innovative contribution, the commercial licensee who advances the technology prior to sublicensing, or the added value aggregator who helps overcome legal barriers to product development, the kind of aggregator described in this paragraph typically extracts payments in the absence of any enhancement to the licensed

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technology.<sup>1</sup> Without delving more deeply into the very real issues of patent misuse and bad-faith dealing by such aggregators, suffice it to say that universities would better serve the public interest by ensuring appropriate use of their technology by requiring their licensees to operate under a business model that encourages commercialization and does not rely primarily on threats of infringement litigation to generate revenue.

#### **Point 9**

#### **Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world**

Universities have a social compact with society. As educational and research institutions, it is our responsibility to generate and transmit knowledge, both to our students and the wider society. We have a specific and central role in helping to advance knowledge in many fields and to manage the deployment of resulting innovations for the public benefit. In no field is the importance of doing so clearer than it is in medicine.

Around the world millions of people are suffering and dying from preventable or curable diseases. The failure to prevent or treat disease has many causes. We have a responsibility to try to alleviate it, including finding a way to share the fruits of what we learn globally, at sustainable and affordable prices, for the benefit of the world's poor. There is an increased awareness that responsible licensing includes consideration of the needs of people in developing countries and members of other underserved populations.

The details involved in any agreement provisions attempting to address this issue are complex and will require expert planning and careful negotiation. The application will vary in different contexts. The principle, however, is simple. Universities should strive to construct licensing arrangements in ways that ensure that these underprivileged populations have low- or no-cost access to adequate quantities of these medical innovations.

We recognize that licensing initiatives cannot solve the problem by themselves. Licensing techniques alone, without significant added funding, can, at most, enhance access to medicines for which there is demand in wealthier countries. Diseases that afflict only the global poor have long suffered from lack of investment in research and development: the prospects of profit do not exist to draw commercial development, and public funding for diseases suffered by those who live far away from nations that can afford it is difficult to obtain and sustain. Through thoughtful management and licensing of intellectual property, however, drugs, therapies, and agricultural technologies developed at universities can at least help to alleviate suffering from disease or hunger in historically marginalized population groups.

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<sup>1</sup> A somewhat related issue is that of technology 'flipping', wherein a non-aggregator licensee of a university patent engages in sublicensing without having first advanced the technology, thereby increasing product development costs, potentially jeopardizing eventual product release and availability. This problem can be addressed most effectively by building positive incentives into the license agreement for the licensee to advance the licensed technology itself – e.g., design instrumentation, perform hit-to-lead optimization, file an IND. Such an incentive might be to decrease the percentage of sublicense revenues due to the university as the licensee meets specific milestones.

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### **Summary**

As often is the case, guidance as to implementation of practices that will advance the mission of university technology transfer lags behind our collective awareness of both the needs that exist and our obligations to foster an environment in which they can effectively be met. While we may generally agree on the commonality of the above challenges, a multiplicity of approaches are possible to address the dual goals of nurturing future research and using the innovations of university research to provide the broadest possible benefit to the public. The participating universities put forth these considerations in an aspirational sense and we encourage all of our colleagues to stretch the boundaries of conventional technology transfer practice and share with the greater technology transfer community the insights that they gain in doing so.

## APPENDIX

### 1. Commentary and examples of reserved or retained rights clauses and annotations as discussed in Point 1

#### Example 1

*“Institution retains the right, on behalf of itself and all other non-profit academic research institutions, to practice the Licensed Patent and use Technology for any non-profit purpose, including sponsored research and collaborations. Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution. Institution and any such other institution have the right to publish any information included in the Technology or a Licensed Patent.”*

#### Example 2

*“Nothing in this Agreement will be deemed to limit the right of the Institution to publish any and all technical data resulting from any research performed by the Institution relating to the Invention and to make and use the Invention, Licensed Product, and Licensed Services and to practice the Licensed Method and associated technology and allow other educational and non-profit institutions to do so for educational and research purposes.”*

#### Example 3

*“INSTITUTION reserves the rights, for itself and others, to*

*(i) make and use, solely for NON-COMMERCIAL RESEARCH PURPOSES, the subject matter described and claimed in PATENT RIGHTS and covered by PROPERTY RIGHTS; and*

*(ii) provide to others the BIOLOGICAL MATERIALS;*

*each solely for NON-COMMERCIAL RESEARCH PURPOSES.*

*As used herein, the term “NON-COMMERCIAL RESEARCH PURPOSES” means: Use of PATENT RIGHTS for academic research or other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not use PATENT RIGHTS in*

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*the production or manufacture of products for sale or the performance of services for a fee.”*

Definitions of non-commercial uses should be considered in light of John M.J. Madey v. Duke University. 307 F.3d 1351; 64 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2002), *cert. denied*, 123 S. Ct. 2639; 156 L. Ed. 2d 656; 71 U.S.L.W. 3799. In Madey, the Court of Appeals of the Federal Circuit narrowly interpreted the so-called “experimental use” exception to patent infringement, such that use of patented technologies in the course of “business” activities of universities and other not-for-profit organizations (which activities include education of students, making application for grant funding and patenting of inventions) falls outside its scope. The decision effectively limits permitted uses of unlicensed technology to aimless tinkering with patented technologies, and sets the stage for infringement suits against non-commercial researchers.

To address the Madey issue in recent agreements, we have attempted to make clear that we are reserving rights broader than those of a mere unlicensed party, and that activities held under Madey to be the “business” activities of universities are within the scope of our reserved rights. One current example reads:

*“NON-COMMERCIAL RESEARCH PURPOSES” means: Use or practice of LICENSED PATENT RIGHTS for academic research and other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not involve the production or manufacture of products for sale or the performance of services for a fee. Without limiting the foregoing: (i) “academic research and other not-for-profit or scholarly purposes” includes, in non-limiting fashion, research that leads, or may lead, to patentable or unpatentable inventions that may be licensed or otherwise transferred, either directly or indirectly, to third parties; and (ii) neither (A) receipt of license revenues on account of such inventions or receipt of reimbursements for the costs of preparation and shipping of samples of materials provided to third parties as a professional courtesy, in response to post-publication requests or otherwise in accordance with academic custom nor (B) receipt of funding to cover the direct and/or indirect costs of research, shall constitute sale of products or performance of service for a fee.*

Another case (Merck KGaA v. Integra Lifesciences I, Ltd.) clarifies the scope of a 1984 safe-harbor that exempts some patent users from suit for patent infringement. That case, as reviewed by the Supreme Court, protects infringing activities that are directed at the generation of data in support of FDA filings; however, it affords academic researchers and institutions far less cover than it does corporate infringers who actually are preparing FDA filings. Typically, academic research is too remote from the regulatory filing process to fall within the safe harbor, for which reason it remains crucial to reserve under license agreements all of the rights, for one’s own institution and others, that will enable academic research to proceed unimpeded.

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In drafting reservation of rights clauses and associated definitions, it is always important to keep both the *Madey* and *Merck* decisions in mind.

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## **2. Commentary and examples of exclusive license terms that encourage technology development as discussed in Point 2**

While reservations of rights, above, enable continued innovation in non-profit and governmental laboratories, the suggestions contained in this section are intended to ensure that licensed inventions achieve broad commercialization.

### **2.1 Restrictions on fields of use, territory and term**

- “Field-restricted” licenses grant rights that cover only specific products that a licensee is able, and will undertake a firm commitment, to develop. This approach safeguards the licensee’s investment in a technology, while still leaving it open for development by other parties who do not compete with them (i.e., those who do not operate in the field of the exclusive license grant).
- “Co-exclusive” licenses may be granted to a small, limited number of licensees. Such a licensing structure has the advantage of permitting competitive optimization of a product by spurring each member of the limited pool of licensees to attempt to achieve product launch and market penetration first, or to develop a product that is simply better than that which is marketed by the other licensees. This strategy, in which multiple licensees carry out their research and development efforts in parallel, is particularly justified where there is a significant unmet need for a given product (e.g., a critically-needed diagnostic test or vaccine), as it minimizes the delay inherent in an exclusive license, where failure by the licensee to appropriately develop a product necessitates license termination, identification of a new licensee, negotiation of a new license and re-initiation of product development efforts, perhaps from scratch.
- “Convertible exclusive” licenses permit the licensor to render an exclusive license either co- or non-exclusive if a third party wishes to develop products not yet made available by the exclusive licensee, usually after the initial licensee has had a time-limited opportunity to bring to market the product in question.
- “Convertible nonexclusive” licenses where if additional expressions of interest are not received within a defined period of time, then a non-exclusive license converts to exclusivity, at least within a particular territory or field of use.

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- “Term-limited” licenses, wherein the period of exclusivity is limited to the time necessary to afford the licensee the competitive advantage conferred by early market penetration and to permit them to make a reasonable profit on their investment in research and development, after which the grant converts to that of a nonexclusive license and the market opens up to other companies. Times may vary from a few years for a technology that requires little optimization to much longer times for products requiring many years of development and/or testing to obtain regulatory approval.
- Territorial limitations, where patent rights exist in multiple jurisdictions (e.g., the U.S. or North America; Europe; Asia; major-market countries; or developing countries)

Hybrid license grants that combine features of those described above (e.g., a non-exclusive license with a standstill for a given area of art, for a given period of time) expand the range of creative possibilities for delineating an exclusive licensee’s rights.

## **2.2 Mandatory sublicensing**

The concept is that when the University grants a broad exclusive license then we must have a mechanism to ensure that the market demand is met. As future, perhaps unanticipated, new uses arise we have an obligation to fill new market niches for the public good. This is especially important when our inventions are developed using federal funds. If we become aware of a new use that our licensee is not addressing, or if a third party approaches us for the (licensed) rights in order to develop a new use or other unmet need then we ask our licensee to tell us within 90 days if it will: (a) develop the new application on its own, or (b) grant a sublicense to the third party. If the licensee chooses to develop the new application then it must diligently undertake the new development (and report such progress to us).

Suggested language:

*"If Institution or if a third party discovers and notifies the Institution that the INVENTION is useful for an application covered by the LICENSED FIELD OF USE but for which LICENSED PRODUCTS have not been developed or are not currently under development by LICENSEE, then the Institution shall give written notice to the LICENSEE, except for: 1) information that is subject to restrictions of confidentiality with third parties, and 2) information which originates with Institution personnel who do not assent to its disclosure to LICENSEE.*

*Within ninety (90) days following LICENSEE’s receipt of Institution’s notification LICENSEE shall give Institution written*

*notice stating whether LICENSEE elects to develop LICENSED PRODUCTS for the application.*

*If LICENSEE elects to develop and commercialize the proposed LICENSED PRODUCTS for the new application, LICENSEE shall submit a progress report describing LICENSEE's commercialization efforts in developing the new application every six months to Institution pursuant to Article xx herein."*

## **2.3 Examples of diligence requirements/milestone clauses**

### **Example 1**

*"Milestones. Because the invention is not yet commercially viable as of the Effective Date, Licensee will diligently develop, manufacture, and sell Licensed Product and will diligently develop markets for Licensed Product. In addition, Licensee will meet the milestones shown in Appendix X, and notify Institution in writing as each milestone is met."*

### **Example 2**

A second approach, drawn from a distribution license covering a nucleic acid sequencing reagent, reads:

*X.1 Appendix A sets forth the development and commercialization plan under which LICENSEE intends to develop and sell LICENSED PRODUCTS (the "PLAN"). LICENSEE shall be entitled, from time to time, to make such adjustments to the then-applicable PLAN as LICENSEE believes, in its good faith judgment, are needed in order to improve LICENSEE's ability to meet the PERFORMANCE MILESTONES, as defined below.*

*X.2 LICENSEE shall use reasonable efforts (including, without limitation, commitment of funding and personnel consistent therewith) and/or shall cause its AFFILIATES and/or SUBLICENSEES to use reasonable efforts (including, without limitation, commitment of funding and personnel consistent therewith): (i) to develop LICENSED PRODUCTS in accordance with the PLAN during the periods and within the timetable specified therein, (ii) to introduce LICENSED PRODUCTS into the commercial market and (iii) to market LICENSED PRODUCTS, and to keep each LICENSED PRODUCT reasonably available to the public, following introduction thereof into the market.*

*In addition, LICENSEE shall achieve the following within the designated time periods:*

*(a) On or before January 1, 2009, offer for sale a first LICENSED PRODUCT or SERVICE for nucleic acid sequencing.*

*(b) On or before January 1, 2009, initiate pre-clinical tests of a LICENSED PRODUCT that is a diagnostic kit for the detection of disease in humans.*

*(c) On or before January 1, 2012, offer for sale a first clinical diagnostic LICENSED PRODUCT or SERVICE for the detection of disease in humans.*

*Each of the activities recited in this Paragraph X.2 shall be referred to herein as a "PERFORMANCE MILESTONE".*

*X.3 LICENSEE shall inform INSTITUTION, on or before the deadline for meeting any PERFORMANCE MILESTONE, whether such PERFORMANCE MILESTONE has been met.*

*X.4 No later than sixty (60) days after December 31<sup>st</sup> of each calendar year, LICENSEE shall provide to INSTITUTION a written annual progress report describing progress by LICENSEE and any SUBLICENSEE(s) on research and development, regulatory approvals, manufacturing, sublicensing, marketing and sales during the most recent twelve (12) month period ending December 31<sup>st</sup> and plans for the forthcoming year. If multiple technologies are covered by the license granted hereunder, the progress report shall provide the information set forth above for each technology. LICENSEE also shall provide any additional data INSTITUTION reasonably requires to evaluate LICENSEE's performance and compliance with the terms of this Agreement.*

*X.5 If LICENSEE fails to meet any of its obligations pursuant to Paragraphs X.1 through X.4 of this Agreement, INSTITUTION may notify LICENSEE in writing of LICENSEE's failure and, in such event, shall allow LICENSEE ninety (90) days to cure. LICENSEE's failure to cure such breach within such ninety (90) days shall constitute a material breach of this Agreement and*

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*INSTITUTION shall have the right to terminate this Agreement forthwith.*

A version of Paragraph X.2 drawn from a clinical diagnostics license sets forth the following Performance Milestones:

*(a) within one (1) year after EFFECTIVE DATE, establish a Scientific Advisory Board that will oversee the development of LICENSED PRODUCTS;*

*(b) commence a human clinical trial of a first LICENSED PRODUCT as follows: (i) if the patient data collected in the RESEARCH can be used to support the filing of an investigational device exemption (IDE), within two (2) years of the EFFECTIVE DATE or, (ii) if the patient data collected in the RESEARCH cannot be used to support the filing of an investigational device exemption (IDE), then within three (3) years of the EFFECTIVE DATE; and*

*(c) within two years of commencement of the human clinical trial described in clause (b), conclude analysis of data from such clinical trial and submit to the FDA any and all documentation required for marketing approval of a first LICENSED PRODUCT.*

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### **3. Commentary and examples of limitations on grants of rights in improvements as discussed in Point 3**

#### **Example 1**

*"Patent Rights" means the Valid Claims of, to the extent assigned to or otherwise obtained by the Institution, the United States patents and patent applications, corresponding foreign patents and patent applications (requested under Paragraph xx.x herein), and any reissues, extensions, substitutions, continuations, divisions, and continuation-in-part applications (only to the extent, however, that Valid Claims in the continuation-in-part applications are entirely supported in the specification and entitled to the priority date of the parent application) based on the following patents and patent applications: \_\_\_\_\_.* This definition of Patent Rights excludes any rights in and to New Developments.

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*"New Developments" means inventions, or claims to inventions, which constitute advancements, developments, or improvements, whether or not patentable and whether or not the subject of any patent application, but if patentable, are not sufficiently supported by the specification of a previously-filed patent or patent application within the Patent Rights to be entitled to the priority date of the previously-filed patent or patent application.*

### **Example 2**

*"Continuations-in-Part" means all continuation-in-part patent applications that are filed within two years of the original application and only to the extent that they cover technology disclosed, claimed in and dominated by the original application. The continuations-in-part also do not include continuations-in-part that have different named inventors than the original application or that are burdened by, for example, sponsored research or any other collaboration between Institution and a third party.*

### **Example 3**

*"IMPROVEMENT" means: Any invention the practice of which would infringe at least one claim within the PATENT RIGHTS, which invention is made by at least one or both of the INVENTORS and is owned and controlled by INSTITUTION.*

In a license that contains a field-exclusive grant of rights under PATENT RIGHTS and IMPROVEMENTS, PATENT RIGHTS are defined, in relevant part, as including any claim of a continuation-in-part application that is (i) directed at subject matter described in at least one listed patent application or patent and (ii) is entitled to the priority date thereof. The effect is to grant rights in technology dominated by what exists at the time of license. Tracking of the promised improvements is facilitated by their limitation to the work product of a defined pool of inventors. The institution is further buffered against liability (i.e., for breach of contract on account of inadvertent grants to different parties of overlapping rights or failure to meet obligations as to licensee participation in patent prosecution) by restricting IMPROVEMENTS only to those which the institution owns and controls.

### **Example 4**

*"IMPROVEMENT" means: Any invention the practice of which would infringe at least one claim within the PATENT RIGHTS, which invention is made by at least one or both of the INVENTORS and is owned and controlled by INSTITUTION and is disclosed to the TLO within 3 years of the date of the license and subject to any rights of sponsors in the research leading to the invention.*

## **Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies**

### Background

Universities have a fundamental role in fostering public health. Their greatest contributions may occur through discovery of new knowledge, education of students, and dissemination of knowledge for others to build upon through publications, library collections, and most recently, open courseware.

In addition, universities in the developed world work to facilitate the commercialization of the health-related inventions of academic researchers by developing and disseminating these technologies for the public good. We have created new methods to deploy cutting-edge knowledge toward potential public benefit by enticing risk takers to invest in our early stage technology in the hope of possible downstream commercial applications. In recent years, the licensing practices involved in such commercialization have expanded to promote explicitly global access to university-developed technologies, ensuring that advances in health reach those who need them most.

This sensitivity to global health was reflected in *Nine Points to Consider in Licensing University Technology*, a statement endorsed by nearly seventy universities and other organizations since the spring of 2007. In acknowledgement that conventions in this field are ever evolving, and building on recent experience, the institutions named below believe a more concrete statement of goals as well as licensing practices would help to promote further progress in advancing health in developing countries. The principles reflect the current state of the art that can vary considerably from case to case and from institution to institution. The principles represent the collective voice of the following institutions:

**Association of University Technology Managers (AUTM)**  
**Boston University**  
**Brown University**  
**Harvard University**  
**Oregon Health & Science University**  
**University of Pennsylvania**  
**Yale University**

### Statement of Principles and Strategies

We are committed to implementing effective technology transfer strategies that promote the availability of health-related technologies<sup>1</sup> in developing countries for essential

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<sup>1</sup> The decision about precisely which health-related technologies merit global access licensing is complicated and will be the subject of ongoing evaluation by our organizations. While the principles articulated in this statement currently are directed primarily at therapeutics and vaccines, their application

medical care. This Statement primarily addresses one area of engagement through which universities contribute to the broader effort to address the challenges of global health: the management and licensing of medical innovations. Other approaches include the development and dissemination of new knowledge and technologies, the training of physicians and medical researchers, and the delivery of treatment and care.

Because each license is unique, as it reflects the complexities of its subject technology, our approaches will vary from case to case. Our aspirations are constrained by the limits of the role our early stage technologies can play, as well as the modest leverage our technology transfer professionals can exert, in the complex interplay of a delicate ecosystem in which essential medical innovations are made, developed and distributed. We will, nonetheless, be innovative and persistent in order to achieve our goals through patenting and licensing. Toward these goals, the technology transfer offices of the institutions named above commit to follow these guiding principles:

1. In our negotiations with potential licensees we will make vigorous efforts to develop creative and effective licensing strategies that help to promote global access to health-related technologies:
  - We will apprise potential commercial partners of our institutions' commitment to contribute to the health and well-being of populations throughout the developing world and to cultivate productive relationships with companies that share our values and are able and willing to advance our global health mission; and
  - We will recognize, and fairly balance, both the early-stage nature of our institutions' biomedical innovations and the importance of originator pharmaceutical and biopharmaceutical companies in making the substantial investment needed to demonstrate the safety and efficacy of new medicines which, in turn, will allow them to be brought to market in developing countries.
2. Our intellectual property should not become a barrier to essential health-related technologies needed by patients in developing countries. In cases where universities can fully preclude intellectual property barriers to generic provision by not patenting in developing countries, or by filing and abandoning patents, we will pursue these strategies. Early publication and wide dissemination of results will be encouraged to reduce opportunities for interfering patents. While there are many additional barriers to access, such as insufficient healthcare infrastructure, preventing intellectual property barriers is critical to achieving access.
  - We will seek patent protection for such technologies in developing countries only in a manner that is consistent with our objective of facilitating global access. For example, it may be necessary to account for special circumstances

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to medical diagnostics and devices will be assessed case-by-case on an ongoing basis.

(e.g., in India, China or Brazil) that may warrant patenting in such countries on a case-by-case basis, including but not limited to:

- The existence in a developing country of pharmaceutical manufacturing capacity suitable to support product distribution both within and outside the developing world; or
- The opportunity to gain greater leverage in seeking concessions, such as access to others' intellectual property, that would help to ensure that the health-related technology can be made available affordably; or
- To enable our licensee(s) to implement tiered pricing in those developing countries where a significant private market exists.

3. In those cases where we pursue patent rights, we will negotiate license agreements that draw upon a variety of strategies that seek to align incentives among all stakeholders to promote broad access to health-related technologies in developing countries. Those strategies include, but are not limited to:

- Financial incentives to licensees (e.g., elimination or adjustments to royalty rates);
- Reserved or 'march-in' rights, mandatory sublicenses or non-assert provisions;
- Affirmative obligations of diligence, with license reduction, conversion (i.e., to non-exclusivity) or termination as the penalty for default; and
- Tiered- or other appropriate pricing on a humanitarian basis (e.g., subsidized, at-cost or no-cost).

4. It is not always possible at the time of license negotiation to anticipate all of the ways a health-related technology may be used in developing countries. Accordingly, we will strive to preserve our institutions' future rights to negotiate effective global access terms through implementation of such measures as notice requirements coupled with "agreements to agree."

5. Without regard to the economic value to our respective institutions, we will further support the development of new health-related technologies aimed at diseases that disproportionately burden individuals in the developing world, such as tuberculosis, AIDS, water-borne disease, tropical- and other region-specific ailments and parasitic infections endemic to the developing world, through such means as:

- Continued partnerships with not-for-profit and charitable organizations to provide much-needed collaboration and funding for research in neglected disease areas;
  - Active efforts to attract and secure appropriate commercial partnerships in further support of such research; and
  - Engagement with public-private partnerships that can advance the resulting health-related technologies toward regulatory approval.
6. We will work together to develop and apply meaningful metrics to evaluate the success of our efforts to facilitate global access and support continued innovation with particular relevance to global health.
7. We acknowledge that best practices with respect to ensuring that the fruits of university research benefit those in greatest need are emerging and evolving rapidly. To avoid unintended negative consequences with respect to product development in general, and availability in developing countries in particular, flexibility and creativity must be maintained. We understand that this Statement must be a “living document” which, by its nature, needs to evolve and mature in a manner consistent with - and guided by - our accumulated knowledge. Therefore, consistent with all applicable laws and regulations, we will:
- Share with one another our collective experiences from working with our licensees in implementing these principles to continually advance our goals. To that end, we will cooperate in the creation of:
    - A compendium of best practices, tools and techniques; and
    - A consistent means of reporting on our global access initiatives and activities.
  - Educate others and encourage their consideration, endorsement and application of the principles articulated in this statement; and
  - Revisit these principles on a biennial basis, to ensure that they reflect currently-understood best practices.



UAEM welcomes the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies (SPS) published on November 9, 2009, and signed by 20 institutions as of March, 2010, including the Centers for Disease Control, the National Institute of Health, and the Association of University Technology Managers.

UAEM has worked intensively with universities on global access licensing since 2001, and we commend all of the signatories for their commitment to the principles and strategies laid out in the document. UAEM supports the publication of the SPS, and looks forward to working with its signatories to implement and improve the document over the coming years.

In early 2009, UAEM released the Global Access Licensing Framework (endnote 1) which lays out in detail the type of technology transfer practices that we believe are essential to enhancing global access to university-developed medical technologies. For the reasons explained below, that Framework remains a rigorous standard for achieving global access, and UAEM will continue to advocate for adoption of robust university policies in line with the Framework.

This brief memorandum is intended to help students, scholars, activists, university administrators, and other interested parties understand the strengths and the shortcomings of the SPS.

This memorandum begins by describing the important advancements represented by the SPS. It then identifies the document's shortcomings. Finally, it makes substantive and procedural recommendations for improving the document.

## **An Important Step Forward**

The SPS is an important step forward and those who worked on the principles deserve praise for advancing the global dialogue about the role of universities in enhancing access to medical technologies.

We commend the signatories for building upon the earlier "Nine Points" statement and announcing both concrete principles and specific strategies. In particular, we applaud them for:

- recognizing that university "intellectual property should not become a barrier to essential health-related technologies needed by patients in developing countries" and the corollary commitment either not to patent (or to file and abandon patents) in developing countries in order to "preclude intellectual property barriers to generic provision." The SPS also mentions other innovative licensing strategies, most importantly the use of "reserved or 'march-in' rights, mandatory sublicenses or non-assert provisions."
- adopting language broad enough to cover all therapeutics and vaccines, as opposed to addressing only those for neglected disease
- committing to "develop and apply meaningful metrics"



- committing to revisit the SPS “on a biennial basis, to ensure that [it] reflect[s] currently-understood best practices,” in recognition of the need to continue evolving the statement.
- committing to neglected disease research

We are encouraged that the statement affirmed these principles and strategies and that the signatories are committed to educating others about them and to obtaining additional endorsements.

We particularly emphasize the importance of Point 2 of the SPS, which recognized generic provision as an approach to ensuring access to medicines. Extensive empirical evidence shows that generic competition is unquestionably the most effective means for driving down the price of medicine and thus expanding global access (endnote 2).

Generic provision enlists competitive market forces to develop the cheapest, most efficient ways to get drugs to patients and providers. Generic companies are in the business of supplying a large volume of drugs as cheaply as possible. In contrast, pharmaceutical companies’ drug donation programs do not provide an effective long-term solution—charitable providers have fewer incentives to drive down their costs and do not have the expertise or distribution networks that are necessary to get drugs to patients in resource-limited countries (endnote 3).

In addition, generic provision eliminates the measurement and enforcement problems inherent in “at-cost” approaches (endnote 4). Finally, generic licensing approaches foster important innovations specific to the developing-world. For example, such approaches allow generic companies to create pediatric and heat-stable formulations of new drugs (endnote 5).

## **Room for Significant Improvement and Shortcomings that Must Be Addressed**

Although the SPS represents an important step towards improving global access, it has a number of significant shortcomings. UAEM looks forward to working with current and future signatories to improve and implement the document to account for the issues raised here.

(1) It remains unclear how the signatories propose to treat China, India, and Brazil and countries similarly situated. More than a billion poor people live in those three countries. Although a small portion of these countries’ population may be able to afford to pay monopoly prices for medicines and vaccines, the vast majority cannot. As research institutions dedicated to the public interest, universities cannot prioritize marginal increases in pharmaceutical company profit above the health of hundreds of millions of people. Generic provision is the most effective means to ensure access in these countries. China, India, and Brazil and other countries in similar situations must be covered by universities’ global access licensing policies.

Coverage in these three countries is doubly important because they serve as the pharmacies for the rest of the world’s developing countries. If patents and licensing agreements preclude



pharmaceutical companies in these countries from producing generic drugs for export to the rest of the developing world, then generic versions drugs will not be produced anywhere. Asserting patent protection in these countries would cut off generic production at the source, rendering meaningless any university efforts to avoid creating intellectual property barriers to generic provision in the developing world.

(2) Although Point 2 of the SPS identifies generic provision as one important approach to ensuring access to medicine, the document fails to recognize the preeminent importance of generics as the most effective means for driving down price and expanding access. More broadly, while the SPS lays out an array of useful strategies for improving access in poor countries, it fails to prioritize one strategy over another. All strategies are not equally effective. For example, mandatory sub-licenses, which allow generic sub-licensees to disseminate drugs and vaccines widely, will be far more effective at ensuring access than will reduced royalty rates or due diligence clauses. Open licensing, one approach that the SPS fails to mention, should be recognized as a valuable strategy for expanding access.

In addition, the SPS does not commit its signatories to using global access strategies every time a technology with actual or potential global health applications (endnote 6) is patented or licensed. Pharmaceutical companies that are resistant to the use of global access strategies will only accept such provisions if they become an indispensable component of all university technology transfer agreements.

(3) Although the signatories to the SPS have made the highly commendable commitment that university intellectual property should not become a barrier to patient access to essential health-related technologies, the commitment will be meaningless unless it allows patients to have access to the final end product. To ensure access, universities must also ensure that their licensees' intellectual property does not become such a barrier. If universities do not adopt such pro-active measures, then a licensee may preclude access by filing follow-on product, process, or use patents, utilizing trade secret protection, or exercising data exclusivity.

(4) While the statement is to be commended for incorporating a commitment to metrics and a biennial process for review, it fails to call for greater transparency and accountability in university patenting and licensing. Such features are essential to ensure effective governance at the university level. In cases where redacted licenses cannot be made available, such governance may be accomplished by committees that, like institutional review boards, have public stewardship and review responsibilities. Such committees should be representative of the broader university community, including faculty with expertise in medical research and global health, as well as students and administrators.

(5) It is also essential to recognize that the SPS itself was not developed in a transparent process befitting the world's great universities. While students and faculty were contacted for input, no attempt was made to solicit comments or feedback from the access to medicines community or the broader university stakeholder community during the drafting process of the document. This is true despite the extensive expertise that exists among faculty at the signatory universities and at non-profit organizations with missions closely related to the missions of universities.

(6) Finally, carrying out the SPS's goal of promoting access to health technologies in developing countries will require looking beyond technology transfer to consider the impact universities have in a broader social and political context. In recent years, universities have lobbied actively for legislation that obstructs access to health technologies by strengthening and lengthening monopoly protection on biologics. Also recently, AUTM, one of the SPS signatories, publicly opposed a set of federal recommendations seeking to expand access to research and diagnostic testing performed with gene patents (while protecting product development based on gene patents). Too often, these positions are indistinguishable from those taken by industry, failing to recognize the distinct needs and objectives of universities as not-for-profit research institutions. These actions undercut the commitments made by signatories in the SPS. Universities must work to promote access to knowledge in all areas of university policy in order to fully implement the spirit of this document.

## **Recommendations for Next Steps**

In order for the SPS to represent a truly transformative set of principles and strategies, UAEM recommends that the following modifications be adopted:

(1) The biennial review of the SPS should be undertaken through a transparent and open process that allows for meaningful contribution by the access to medicines advocacy community, academic faculty (especially those scientists responsible for medical discoveries and experts on global health and development and technological innovation), and the broader public. This input should include some mechanism for feedback on revisions to the document during the drafting process.

(2) The next iteration of the SPS should prioritize among strategies by recognizing mechanisms that work best to assure the broadest possible access. The best current evidence makes clear that generic provision, through such approaches such as open licensing and mandatory sub-licensing, is more effective at ensuring access. These more effective approaches should be privileged over royalty reductions or commitments to tiered-pricing.

(3) The next iteration of the SPS should clearly announce the signatories' commitment to ensuring affordable medicines for patients in China, India, and Brazil and similarly situated countries, and to the rights of companies in those countries to produce generic therapies and vaccines for export into other developing countries.

(4) The signatories should provide for effective governance mechanisms. This should include fulfilling the statement's commitment to developing "meaningful metrics to evaluate the success of our efforts to facilitate global access and support continued innovation." These metrics should include operational or process measures of university licensing activities in order to support and further develop technology transfer strategies that prioritize access. Such metrics should measure not only university implementation of SPS principles through concrete licensing terms and provisions, but also the frequency of implementation of such terms for all health-related invention disclosures. The indicators should be clear, publicly-available, and all signatories should be expected to participate. Revisions to the SPS should be responsive to these metrics. UAEM has worked extensively in this area with



signatories and looks forward to further collaboration in developing these metrics. Universities should also promote greater transparency and accountability by making the redacted terms of licenses publicly available, or where such measures are impracticable, establishing review committees that include representation from the broader university community, including medical and global health faculty, students, and administrators.

(5) The SPS should recommend inclusion of medical devices and diagnostics in Global Access Licensing programs.

(6) Individual signatories and university consortia of which signatories are members should stand by the spirit of the statement by promoting access to knowledge in all areas of university policy. This includes maintaining a separate identity from for-profit industry and taking positions on local, national, and international legislation that encourage access to knowledge, in particular knowledge relating to global health.

## **Guidance for UAEM Chapters**

While UAEM sincerely welcomes the SPS, we do not believe that it represents a fully adequate response to the access to medicines crisis on the part of our universities. We therefore believe that after signing the statement universities maintain a responsibility to strengthen their own policies, in line with the UAEM-developed Framework.

When working for a global access licensing policy on campus, universities should be asked to adopt a binding policy in line with the Framework. Chapters should urge universities wishing to sign the SPS to address the shortcomings of the document, which are noted above, by implementing stronger policies on their home campuses. Universities should be urged to utilize transparent policies in adopting the document, including seeking feedback from students, faculty, and other university stakeholder.

The SPS represents a step on the path to achieving equitable access to medicine, but there remains a long way to go. In response, we, the students of our institutions, must continue to be a voice working alongside those unjustly denied access to life-saving medicines in demanding true accountability of these non-profit institutions.



Endnote 1: The Global Access Licensing Framework may be found at <http://essentialmedicine.org/projects/university-technology-transfer>

Endnote 2: Report to Congress by the U.S. Global AIDS Coordinator on the Use of Generic Drugs in the President's Emergency Plan for AIDS Relief, PEPFAR (May 2008), <http://www.pepfar.gov/documents/organization/105842.pdf>.

Endnote 3: E-mail from Daniel Berman et al., MSF, to Robert Lefebvre, Bristol-Myers Squibb (Feb. 8, 2002), <http://www.essentialdrugs.org/edrug/archive/200202/msg00055.php>.

Endnote 4: Amy Kapczynski et al., Addressing Global Health Inequities: An Open Licensing Approach for University Innovations, Berkeley Tech. L.J., 20, 1031 (2005).

Endnote 5: UNITAID and CHAI Announce Lower Prices for AIDS Drugs and Affordable Formulations for Children, UNITAID (Apr. 28, 2008), <http://www.unitaid.eu/index.php/en/NEWS/UNITAID-and-CHAI-announce-Lower-Prices-for-AIDS-Drugsand-Affordable-Formulations-for-Children.html>.

Endnote 6: Global health concerns are not limited to communicable diseases. The World Health Organization reports that 80% of the deaths from chronic diseases such as cardiovascular disease, chronic respiratory diseases, cancer, and diabetes occur in low and middle income countries. Universities Allied for Essential Medicines (UAEM) is sensitive to the opinion that generic production is not essential for medicines indicated for "lifestyle" conditions such as hair loss, acne, or erectile dysfunction. However, even products that are originally licensed for lifestyle indications may later be discovered to have new indications that can have an impact on global health. For this reason, all health technologies should have access provisions in their licenses that automatically allow for generic production for newly discovered global health indications.

## **Global strategy and plan of action on public health, innovation and intellectual property**

The Sixty-first World Health Assembly,

Having considered the report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property;<sup>1</sup>

Recalling the establishment pursuant to resolution WHA59.24 of an intergovernmental working group to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission on Intellectual Property, Innovation and Public Health, and to secure, inter alia, an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;

Recalling resolutions WHA49.14 and WHA52.19 on revised drug strategy, WHA53.14 and WHA54.10 and WHA57.14 on HIV/AIDS, WHA56.27 on intellectual property rights, innovation and public health, WHA58.34 on the Ministerial Summit on Health Research, WHA59.26 on international trade and health; and WHA60.30 on public health, innovation and intellectual property;

Welcoming the progress made by the Intergovernmental Working Group in elaborating the global strategy and the identification of the stakeholders in the plan of action,

1. ADOPTS the global strategy and the agreed parts of the plan of action<sup>2</sup> on public health, innovation and intellectual property, attached to this resolution;

2. URGES Member States:<sup>3</sup>

(1) to implement the specific actions recommended in the global strategy and plan of action on public health, innovation and intellectual property;

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<sup>1</sup> Document A61/9.

<sup>2</sup> On the specific actions and stakeholder components.

<sup>3</sup> Where applicable, also regional economic integration organizations.

- (2) to support actively the wide implementation of the global strategy and plan of action on public health, innovation and intellectual property, and to consider providing adequate resources for its implementation;
3. CALLS UPON relevant international organizations and other relevant stakeholders to give priority within their respective mandates and programmes to implementing the global strategy and plan of action on public health, innovation and intellectual property;
  4. REQUESTS the Director-General in implementing the global strategy and agreed parts of the plan of action without prejudice to the existing mandates:
    - (1) to provide support for Member States, upon request, in implementing the global strategy and plan of action on public health, innovation and intellectual property and in monitoring and evaluating its implementation;
    - (2) to support effective promotion and implementation of the global strategy and plan of action on public health, innovation and intellectual property;
    - (3) to continue to implement the mandates contained in resolutions WHA49.14 and WHA52.19 on revised drug strategy, WHA53.14 and WHA54.10, WHA57.14 and WHA56.30 on HIV/AIDS, WHA56.27 on intellectual property rights, innovation and public health, WHA59.26 on international trade and health, and WHA60.30 on public health, innovation and intellectual property, as well as WHA55.11 on health and sustainable development, WHA55.14 on ensuring accessibility of essential medicines, and WHA60.18 on malaria, including proposal for establishment of World Malaria Day;
    - (4) to finalize urgently the outstanding components of the plan of action, concerning timeframes, progress indicators and estimated funding needs, and to submit the final plan of action including the open paragraphs on stakeholders for consideration by the Sixty-second World Health Assembly through the Executive Board;
    - (5) to coordinate with other relevant international intergovernmental organizations, including WIPO, WTO and UNCTAD, to effectively implement the global strategy and plan of action;
    - (6) notwithstanding the request in subparagraph (4) above, to prepare a quick start programme with adequate budget provision and begin immediately to implement the elements of the global strategy and plan of action on public health, innovation and intellectual property that fall under the responsibility of WHO;
    - (7) to establish urgently a results-oriented and time-limited expert working group to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases, and open to consideration of proposals from Member States, and to submit a progress report to the Sixty-second World Health Assembly and the final report to the Sixty-third World Health Assembly through the Executive Board;
    - (8) to reflect, as appropriate, the global strategy and plan of action on public health, innovation and intellectual property in the further development of WHO's research strategy;

(9) to include adequate resources in the forthcoming proposed programme budgets for effective implementation of the global strategy and plan of action on public health, innovation and intellectual property;

(10) to monitor performance and progress in implementing the global strategy and plan of action on public health, innovation and intellectual property, and to report progress to the Sixty-third World Health Assembly through the Executive Board, and subsequently every two years, until the fulfilment of the time frame, to the Health Assembly, through the Executive Board.



## ANNEX

## Global strategy on public health, innovation and intellectual property

*The context*

1. In resolution WHA59.24 the Health Assembly recognized the growing burden of diseases and conditions that disproportionately affect developing countries, and particularly women and children. Reducing the very high incidence of communicable diseases in those countries is an overriding priority. At the same time, it is important for WHO Member States and the WHO Secretariat to recognize and better address the increasing prevalence of noncommunicable diseases in those countries.
2. Currently, 4.8 billion people live in developing countries, representing 80% of the world population. Of this number, 2.7 billion, representing 43% of the world population, live on less than US\$ 2 a day. Communicable diseases account for 50% of the developing countries' burden of disease. Furthermore, poverty, among other factors, directly affects the acquisition of health products<sup>1</sup> and medical devices, especially in developing countries.
3. Member States,<sup>2</sup> the pharmaceutical industry, charitable foundations and nongovernmental organizations have taken initiatives in recent years to develop new products against diseases affecting developing countries and to increase access to existing health products and medical devices. However, these initiatives are not sufficient to surmount the challenges of meeting the goal of ensuring access and innovation for needed health products and medical devices. More efforts should be made to avoid suffering and reduce preventable mortality and to meet the health-related Millennium Development Goals and to implement States' obligations and commitments arising under applicable international human rights instruments with provisions relevant to health.
4. Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries.
5. Advances in biomedical science have provided opportunities to develop new, affordable, safe and effective health products and medical devices, particularly those that meet public health needs. Urgent efforts should be made to make these advances more affordable, accessible and widely available in developing countries.

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<sup>1</sup> The term "health products" hereafter should be understood to include vaccines, diagnostics and medicines in accordance with resolution WHA59.24.

<sup>2</sup> Where applicable, also regional economic integration organizations.

6. The Report of the Commission on Intellectual Property Rights, Innovation and Public Health provides an analysis of the problems and makes recommendations that form a basis of future actions.
7. Intellectual property rights are an important incentive for the development of new health-care products. This incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain.
8. The Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the agreement does not and should not prevent Members from taking measures to protect public health. The declaration, while reiterating commitment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO Members to protect public health and, in particular, to promote access to medicines for all.
9. Article 7 of the TRIPS agreement states that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation into the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.
10. The Universal Declaration of Human Rights provides that “everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits” and that “everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”.
11. The price of medicines is one of the factors that can impede access to treatment.
12. International intellectual property agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. However, developing countries may face obstacles in the use of these flexibilities. These countries may benefit, inter alia, from technical assistance.

*The aim*

13. The global strategy on public health, innovation and intellectual property aims to promote new thinking on innovation and access to medicines, as well as, based on the recommendations of the CIPIH report, provide a medium-term framework for securing an enhanced and sustainable basis for needs driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for R&D, and estimating funding needs in this area.

14. The elements of the global strategy, which are designed to promote innovation, build capacity, improve access and mobilize resources, will:

- (a) provide an assessment of the public health needs of developing countries with respect to diseases that disproportionately affect developing countries and identify their R&D priorities at the national, regional and international levels
- (b) promote R&D focusing on Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases<sup>1</sup>
- (c) build and improve innovative capacity for research and development, particularly in developing countries
- (d) improve, promote and accelerate transfer of technology between developed and developing countries as well as among developing countries
- (e) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries, protects public health and promotes access to medicines for all, as well as explore and implement, where appropriate, possible incentive schemes for R&D
- (f) improve delivery of and access to all health products and medical devices by effectively overcoming barriers to access
- (g) secure and enhance sustainable financing mechanisms for R&D and to develop and deliver health products and medical devices to address the health needs of developing countries
- (h) develop mechanisms to monitor and evaluate the implementation of the strategy and plan of action, including reporting systems.

#### *The principles*

15. The WHO Constitution states that “the objective of WHO shall be the attainment by all peoples of the highest possible level of health”. Accordingly, the WHO shall play a strategic and central role in the relationship between public health and innovation and intellectual property within its mandates (including those contained in relevant WHA resolutions), capacities and constitutional objectives, bearing in mind those of other relevant intergovernmental organizations. In this context, the WHO, including the regional and, when appropriate, country offices, need to strengthen its institutional competencies and relevant programs in order to play its role in implementing this global strategy with its plan of action.

16. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

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<sup>1</sup> For the purposes of this strategy, the definitions of Type I, II and III diseases, are as referred to by the Commission on Macroeconomics and Health and as further elaborated in the CIPIH report: *Type I diseases* are incident in both rich and poor countries, with large numbers of vulnerable populations in each. *Type II diseases* are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. *Type III diseases* are those that are overwhelmingly or exclusively incident in developing countries. The prevalence of diseases and thereby their categorization in the typology can evolve over time.

17. *(Deleted)*
18. *(Deleted)*
19. The promotion of technological innovation and the transfer of technology should be pursued by all states and supported by intellectual property rights.
20. Intellectual property rights do not and should not prevent Member States from taking measures to protect public health.
21. International negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health.
22. The strengthening of the innovative capacity of developing countries is essential to respond to the needs of public health.
23. Research and development of developed countries should better reflect the health needs of developing countries.
24. The global strategy and the plan of action should promote the development of health products and medical devices needed by Member States, especially developing countries, that are:
- (i) developed in an ethical manner
  - (ii) available in sufficient quantities
  - (iii) effective, safe and of good quality
  - (iv) affordable and accessible
  - (v) used in a rational way.
25. Intellectual property rights are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain.
26. Several factors contribute to the price of health products and medical devices, and public policies should address these factors to increase their affordability and accessibility. Among others, competition and reduction or elimination of import tariffs on these products and devices can contribute to the reduction of prices. Countries should monitor carefully supply and distribution chains and procurement practices to minimize costs that could adversely influence the price of these products and devices.

### *The elements*

#### *Element 1. Prioritizing research and development needs*

27. Health research and development policies of developed countries need to reflect adequately the health needs of developing countries. Gaps in research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases need to be identified

urgently. A better understanding of the developing countries' health needs, and their determinants is essential to drive sustainable research and development on new and existing products.

28. The actions to be taken to prioritize research and development needs are as follows:

(1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries

*(a) develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific R&D needs in relation to Type I diseases*

*(b) disseminate information on identified gaps, and evaluate their consequences on public health*

*(c) provide an assessment of identified gaps at different levels – national, regional and international – to guide research aimed at developing affordable and therapeutically sound products to meet public health needs.*

(1.2) formulating explicit prioritized strategies for research and development at country and regional and inter-regional levels

*(a) set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments*

*(b) conduct research appropriate for resource-poor settings and research on technologically appropriate products for addressing public health needs to combat diseases in developing countries*

*(c) include research and development needs on health systems in a prioritized strategy*

*(d) urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for R&D to address public health need*

*(e) increase overall R&D efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public health needs, user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability).*

(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples

*(a) set research priorities in traditional medicine*

*(b) support developing countries to build their capacity in research and development in traditional medicine*

- (c) *promote international cooperation and the ethical conduct of research*
- (d) *support South-South cooperation in information exchange and research activities*
- (e) *support early-stage drug research and development in traditional medicine systems in developing countries.*

### ***Element 2. Promoting research and development***

29. There are many determinants of innovation capacity. Political, economic and social institutions in each country should participate in the development of health research policy, taking into consideration their own realities and needs. The range of measures to promote, coordinate and finance public and private research in both developed and developing countries into Type II and Type III diseases and into the needs of developing countries in relation to Type I diseases needs to be substantially enhanced. Greater investment, in both developed and developing countries, is essential.

30. The actions to be taken to promote research and development are as follows:

(2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area

- (a) *promote cooperation between private and public sectors on research and development*
- (b) *provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding*
- (c) *support governments in establishing health-related innovation in developing countries.*

(2.2) promoting upstream research and product development in developing countries

- (a) *support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products*
- (b) *promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries*
- (c) *identify incentives and barriers, including intellectual property-related provisions, at different levels – national, regional and international – that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools*
- (d) *support basic and applied scientific research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases*

- (e) *support early-stage drug research and development in developing countries*
- (f) *build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international ethical standards and the needs of developing countries*
- (g) *promote the generation, transfer, acquisition upon agreed terms and voluntary sharing, of new knowledge and technologies, consistent with national law and international agreements, to facilitate the development of new health products and medical devices to tackle the health problems of developing countries.*

(2.3) *improving cooperation, participation and coordination of health and biomedical research and development*

- (a) *stimulate and improve global cooperation and coordination in research and development, in order to optimize resources*
- (b) *enhance existing fora and examine the need for new mechanisms, in order to improve the coordination and sharing of information on research and development activities*
- (c) *encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, an essential health and biomedical R&D treaty*
- (d) *support active participation of developing countries in building technological capacity*
- (e) *promote the active participation of developing countries in the innovation process.*

(2.4) *Promoting greater access to knowledge and technology relevant to meet public health needs of developing countries*

- (a) *promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant publications by universities, institutes and technical centers, especially in developing countries*
- (b) *promote public access to the results of government funded research, by strongly encouraging that all investigators funded by governments submit to an open access database an electronic version of their final, peer-reviewed manuscripts*
- (c) *support the creation of voluntary open databases and compound libraries including voluntary provision of access to drug leads identified through the screening of such compound libraries*
- (d) *encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms*

*(e) consider, where appropriate, use of a “research exception” to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights.*

(2.5) Establishing and strengthening national and regional coordinating bodies on research and development

*(a) develop and coordinate a research and development agenda*

*(b) facilitate the dissemination and use of research and development outcomes.*

### ***Element 3. Building and improving innovative capacity***

31. There is a need to frame and develop and support effective policies that promote the development of capacities in developing countries related to health innovation. Key areas for investment are capacities relating to science and technology, local production of pharmaceuticals, clinical trials, regulation, intellectual property and traditional medicine.

32. The actions to be taken to build and improve innovative capacity are as follows:

(3.1) building capacity of developing countries to meet research and development needs for health products

*(a) support investment by developing countries in human resources and knowledge bases, especially in education and training including in public health*

*(b) support existing and new research and development groups and institutions, including regional centres of excellence, in developing countries*

*(c) strengthen health surveillance and information systems.*

(3.2) Framing, developing and supporting effective policies that promote the development of capacities for health innovation

*(a) establish and strengthen regulatory capacity in developing countries*

*(b) strengthen human resources in research and development in developing countries through long-term national capacity building plans*

*(c) encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries*

*(d) urge Member States to establish mechanisms to mitigate the adverse impact of the loss of health personnel in developing countries, particularly researchers, through migration, including by ways for both receiving and originating countries to support the strengthening of national health and research systems, in particular human resource development in the countries of origin, taking into account the work of WHO and other relevant organizations.*

(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries

- (a) develop successful health innovation models in developing innovative capacity*
- (b) intensify North–South and South–South partnerships and networks to support capacity building*
- (c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries.*

(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments

- (a) establish and strengthen national and regional policies to develop, support, promote traditional medicine*
- (b) encourage and promote policies on innovation in the field of traditional medicine*
- (c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards*
- (d) encourage research on mechanisms for action and pharmacokinetics of traditional medicine*
- (e) promote South-South collaboration in traditional medicine*
- (f) formulate and disseminate guidelines on good manufacturing practices for traditional medicines and laying down evidence-based standards for quality and safety evaluation.*

(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation

- (a) encourage the establishment of award schemes for health-related innovation*
- (b) encourage recognition of innovation for purposes of career advancement for health researchers.*

#### ***Element 4. Transfer of technology***

33. North–South and South–South development cooperation, partnerships and networks need to be supported in order to build and improve transfer of technology related to health innovation. Article 7 of the TRIPS Agreement states that the protection and the enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to the balance of rights and obligations.

34. The actions to be taken in relation to this element are as follows:

(4.1) promoting transfer of technology and the production of health products in developing countries

*(a) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development, particularly in developing countries*

*(b) promote transfer of technology and production of health products in developing countries through investment and capacity building*

*(c) promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate.*

(4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development

*(a) encourage North–South and South–South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry*

*(b) facilitate local and regional networks for collaboration on research and development and transfer of technology*

*(c) continue to promote and encourage technology transfer to least-developed country members of the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights*

*(d) promote the necessary training to increase absorptive capacity for technology transfer.*

(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies

*(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices*

*(b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific R&D needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the TRIPS agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health.*

***Element 5. Application and management of intellectual property to contribute to innovation and promote public health***

35. The international regimes on intellectual property aim, inter alia, to provide incentives for the development of new health products. However, incentive schemes for research and development, especially on Type II and Type III diseases and the specific R&D needs of developing countries in respect of Type I diseases, need to be explored and implemented, where appropriate. There is a crucial need to strengthen innovation capacity as well as capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the TRIPS Agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health.

36. The actions to be taken in relation to this element are as follows:

(5.1) supporting information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries

*(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS agreement and other WTO instruments related to that agreement and meets the specific R&D needs of developing countries*

*(b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries*

*(c) facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents.*

*(d) stimulate collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions, in order to promote information sharing relevant to public health needs*

*(e) strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement*

*(f) facilitate, where feasible and appropriate, possible access to traditional medicinal knowledge information for use as prior art in examination of patents, including, where appropriate, the inclusion of traditional medicinal knowledge information in digital libraries*

(g) *promote active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs*

(h) *strengthen efforts to effectively coordinate work relating to intellectual property and public health among the Secretariats and governing bodies of relevant regional and international organizations to facilitate dialogue and dissemination of information to countries.*

(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products

(a) *consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003*

(b) *take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States*

(c) *take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003*

(d) *consider, where appropriate, taking necessary measures in countries with manufacturing capacity to, facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003*

(e) *encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate legislative and other measures to help prevent misappropriation of such traditional knowledge.*

(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases

(a) *explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through*

*the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries*

*(b) (Deleted)*

*(c) (Deleted)*

*(d) (Deleted)*

*(e) (Deleted)*

#### ***Element 6. Improving delivery and access***

37. Support for and strengthening of health systems is vital for the success of the strategy, as are the stimulation of competition and the adoption of appropriate pricing and taxation policies for health products. Mechanisms to regulate the safety, quality and efficacy of medicines and other health products, coupled with adherence to good manufacturing practices and effective supply chain management, are critical components of a well-functioning health system.

38. International agreements that may have an impact on access to health products in developing countries need to be regularly monitored with respect to their development and application. Any flexibilities in such agreements, including those contained in the TRIPS agreement and recognized by the Doha Declaration on the TRIPS Agreement and Public Health that would permit improved access need to be considered for action by national authorities in the light of the circumstances in their countries. The impact of such actions on innovation needs to be monitored.

39. The actions to be taken to improve delivery and access are as follows:

(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system

*(a) invest in developing health-delivery infrastructure and encourage financing of health products*

*(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016<sup>1</sup>*

*(c) prioritize health care in national agendas*

*(d) encourage health authorities to improve domestic management capacities in order to improve delivery and access to medicines and other health products with quality,*

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<sup>1</sup> In line with the extension, provided to least-developed countries, by Article 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

*efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines*

- (e) increase investment in human resource development in the health sector*
- (f) develop effective country poverty reduction strategies that contain clear health objectives*
- (g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate.*

(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices

- (a) develop and/or strengthen the capacity of national regulatory authorities to monitor the quality, safety and efficacy of health products while sustaining ethical review standards*
- (b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in high disease-burden settings*
- (c) comply with good manufacturing practices for safety standards, efficacy and quality of health products*
- (d) strengthen the WHO pre-qualification programme*
- (e) (Deleted)*
- (f) where appropriate, initiate programmed actions on regional and sub-regional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals*
- (g) promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines*
- (h) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines evaluation and approval.*

(6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs

- (a) support the production and introduction of generic versions, in particular of essential medicines, in developing countries, through the development of national legislation and/or policies that encourage generic production and entry, including a “regulatory exception” or “Bolar”-type provision, and which are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement*

- (b) *frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements*
- (c) *consider where appropriate, inter alia, the reduction or elimination of import tariffs on health products and medical devices and the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access*
- (d) *encourage pharmaceutical companies and other health-related industries to consider policies, including differential pricing policies, that are conducive to promoting access to quality, safe, efficacious and affordable health products in developing countries, consistent with national law*
- (e) *consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products; further support WHO's ongoing work on pharmaceutical pricing*
- (f) *Consider, where necessary, and provided that they are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products*
- (g) *increase information among policy makers, users, doctors and pharmacists regarding generic products.*

#### ***Element 7. Promoting sustainable financing mechanisms***

40. In recent years donors have provided substantial additional financing to make health products available in developing countries through new mechanisms. Additional financing has also been secured for research and development activities relevant for the control and treatment of the diseases covered by this strategy. Nonetheless, further funding on a sustainable basis is essential to support a long-term research and development effort for products to meet the health needs of developing countries. The most serious gaps in financing for health products and research and development covered by this strategy need to be identified and analysed.
41. It is important to make maximum use of and complement as appropriate and feasible current initiatives, thereby contributing to a flow of resources into innovation and implementation.
42. The actions to be taken to promote sustainable financing mechanisms are as follows:
- (7.1) endeavouring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries
- (a) *establish a results-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and*

*innovative sources of financing to stimulate R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases*

*(b) consider channelling additional funds to health-oriented research organizations as appropriate in both the private and public sector of developing countries and promote good financial management to maximize its effectiveness as recommended by the resolution WHA58.34*

*(c) create a database of possible sources of financing for R & D.*

(7.2) facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public-private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices

*(a) document and disseminate best practices in public-private and product development partnerships*

*(b) develop tools to periodically assess performance of public-private and product development partnerships*

*(c) support public-private and product development partnerships and other appropriate research and development initiatives in developing countries.*

#### ***Element 8. Establishing monitoring and reporting systems***

43. Systems should be established to monitor performance and progress of this strategy. A progress report will be submitted to the Health Assembly through the Executive Board every two years. A comprehensive evaluation of the strategy will be undertaken after four years.

44. Steps to be taken will include:

(8.1) measuring performance and progress towards objectives contained in the strategy and plan of action

*(a) establish systems to monitor performance and progress of the implementation of each element of the global strategy and plan of action*

*(b) monitor and report periodically to WHO's governing bodies on the gaps and needs related to health products and medical devices in developed and developing countries*

*(c) continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the report of the Commission on Intellectual Property Rights, Innovation and Public Health, on the development of, and access to, health care products, and to report thereon to the Health Assembly*

*(d) monitor and report on the impact of incentive mechanisms on innovation of and access to health products and medical devices*

*(e) monitor and report on investment in research and development to address the health needs of developing countries.*

## Appendix

**Plan of Action****Explanatory notes****\* Stakeholder(s)**

Lead stakeholders are indicated by bold typeface.

Reference to **Governments** means that WHO Member States<sup>1</sup> are urged to take action.

**WHO** means that the Director-General is requested to take action.

**Other international intergovernmental organizations**, both global and regional, means that WHO Member States, or WHO Secretariat as mandated by Member States through this plan of action, invite these organizations to take action. Member States are urged to raise appropriate issues in the governing bodies of the organizations. The Director-General is requested to bring this global strategy and plan of action to the attention of all relevant international organizations and invite them to consider the relevant provisions of this global strategy and plan of action.

**Other relevant stakeholders** means that WHO Member States, or WHO Secretariat as mandated by its Member States through this plan of action, invite these relevant actors to take action. These include inter alia, as appropriate, international and national research institutions; academia; national and regional regulatory agencies; relevant health-related industries, including both public and private; public-private partnerships; public-private and product development partnerships; nongovernmental organizations; concerned communities; development partners; charitable foundations; publishers; research and development groups; and regional bodies; and regional organizations.

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<sup>1</sup> Where applicable, also regional economic integration organizations.

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
<b>Element 1. Prioritizing research and development needs</b> (1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries	(a) develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific R&D needs in relation to Type I diseases (b) disseminate information on identified gaps, and evaluate their consequences on public health (c) provide an assessment of identified gaps at different levels – national, regional and international – to guide research aimed at developing affordable and therapeutically sound products to meet public health needs	<b>WHO</b> ; Governments; other relevant stakeholders  <b>WHO</b> ; Governments; other relevant stakeholders  <b>WHO</b> ; Governments; other relevant stakeholders	2008-2015  2008-2015  2008-2015
(1.2) formulating explicit prioritized strategies for research and development at country and regional and inter-regional levels	(a) set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments (b) conduct research appropriate for resource-poor settings and research on technologically appropriate products for addressing public health needs to combat diseases in developing countries (c) include research and development needs on health systems in a prioritized strategy	<b>Governments; regional organizations</b>  Governments; WHO; other relevant stakeholders (including academia, relevant health-related industries, national research institutions and public-private partnerships)  Governments; WHO; other relevant stakeholders (including academia, national research institutions, and public-private partnerships)	2008–2015  2008–2015  2008-2015

	<p>(d) urge the leadership and commitment of governmental, regional and international organizations and the private sector in determining priorities for R&amp;D to address public health needs</p>	<p><b>WHO</b>; Governments; other international intergovernmental organizations; other relevant stakeholders (including private sector)</p>	2008-2015
	<p>(e) increase overall R&amp;D efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public health needs, user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability)</p>	<p><b>Governments</b>; WHO; other relevant stakeholders (including academia, relevant health related industries, national research institutions, and public-private partnerships)</p>	2008-2015
<p>(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples</p>	<p>(a) set research priorities in traditional medicine</p>	<p><b>Governments</b>; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; national research institutions; public-private partnerships; and concerned communities)</p>	2008-2015
	<p>(b) support developing countries to build their capacity in research and development in traditional medicine</p>	<p><b>Governments</b>; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia, relevant health-related industries, national research institutions, public-private partnerships)</p>	2008-2015
	<p>(c) promote international cooperation and the ethical conduct of research</p>	<p><b>Governments</b>; WHO; other international intergovernmental organizations; other relevant stakeholders</p>	2008-2015

<b>Elements and sub-elements</b>		<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 2. Promoting research and development</b>			
(2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area	(d) support South-South cooperation in information exchange and research activities	<b>Governments; WHO; other international intergovernmental organizations; regional organizations; other relevant stakeholders</b>	2008-2015
	(e) support early-stage drug research and development in traditional medicine systems in developing countries	<b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders</b>	2008-2015
(2.2) promoting upstream research and product development in developing countries	<b>Specific actions</b>		
	a) promote cooperation between private and public sectors on research and development	<b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders</b>	2008-2015
	b) provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding	<b>Governments; regional organizations; WHO (technical assistance); other relevant stakeholders</b>	2008-2015
	c) support governments in establishing health-related innovation in developing countries	<b>Governments; regional organizations; WHO (technical assistance); other relevant stakeholders</b>	2008-2015
	a) support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products	<b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders</b>	2008-2015
b) promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries	<b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders</b>	2008-2015	

<p>(c) identify incentives and barriers, including intellectual property-related provisions, at different levels – national, regional and international – that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools</p>	<p><b>Governments; WHO;</b> other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders</p>	<p>2008-2015</p>
<p>(d) support basic and applied scientific research on Type II and Type III diseases and on the specific R&amp;D needs of developing countries in relation to Type I diseases</p>	<p><b>Governments; WHO;</b> other international intergovernmental organizations; other relevant stakeholders</p>	<p>2008-2015</p>
<p>(e) support early-stage drug research and development in developing countries</p>	<p><b>Governments; WHO;</b> other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, academia, international and national research institutions; donor agencies; development partners; nongovernmental organizations)</p>	<p>2008–2015</p>
<p>(f) build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international ethical standards and the needs of developing countries</p>	<p><b>Governments; WHO;</b> other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries; academia; development partners; charitable foundations; public-private partnerships; nongovernmental organizations)</p>	<p>2008–2015</p>

	<p>(g) promote the generation, transfer, acquisition upon agreed terms and voluntary sharing, of new knowledge and technologies, consistent with national law and international agreements, to facilitate the development of new health products and medical devices to tackle the health problems of developing countries</p>	<p><b>Governments; WHO; other international intergovernmental organizations, other relevant stakeholders (including: academia, international and national research institution; relevant health-related industries and development partners)</b></p>	
<p>(2.3) improving cooperation, participation and coordination of health and biomedical research and development</p>	<p>(a) stimulate and improve global cooperation and coordination in research and development, in order to optimize resources</p> <p>(b) enhance existing fora and examine the need for new mechanisms, in order to improve the coordination and sharing of information on research and development activities</p> <p>(c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&amp;D, including inter alia, an essential health and biomedical R&amp;D treaty</p> <p>(d) support active participation of developing countries in building technological capacity</p> <p>(e) promote the active participation of developing countries in the innovation process</p>	<p><b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders</b></p> <p><b>Governments; WHO; other relevant stakeholders</b></p> <p><b>Interested Governments; [WHO]; other relevant stakeholders (including nongovernmental organizations)</b></p> <p><b>Governments; WHO; other relevant stakeholders</b></p> <p><b>Governments; WHO; other relevant stakeholders</b></p>	<p>2008–2015</p> <p>2008–2015</p> <p>[2008–2010]</p> <p>2008-2015</p> <p>2008-2015</p> <p>2008-2015</p>
<p>(2.4) promoting greater access to knowledge and technology relevant to meet public health needs of developing countries</p>	<p>(a) promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant</p>	<p><b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders</b></p>	<p>2008-2015</p>

<p>publications by universities, institutes and technical centres, especially in developing countries</p>	<p>(b) promote public access to the results of government funded research, by strongly encouraging that all investigators funded by governments submit to an open access database an electronic version of their final, peer-reviewed manuscripts</p>	<p>(including academia, research institutions, relevant health-related industries; nongovernmental organizations; publishers)</p>	<p>2008-2015</p>
<p>(c) support the creation of voluntary open databases and compound libraries including voluntary provision of access to drug leads identified through the screening of such compound libraries</p>	<p>(d) encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms</p>	<p><b>Governments; WHO;</b> other international intergovernmental organizations (including WIPO); other relevant stakeholders (including academia and research institutions)</p>	<p>2008-2015</p>
<p>(e) consider, where appropriate, use of a “research exception” to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights</p>	<p><b>Governments</b></p>	<p><b>Governments;</b> WHO; other international intergovernmental organizations; other relevant stakeholders (including academia and national research institutions)</p>	<p>2008-2015</p>

2.5 establishing and strengthening national and regional coordinating bodies on research and development	(a) develop and coordinate a research and development agenda	Governments; regional organizations; WHO; other relevant stakeholders	2008–2015
	(b) facilitate the dissemination and use of research and development outcomes	Governments; regional organizations; WHO; other relevant stakeholders	2008–2015
<b>Elements and sub-elements</b>		<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 3. Building and improving innovative capacity</b>			
(3.1) building capacity of developing countries to meet research and development needs for health products	(a) support investment by developing countries in human resources and knowledge bases, especially in education and training including in public health	<b>Governments</b> ; other international intergovernmental organizations; other relevant stakeholders (including development partners)	2008–2015
	(b) support existing and new research and development groups and institutions, including regional centres of excellence, in developing countries	<b>Governments</b> ; other international intergovernmental organizations; other relevant stakeholders (including research and development groups, relevant health-related industries and development partners)	2008–2015
(3.2) framing, developing and supporting effective policies that promote the development of capacities for health innovation	(c) strengthen health surveillance and information systems	<b>Governments</b> ; <b>WHO</b> ; other international intergovernmental organizations; other relevant stakeholders (including nongovernmental organizations, research institutions, academia)	2008–2015
	(a) establish and strengthen regulatory capacity in developing countries	<b>Governments</b> ; <b>WHO</b> ; other relevant stakeholders (including national and regional regulatory agencies)	2008–2015

	(b) strengthen human resources in research and development in developing countries through long-term national capacity building plans	<b>Governments</b> ; other international intergovernmental organizations; other relevant stakeholders (including development partners; international and national research institutions)	2008–2015
	(c) encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries	<b>Governments</b> ; WHO; other international intergovernmental organizations (including International Organization for Migration and ILO); other relevant stakeholders	2008–2015
	(d) urge Member States to establish mechanisms to mitigate the adverse impact of the loss of health personnel in developing countries, particularly researchers, through migration, including by ways for both receiving and originating countries to support the strengthening of national health and research systems, in particular human resource development in the countries of origin, taking into account the work of WHO and other relevant organizations	<b>Governments</b>	2008–2015
(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries	(a) develop successful health innovation models in developing innovative capacity	<b>Governments</b> ; WHO; other international intergovernmental organizations (including WIPO, OECD and UNCTAD); other relevant stakeholders (including academia; research institutions; health related industries and developmental partners)	2008–2015

	<p>(b) intensify North–South and South–South partnerships and networks to support capacity building</p>	<p><b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders</b> (including academia, research institutions, relevant health-related industries)</p>	2008–2015
	<p>(c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries</p>	<p><b>Governments; WHO; other relevant stakeholders</b> (including academia and research institutions)</p>	2008–2015
<p>(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments</p>	<p>(a) establish and strengthen national and regional policies to develop, support, promote traditional medicine</p>	<p><b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders</b> (including concerned communities)</p>	2008–2015
	<p>(b) encourage and promote policies on innovation in the field of traditional medicine</p>	<p><b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders</b> (including international and national research institutions, <b>concerned communities</b>)</p>	
	<p>(c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards</p>	<p><b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders</b> (including national and regional regulatory agencies; international and national research institutions; development partners; concerned communities)</p>	

	<p><b>Governments; WHO;</b> other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institutions; relevant health-related industries; concerned communities)</p>	<p>(d) encourage research on mechanisms for action and pharmacokinetics of traditional medicine</p>	
2008–2015	<p><b>Governments; WHO;</b> other international intergovernmental organizations; other relevant stakeholders (including research institutions, regional bodies, academia)</p>	<p>(e) promote South-South collaboration in traditional medicine</p>	
2008–2015	<p><b>Governments; WHO;</b> other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies, relevant health-related industries)</p>	<p>(f) formulate and disseminate guidelines on good manufacturing practices for traditional medicines and laying down evidence-based standards for quality and safety evaluation</p>	

<p>(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation</p>	<p>(a) encourage the establishment of award schemes for health-related innovation</p>	<p><b>Governments;</b> [WHO]/[WHD]/[WHO]; other international intergovernmental organizations [(including WIPO)]; other relevant stakeholders (including academia; international and national research institutions; development partners; charitable foundations)</p>	
<p><b>Element 4. Transfer of technology</b></p> <p>(4.1) promoting transfer of technology and the production of health products in developing countries</p>	<p>(a) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development, particularly in developing countries</p> <p>(b) promote transfer of technology and production of health products in developing countries through investment and capacity building</p>	<p><b>Governments;</b> WHO; other international intergovernmental organizations (including WTO, UNCTAD, UNIDO, WIPO); other relevant stakeholders (including; international and national research institutions; relevant health-related industries)</p> <p><b>Governments;</b> WHO; other intergovernmental organizations; other relevant stakeholders (including <b>health-related industries</b>)</p>	<p><b>Time frame</b></p>

	(c) promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate	<b>Governments</b> ; WHO; other international intergovernmental organizations; other relevant stakeholders (including <b>relevant health-related industries</b> ; academia; nongovernmental organizations; development partners; charitable foundations)	2008–2015
(4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development	(a) encourage North–South and South–South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry	<b>Governments</b> ; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including relevant health-related industries; international and national research institutions; academia; nongovernmental organizations; development partners)	2008–2015
	(b) facilitate local and regional networks for collaboration on research and development and transfer of technology	<b>Governments</b> ; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, national research institutions, academia; nongovernmental organizations)	2008–2015
	(c) continue to promote and encourage technology transfer to least-developed country members of the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights	<b>Governments</b>	2008–2015

	(d) promote the necessary training to increase absorptive capacity for technology transfer	<b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including research institutions)</b>	2008–2015
(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies	(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices	<b>Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including international and national research institution; relevant health-related industries, nongovernmental organizations; academia)</b>	
	(b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific R&D needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the TRIPS agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health	<b>Governments; WHO; other international intergovernmental organizations (including WIPO, WTO); other relevant stakeholders (including health-related industries)</b>	

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
<p><b>Element 5. Application and Management of intellectual property to innovation and promote public health</b></p> <p>(5.1) support information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries</p>	<p>(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS agreement and other WTO instruments related to that agreement and meets the specific R&amp;D needs of developing countries</p>	<p>[Governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD); other relevant stakeholders (including international and national research institutions and development partners)]</p> <p>[Governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD); other relevant stakeholders (including international and national research institutions and development partners)]</p>	
<p>(b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries</p>	<p>[Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including international and national research institutions and development partners)]</p>	<p>[Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including international and national research institutions and development partners)]</p>	
<p>(c) Facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-</p>	<p>[Governments]; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including international and national research institutions and development partners)]</p>	<p>[Governments]; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including international and national research institutions and development partners)]</p>	

	related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents.	international and national research institutions and development partners]]	
	(d) stimulate collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions, in order to promote information sharing relevant to public health needs	<b>Governments;</b> WHO; Other international intergovernmental organizations; Other relevant stakeholders (including academia; international and national research institutions; development agencies; nongovernmental organizations; relevant health-related industries)	
	(e) strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement	Governments; <b>[WHO]/[WHO]</b> ; other international intergovernmental organizations (including <b>[WIPO]/[WIPO]</b> , <b>[WTO]/[WTO]</b> , <b>[UNCTAD]/[UNCTAD]</b> ); other relevant stakeholders (including international and national research institutions and development partners)	
	(f) facilitate, where feasible and appropriate, possible access to traditional medicinal knowledge information for use as prior art in examination of patents, including,	<b>Governments;</b> [WHO; other international intergovernmental organizations; other relevant stakeholders (including <b>concerned communities</b> )	

		<p>where appropriate, the inclusion of traditional medicinal knowledge information in digital libraries</p> <p>(g) promote active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs</p>	
<p><b>Governments</b></p>			
<p><b>Governments;</b> WHO; other international intergovernmental organizations (including WIPO, WTO, and UNCTAD)</p>	<p>(h) strengthen efforts to effectively coordinate work relating to intellectual property and public health among the Secretariats and governing bodies of relevant regional and international organizations to facilitate dialogue and dissemination of information to countries</p>		
<p><b>Governments;</b> WHO; Other international intergovernmental organizations (including WIPO, WTO and UNCTAD)</p>	<p>(a) consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003</p>	<p>(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products</p>	

	<p><b>Governments;</b> [WHO; Other international intergovernmental organizations (including WIPO, WTO and UNCTAD)]</p>	<p>(b) Take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States</p>	
	<p><b>Governments</b></p>	<p>(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003</p>	
	<p><b>Governments</b></p>	<p>(d) consider, where appropriate, taking necessary measures in countries with manufacturing capacity to, facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003</p>	

	<p>(e) encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate legislative and other measures to help prevent misappropriation of such traditional knowledge</p>	<p><b>Governments;</b> WHO; other international intergovernmental organizations (including WIPO, WTO, UNEP/Secretariat of the Convention on Biological Diversity); other relevant stakeholders (including <b>concerned communities</b>)</p>	
<p>(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases</p>	<p>(a) explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries</p>	<p><b>[Governments;</b> [WHO]/[WHO]; other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; development partners; charitable foundations; relevant health related industries; nongovernmental organizations)]</p>	
<p><b>Elements and sub-elements</b></p>		<p><b>Stakeholder(s)*</b></p>	<p><b>Time frame</b></p>
<p><b>Element 6. Improving delivery and access</b></p>			
<p>(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system</p>	<p>(a) invest in developing health-delivery infrastructure and encourage financing of health products</p>	<p><b>Governments;</b> WHO; other international intergovernmental stakeholders (including development partners, charitable foundations, private sector and relevant health-related industries)</p>	

	<p>(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016<sup>1</sup></p>	<p><b>Governments;</b> WHO; other international intergovernmental organizations (including WTO); other relevant stakeholders</p>	
	<p>(c) prioritize health care in national agendas</p>	<p><b>Governments</b></p>	<p>2008–2015</p>
	<p>(d) encourage health authorities to improve domestic management capacities in order to improve delivery and access to medicines and other health products with quality, efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines</p>	<p><b>Governments; WHO</b></p>	
	<p>(e) increase investment in human resource development in the health sector</p>	<p><b>Governments;</b> WHO; other international intergovernmental stakeholders (including development partners; nongovernmental organizations; charitable foundations)</p>	<p>2008–2015</p>
	<p>(f) develop effective country poverty reduction strategies that contain clear health objectives</p>	<p><b>Governments;</b> other relevant stakeholders (including development partners)</p>	<p>2008–2015</p>

<sup>1</sup> In line with the extension, provided to least-developed countries, by Article 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

			<b>Governments; WHO;</b> other international intergovernmental organizations; other relevant stakeholders	
(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices	(g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate	(a) develop and/or strengthen the capacity of national regulatory authorities to monitor the quality, safety and efficacy of health products while sustaining ethical review standards	<b>Governments; WHO;</b> other relevant stakeholders (including national and regional regulatory agencies and development partners)	
	(b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in high disease-burden settings	(c) comply with good manufacturing practices for safety standards, efficacy and quality of health products	<b>Governments; WHO;</b> other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; nongovernmental organizations, development partners and charitable foundations)	2008–2015
	(d) strengthen the WHO pre-qualification programme		<b>Governments; WHO,</b> other international intergovernmental organizations; other relevant stakeholders (including development partners)	

		(f) where appropriate, initiate programmed actions on regional and sub-regional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals	<b>Governments; [WHO]/[WHO];</b> other relevant stakeholders (including national and regional regulatory agencies, regional bodies and development partners)	
		(g) promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines	<b>Governments; WHO;</b> other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies)	
		(h) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines evaluation and approval	<b>Governments; WHO;</b> other relevant stakeholders (including national and regional regulatory agencies, international and national research institutions, regional bodies and development partners)	
(6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs		(a) support the production and introduction of generic versions, in particular of essential medicines, in developing countries, through the development of national legislation and/or policies that encourage generic production and entry, including a "regulatory exception" or	<b>Governments</b>	

		<p>“Bolar”-type provision, and which are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement</p>	
	<p><b>Governments;</b> WHO; other international intergovernmental organizations (including WTO and WIPO); other relevant stakeholders</p>	<p>(b) frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements</p>	
	<p><b>Governments</b></p>	<p>(c) consider where appropriate, inter alia, the reduction or elimination of import tariffs on health products and medical devices and the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access</p>	
	<p><b>Governments;</b> WHO; other international intergovernmental organizations; other relevant stakeholders (including <b>relevant health-related industries</b>)</p>	<p>(d) encourage pharmaceutical companies and other health-related industries to consider policies, including differential pricing policies, that are conducive to promoting access to quality, safe, efficacious and affordable health products in developing countries, consistent with national law</p>	
	<p><b>Governments</b></p>	<p>(e) consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products; further support WHO’s ongoing work on pharmaceutical pricing</p>	

<b>Elements and sub-elements</b>		<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 7. Promoting sustainable financing mechanisms</b>				
(7.1) endeavoring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries	(f) Consider, where necessary, and provided that they are consistent with the provisions of the Agreement on TRIPS, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products  (g) increase information among policy makers, users, doctors and pharmacists regarding generic products	<b>Governments</b>	<b>Governments</b> ; WHO other relevant stakeholders (including nongovernmental organizations and relevant health related industry)	
		(a) establish a results-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases  (b) consider channelling additional funds to health-oriented research organizations as appropriate in both the private and public sector of developing countries and promote good financial management to	<b>Governments; WHO</b> ; other international intergovernmental organizations; other relevant stakeholders  <b>Governments; WHO</b> ; other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations,	

	maximize its effectiveness as recommended by the resolution WHA58.34	international and national research institutions, academia, private sector and relevant health-related industries)	
	(c) create a database of possible sources of financing for R & D	<b>Governments; WHO; other relevant stakeholders</b>	
(7.2) facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public-private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices	(a) document and disseminate best practices in public-private and product development partnerships	Governments; <b>WHO</b> ; other relevant stakeholders (including research institutions, public-private and product development partnerships)	2008–2015
	(b) develop tools to periodically assess performance of public-private and product development partnerships	Governments; <b>WHO</b> ; other relevant stakeholders (including research institutions; public-private and product development partnerships; charitable foundations)	2008–2009
	(c) support public-private and product development partnerships and other appropriate research and development initiatives in developing countries	Governments; <b>WHO</b> ; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, charitable foundations, development partners, nongovernmental organizations; academia; research institutions)	2008–2015
<b>Elements and sub-elements</b>		<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 8. Establishing monitoring and reporting systems</b>			
(8.1) measuring performance and progress towards objectives contained in the strategy and plan of action	(a) establish systems to monitor performance and progress of the implementation of each element of the global strategy and plan of action	Governments; <b>WHO</b>	From 2009

	(b) monitor and report periodically to WHO's governing bodies on the gaps and needs related to health products and medical devices in developed and developing countries	Governments; <b>WHO</b>	[From 2009]
	(c) to continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the report of the Commission on Intellectual Property Rights, Innovation and Public Health, on the development of, and access to, health care products, and to report thereon to the Health Assembly	Governments; <b>WHO</b> ; other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders	
	(d) monitor and report on the impact of incentive mechanisms on innovation of and access to health products and medical devices	<b>Governments</b> ; <b>WHO</b> ; other international intergovernmental organizations (including WIPO and WTO); Other relevant stakeholders	
	(e) monitor and report on investment in research and development to address the health needs of developing countries	Governments; <b>WHO</b> ; other relevant stakeholders	

Eighth plenary meeting, 24 May 2008  
A61/VR/8

= = =

109TH CONGRESS  
2D SESSION

# S. 4040

To ensure that innovations developed at federally-funded institutions are available in certain developing countries at the lowest possible cost.

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IN THE SENATE OF THE UNITED STATES

SEPTEMBER 29, 2006

Mr. LEAHY introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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## A BILL

To ensure that innovations developed at federally-funded institutions are available in certain developing countries at the lowest possible cost.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Public Research in  
5       the Public Interest Act of 2006”.

6       **SEC. 2. PURPOSE AND FINDINGS.**

7       (a) **PURPOSE.**—The purpose of this Act is to promote  
8       global public health and America’s national security by en-  
9       suring that innovations developed at federally-funded in-

1 stitutions are available in eligible developing countries at  
2 the lowest possible cost.

3 (b) FINDINGS.—Congress finds the following:

4 (1) It is in the national interest of the United  
5 States that people around the world live healthier  
6 lives, and that they perceive the United States in a  
7 more favorable light.

8 (2) The United States Government funds a  
9 major portion of all academic research.

10 (3) Congress funds universities and Federal re-  
11 search laboratories as institutions dedicated to the  
12 creation and dissemination of knowledge in the pub-  
13 lic interest.

14 (4) The Federal Government's investment in  
15 science and technology fuels a thriving pharma-  
16 ceutical industry and rising longevity and quality of  
17 life in the United States. In 2000, a Senate Joint  
18 Economic Committee Report found that public re-  
19 search was instrumental in developing 15 of the 21  
20 drugs considered by experts to have had the highest  
21 therapeutic impact on society.

22 (5) Millions of people with HIV/AIDS in devel-  
23 oping countries need antiretroviral drugs. More than  
24 40,000,000 people worldwide have HIV and 95 per-  
25 cent of them live in developing countries. Malaria,

1 tuberculosis, and other infectious diseases kill mil-  
2 lions of people a year in developing nations.

3 (6) The World Health Organization (“WHO”)  
4 has estimated that  $\frac{1}{3}$  of the world’s population lacks  
5 regular access to essential medicines, including  
6 antiretroviral drugs. The WHO reported that just by  
7 improving access to existing medicines roughly  
8 10,000,000 lives could be saved around the world  
9 every year.

10 (7) To help address the access to medicines cri-  
11 sis, the World Health Organization’s 2006 Commis-  
12 sion on Intellectual Property Rights, Innovation, and  
13 Public Health recommended that universities adopt  
14 licensing practices designed to increase access to  
15 medicines in developing countries.

16 (8) The Department of State has reported to  
17 Congress under the President’s Emergency Plan for  
18 AIDS Relief that, “[I]n every case generics prices  
19 present an opportunity for cost savings; in some  
20 cases, the branded price per pack of a drug is up to  
21 11 times the cost of the approved generic version.”.

22 (9) Since sales of the patented, brand-name  
23 versions of such medicines are minimal or non-exist-  
24 ent in many impoverished regions of the world, al-  
25 lowing generic versions of those medicines will have

1 minimal impact on the sales of brand-name, pat-  
2 ented versions in such regions, or the licensing reve-  
3 nues of publicly funded research institutions, while  
4 saving an untold number of lives.

5 **SEC. 3. DEFINITIONS.**

6 In this Act:

7 (1) ASSOCIATED MEDICAL PRODUCT.—The  
8 term “associated medical product”, when used in re-  
9 lation to a subject invention, means any medical  
10 product of which the manufacture, use, sale, offering  
11 for sale, import, or export relies upon or is covered  
12 by the rights guaranteed by title in that invention.

13 (2) ASSOCIATED RIGHTS.—The term “associ-  
14 ated rights,” when used in relation to a subject in-  
15 vention, means—

16 (A) all patent and marketing rights, pos-  
17 sessed by a current or former holder of title in  
18 that invention, or licensee of rights guaranteed  
19 by such title, that are reasonably necessary to  
20 make, use, sell, offer to sell, import, export, or  
21 test any associated medical product ever made,  
22 used, sold, offered for sale, imported, or ex-  
23 ported by that party; and

24 (B) the right to rely on biological, chem-  
25 ical, biochemical, toxicological, pharmacological,

1 metabolic, formulation, clinical, analytical, sta-  
2 bility, and other information and data for pur-  
3 poses of regulatory approval of any associated  
4 medical product.

5 (3) DRUG.—The term “drug” has the meaning  
6 given such term in section 201 of the Federal Food,  
7 Drug and Cosmetic Act (21 U.S.C. 321).

8 (4) ELIGIBLE COUNTRY.—The term “eligible  
9 country” means any country of which the economy  
10 is classified by the World Bank as “low-income”, or  
11 “lower-middle-income”.

12 (5) FAIR ROYALTY.—The term “fair royalty”,  
13 when used in relation to a subject invention,  
14 means—

15 (A) for a country classified by the World  
16 Bank as “low-income” at the time of the sales  
17 on which royalties are due, 2 percent of a li-  
18 censee’s net sales of associated medical prod-  
19 ucts in such country; and

20 (B) for a country classified by the World  
21 Bank as “lower-middle-income” at the time of  
22 sales on which royalties are due, 5 percent of  
23 a licensee’s net sales of associated medical prod-  
24 ucts in such country.

1           (6) INVENTION.—The term “invention” means  
2 any invention or discovery which is or may be pat-  
3 entable or otherwise protectable under title 35,  
4 United States Code, or any novel variety of plant  
5 which is or may be protectable under the Plant Vari-  
6 ety Protection Act (7 U.S.C. 2321 et seq.).

7           (7) MEDICAL DEVICE.—The term “medical de-  
8 vice” means a device, as defined in section 201(h)  
9 of the Federal Food, Drug, and Cosmetic Act (21  
10 U.S.C. 321(h)), and includes any device component  
11 of any combination product, as that term is used in  
12 section 503(g) of such Act (21 U.S.C. 353(g)).

13           (8) MEDICAL PRODUCT.—The term “medical  
14 product” means any drug, treatment, prophylaxis,  
15 vaccine, or medical device.

16           (9) NEGLECTED RESEARCH.—The term “ne-  
17 glected research” means any use of a subjected in-  
18 vention or the associated rights in an effort to de-  
19 velop medical products for a rare disease or condi-  
20 tion, as defined in section 526(a)(2) of the Federal  
21 Food, Drug, and Cosmetic Act (21 U.S.C.  
22 360bb(a)(2)).

23           (10) SUBJECT INSTITUTION.—The term “sub-  
24 ject institution” means any institution of higher edu-  
25 cation (as such term is defined in section 101(a) of

1 the Higher Education Act of 1965 (20 U.S.C.  
2 1001(a)) or research that receives federal financial  
3 assistance, including Federal laboratories as defined  
4 in section 12(d) of the Stevenson-Wydler Technology  
5 Innovation Act of 1980 (15 U.S.C. 3710a(d)).

6 (11) SUBJECT INVENTION.—The term “subject  
7 invention” means any invention—

8 (A) conceived or first actually reduced to  
9 practice by a subject institution, or its employ-  
10 ees in the course of their employment, on or  
11 after the effective date of this Act; or

12 (B) in which a subject institution holds  
13 title, provided the invention was first conceived  
14 or reduced to practice on or after the effective  
15 date of this Act.

16 **SEC. 4. ACCESS TO LIFESAVING MEDICINES DEVELOPED AT**  
17 **GOVERNMENT FUNDED INSTITUTIONS.**

18 (a) GRANT OF LICENSE.—

19 (1) IN GENERAL.—As a condition of receiving  
20 Federal assistance, any subject institution that con-  
21 ceives, reduced to practice, or holds title in a subject  
22 invention shall be required to grant irrevocable, per-  
23 petual, nonexclusive licenses to the invention and  
24 any associated rights the institution may own or

1 ever acquire, to any party requesting such a license  
2 pursuant to subsection (g).

3 (2) PURPOSE OF LICENSE.—The licenses de-  
4 scribed under paragraph (1) shall be for the sole  
5 purpose of—

6 (A) supplying medical products in accord-  
7 ance with subsection (e); or

8 (B) conducting neglected research any-  
9 where in the world, royalty-free.

10 (b) INCORPORATION INTO TITLE.—The open-licens-  
11 ing requirement created by subsection (a) and all licenses  
12 granted thereunder shall be part of the subject institu-  
13 tion’s title in a subject invention. No transfer or license  
14 may be interpreted in any manner inconsistent with mak-  
15 ing any grant under subsection (a) effective, or in any  
16 manner that prevents or frees the holder of title in the  
17 invention from granting licenses.

18 (c) SUBSEQUENT LICENSES.—

19 (1) IN GENERAL.—If a subject institution li-  
20 censes or grants rights in a subject invention to any  
21 other party, as a condition of such grant the licensee  
22 or grantee, and any future sublicensees or subse-  
23 quent grantees, ad infinitum, shall also be required  
24 in perpetuity, to grant irrevocable, perpetual, non-  
25 exclusive licenses on any associated rights which the

1 licensee or grantee may own or later acquire, to any  
2 party requesting such a license pursuant to sub-  
3 section (g).

4 (2) PURPOSE OF LICENSE.—The licenses shall  
5 be for the sole purposes described in subsection  
6 (a)(2).

7 (3) APPLICATION OF THIS SUBSECTION.—This  
8 subsection applies to licenses for a subject invention  
9 acquired under subsection (a).

10 (d) CONSTRUCTION.—No grant or licensee of any  
11 subject invention may be interpreted in any manner that  
12 prevents or frees the grantee or licensee from granting li-  
13 censes for associated rights under subsection (c).

14 (e) LICENSE FOR SUPPLY OF MEDICAL PRODUCTS.—

15 (1) IN GENERAL.—A license under subsection  
16 (a)(2)(A) shall be a license for the sole purpose of  
17 permitting the making, using, selling, offering to  
18 sell, importing, exporting, and testing of medical  
19 products in eligible countries and the making and  
20 exporting of medical products worldwide for the sole  
21 purpose of supplying medical products to eligible  
22 countries.

23 (2) LABELING.—If the recipient of a license  
24 under subsection (a) exercises its right to make and  
25 export a medical product in any country other than

1 an eligible country for the sole purpose of export to  
2 an eligible country, then the licensee shall use rea-  
3 sonable efforts to visibly distinguish the medical  
4 product it manufactures from any similar medical  
5 product sold by others in the country of manufac-  
6 ture, provided that such reasonable efforts do not re-  
7 quire the licensee to expend significant expense.

8 (3) ROYALTIES.—

9 (A) LICENSE OF SUBJECT INVENTION.—A

10 license of a subject invention under subsection  
11 (a)(2)(A) shall be irrevocable and perpetual so  
12 long as the licensee submits to the licensor pay-  
13 ment of a fair royalty on sales of any associated  
14 medical product within 90 days of such sales.  
15 Failure or refusal of the licensor to accept the  
16 fair royalty shall not terminate or affect in any  
17 way the license.

18 (B) LICENSE OF ASSOCIATED RIGHTS.—A

19 license of associated rights to a subject inven-  
20 tion under subsection (a)(2)(A) shall be royalty  
21 free.

22 (f) TRANSFER.—In accordance with subsections (a)

23 through (d), any license or other transfer of a subject in-  
24 vention by a subject institution or the licensee or grantee

1 of such institution for a subject invention, shall be invalid  
2 unless—

3 (1) the license or grant includes a clause, “This  
4 grant or license is subject to the provisions of the  
5 Public Research in the Public Interest Act of  
6 2006.”;

7 (2) the licensor or grantor complies with the  
8 notification requirements of subsection (h); and

9 (3) the license or grant does not include any  
10 terms that contradict any requirement of this Act.

11 (g) PROCEDURES FOR ACQUISITION OF LICENSES.—

12 (1) IN GENERAL.—Any party, upon providing  
13 to the Food and Drug Administration—

14 (A) notification of its intent to supply med-  
15 ical products or conduct neglected research as  
16 provided in subsection (a);

17 (B) a specific list of the rights it wishes to  
18 license for those purposes; and

19 (C) the names of the party or parties it be-  
20 lieves are obligated to grant such licenses under  
21 subsections (a) through (d),

22 shall automatically be deemed to receive the license  
23 so requested without the need for any further action  
24 on the part of the licensing party if the party or par-  
25 ties specified in the request do not object and notify

1 the requesting party of such objection, within 30  
2 days of the publication of such request by the Ad-  
3 ministration.

4 (2) ENFORCEMENT ACTION.—

5 (A) IN GENERAL.—If the party or parties  
6 specified under paragraph (1) object to the  
7 grant of a requested license, the requesting  
8 party may bring an action to enforce its right  
9 to a license of a subject invention or associated  
10 rights under subsections (a) through (d).

11 (B) PROCESS.—In any suit under this sub-  
12 section, the requesting party shall be entitled to  
13 separate, expedited review of the legal issues re-  
14 quired to adjudicate whether it is entitled to the  
15 requested license, without prejudice to any  
16 other issues in the lawsuit. If the party object-  
17 ing to the license is found to have objected  
18 without reasonable cause or without a good  
19 faith belief that there was a justifiable con-  
20 troversy under the facts and the law, the party  
21 requesting the license shall be entitled to attor-  
22 ney's fees, other reasonably necessary costs of  
23 the lawsuit, and treble damages from the ob-  
24 jecting party.

1           (3) PUBLICATION.—The Food and Drug Ad-  
2           ministration shall publish any request made under  
3           paragraph (1) within 15 days of receipt of such re-  
4           quest. The Food and Drug Administration shall also  
5           make reasonable efforts to directly notify the parties  
6           named in any such request.

7           (h) NOTIFICATION OF TRANSFER OR LICENSE OF  
8           SUBJECT INVENTIONS.—The holder of title or any license  
9           in a subject invention shall notify the Food and Drug Ad-  
10          ministration of any grant or license of rights in that inven-  
11          tion. The Food and Drug Administration shall publish all  
12          such notifications within 15 days of receipt.

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Medicines Patent Pool (MPP) is an example of a program that should qualify as patents in the pool are of known utility and will actually be utilized by MPP.

- *Reward of a voucher for access to medicines patents only in countries lacking production capacity:* In rewarding vouchers, USPTO must ensure that if there is accessibility to patents for medicines, there is a way to produce the associated product. One could imagine a situation in which patents for a medicine are offered only for Least Developed Countries (LDCs) as defined by the World Bank. In such a situation, there is little likelihood that such patents could be practiced given the lack of manufacturing capacity in LDCs. The USPTO program must ensure that any patents put toward humanitarian use can in reality be practiced. It is also preferable that the patents be used to manufacture products in developing countries whenever possible in order to encourage local sustainability rather than dependence on manufacturing capacity in developed countries.

### **Benefits for U.S. Government Policy of a Successful Program**

The sheer size of the United States President's Emergency Plan for AIDS Relief (PEPFAR) program makes the U.S. one of the largest purchasers of medicines in the world. The massive scale up of HIV/AIDS treatment across the world has been due to access to affordable, safe, generic medicines. Civil society campaigning and expiry of patents on early tri-therapies has meant a drop in price from over \$10,000 in 2000 to less than \$100 today.<sup>9</sup>

Still, newer regimens are required and are much more costly. A successful USPTO program that, for instance, creates incentives for patent holders to participate in the UNITAID-supported Medicines Patent Pool, would have positive effects on other strategic U.S. government goals. The U.S. government has recently shown support for the Medicines Patent Pool by being the first entity to license a patent to the pool which, hopefully, will eventually allow low-cost production of anti-retrovirals enabling further scale up of treatment.<sup>10</sup>

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<sup>9</sup> Medecins sans Frontieres, *Untangling the Web of Antiretroviral Price Reductions*, (13th ed. July 9, 2010) available at [http://www.msfaaccess.org/fileadmin/user\\_upload/diseases/hiv-aids/Untangling\\_the\\_Web/MSF\\_Access\\_Report\\_13th\\_edition.pdf](http://www.msfaaccess.org/fileadmin/user_upload/diseases/hiv-aids/Untangling_the_Web/MSF_Access_Report_13th_edition.pdf).

<sup>10</sup> Hillary Chen, The White House Office of Science and Technology Policy, U.S. Government First to Share Patents with Medicines Patent Pool (Sept. 30, 2010), <http://www.whitehouse.gov/blog/2010/09/30/us-government-first-share-patents-with-medicines-patent-pool>.



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## RESPONSES TO SELECTED USPTO QUESTIONS

### **1. Recipients of the FDA priority review vouchers, as entities that develop drugs which treat a tropical disease under 21 U.S.C. section 360n, should not automatically receive a humanitarian fast-track *ex parte* reexamination.**

Under 21 USC Section 360n, a priority review voucher recipient receives significant benefits for developing and testing treatments for tropical diseases. Allowing an automatic voucher award would do little to further spur innovation given the already strong incentive.

Under FDA Priority Review, a manufacturer may only apply for a voucher after submission of a New Drug Application (NDA) and Biologics Licensing Application (BLA) for permission to market the product.<sup>11</sup> The resulting priority review simply speeds up review time between application and approval decision.

If USPTO issues automatic awards to FDA priority review recipients, the USPTO reexamination award process will inherit the flaws of the FDA priority review. One such flaw was shown with the very first FDA priority review voucher, awarded to Novartis for its anti-malarial drug Coartem. Novartis developed Coartem over a decade before the FDA implemented the priority review award.<sup>12</sup> Therefore, contrary to the goal of the FDA program, Novartis was not incentivized to research and develop treatments for neglected tropical diseases. Automatic awards granted to recipients of the FDA voucher would allow these same exploitations to occur with USPTO reexamination vouchers.

### **2. Omitted.**

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<sup>11</sup> Thaul, Susan, CRS Report for Congress, FDA Fast Track and Priority Review Programs (Feb. 21, 2008), available at <http://www.nationalaglawcenter.org/assets/crs/RS22814.pdf>.

<sup>12</sup> Universities Allied for Essential Medicines, Coartem Receives First Priority Review Voucher (2010) <http://essentialmedicine.org/progress/coartem-receives-first-priority-review-voucher> (citing BIO Ventures for Global Health Extra (April 2009), <http://www.bvgh.org/news/CoartemEarnsFirstPRV.asp> (last visited Nov. 15, 2010)).

### **3. USPTO should consider all humanitarian issues related to global health for inclusion in its voucher program.**

All humanitarian issues concerning global health should be considered for qualification in the voucher program. These issues may include neglected diseases, debilitating health conditions in developing countries, chronic hunger and malnutrition, widespread public health problems such as lack of sanitation or potable water, and other issues predominantly affecting impoverished populations.

While these listed concerns should qualify for priority review, USPTO should take into consideration other humanitarian issues as well. Although lack of access to affordable medications could be considered a “debilitating health condition,” USPTO should explicitly recognize the availability of medicines in developing countries. Access to medicines is a major area of concern for developing nations; the definition of access may be evaluated under the framework set forth by the WHO Commission on Intellectual Property Rights, Innovation and Public Health (“CIPIH”). According to the CIPIH report, the appropriate framework for analysis for access to medicines considers whether the medicine is (1) available in sufficient quantities, (2) acceptable in terms of usability and appropriate given cultural or other regional factors, (3) effective and *of good quality*, and (4) of the lowest possible cost. UAEM strongly urges USPTO to consider an explicit statement that provides for access to medicines in its voucher program. CIPIH provides an excellent framework to determine whether the access to medicines problem is properly addressed.

Furthermore, UAEM urges USPTO to take into account the risk factors that contribute to debilitating health conditions, along with other public health issues. Prevention of disease and injury requires assessment and management of the risks that cause them. For example, WHO

reports twenty-four global health risks such as malnutrition, mineral deficiencies, unsafe water supplies and other factors that represent significant problems linked to diseases. The risk factors studied by WHO are responsible for 44% of global deaths.<sup>13</sup> Accordingly, USPTO should consider disease burden and risk factors rather than specific conditions. While WHO provides a list of some of the highest risk factors that contribute to disease burden and can serve as an excellent starting point, this list is by no means exhaustive. Consideration of access to medicines, disease burden, and global health as a whole, provide the most important factors in USPTO's humanitarian licensing program. These factors can be quantitatively presented by applicants for the program.

#### **4. Omitted**

#### **5. Consideration of statements from independent third parties**

##### **A. USPTO should consider statements on effectiveness or actual use for humanitarian needs from truly independent third-parties.**

The USPTO should consider statements from independent third parties, particularly humanitarian organizations or researchers, on the effectiveness or actual use of an invention to address humanitarian needs. Innovators and patent-applicants have a different focus to their work than organizers, researchers, and advocates. While there may be crossover among all parties in terms of humanitarian motivations or awareness, the amount of information and support for the applications will be enriched by the input of multiple knowledgeable participants.

Independent third parties have an abundance of information to bring to USPTO on the need, effectiveness, and actual use for an invention to address humanitarian needs. Humanitarian

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<sup>13</sup> World Health Organization, *Global Health Risks: Mortality and Burden of Disease Attributable to Selected Major Risks (2009)*, available at [http://www.who.int/healthinfo/global\\_burden\\_disease/GlobalHealthRisks\\_report\\_full.pdf](http://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf).

organizations and researchers often have readily available statistics on the necessity, identity, location, urgency, and reason for needy recipients of humanitarian efforts. Therefore, humanitarian organizations may highlight and uncover for USPTO critical aspects which may have been left out of patent holder's application for the USPTO program.

Statements should only be considered from third-party contributors who are truly independent, and do not have conflicting interests with the patent-holders. At a minimum, conflicts of interest such as receipt by the third-party of contributions from the patent holder must be disclosed. To ensure independence, USPTO might require third parties to sign a certified statement to be included with the submission. The statement should certify that the independent third-party contributor has never participated in the patent-applicant's business, including (but not limited to) never having sat on the board of directors, been a paid speaker, or held a paid research or review position for that entity.

In addition to submission in support of applications, in order to have a fully participatory process, USPTO should also consider submissions opposing grant of vouchers.

#### **B. Should submissions be required to qualify for a voucher?**

Submissions should be required to qualify for a voucher except in exceptional circumstances. Without third-party verification of claims (understanding that the third-parties do not have conflicts of interest), USPTO would have to rely solely on the patent holder. This also highlights why it is desirable to consider oppositions to applications for a voucher. Considering both sides of the argument will allow USPTO to come to the most well-reasoned decision.



**6. Defining certain elements (e.g., neglected diseases, tropical crops, developing countries) of qualifying humanitarian criteria**

USPTO should focus on the areas in which help and assistance are needed, broadly defined. Whether considered a least developed country, developing country, or developed country, the inhabitants who are affected by debilitating diseases or do not have access to existing medicines should take priority over the effort to carve out specific, limited definitions in times of exigency. Thus, USPTO should take a broad view in determining where help is needed rather than simply limiting itself to a particular list of developing nations.

**A. Criteria defined with reference to lists or criteria provided by external organizations experienced in such matters, such as the World Health Organization, National Institutes of Health, Food and Drug Administration, United Nations, or U.S. Agency for International Development**

Elements of each of the criteria provided by external organizations prove instructive in the criteria for any proposed voucher program; however, the elements alone should not exclusively constitute the criteria considered by USPTO. For example, the FDA's humanitarian programs of Humanitarian Use Devices or Orphan Drug Designations may provide starting points for consideration by USPTO; however, USPTO should take a broader view to address global needs. The Food and Drug Administration defines a Humanitarian Use Device ("HUD") as:

- Expected to treat or benefit fewer than 4,000 people in the United States,
- No comparable device is already available,
- The device will not expose the patient to "unreasonable or significant risk of illness or injury," and
- The potential benefits outweigh the risks.<sup>14</sup>

<sup>14</sup> 21 C.F.R. § 814.3(n) (2010); *see also* U.S. FDA, Designating Humanitarian Use Devices (HUDS) (Nov. 3, 2010), <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/DesignatingHumanitarianUseDevicesHUDS/default.htm>.



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One focus of the FDA is a small target group, because HUDs will not be able to obtain the efficacy data typically required for ordinary FDA market approval.

Similar to the HUD program, the FDA also has an Orphan Drug Designation (“ODD”) program. The ODD program provides orphan status to those drugs or biologics involved with treatment or prevention of rare diseases, defined as affecting less than 200,000 people in the United States; if the medicine or technology will affect more than 200,000, there is no expected cost recovery for the development and marketing.<sup>15</sup>

While these two FDA programs have features that may be beneficial to a similar humanitarian voucher program at the USPTO, both FDA programs are too case specific to be generalized, as they each choose a number of people—in the United States only—who may be affected by the new diagnostic or treatment. The USPTO program can take a broader view of the qualification requirements that encompasses global health and safety needs.

Furthermore, while taking a broad view and determining qualification based on disease burden may provide the best model, the USPTO may also consider taking a broad approach with regard to income. The decision to include or exclude a country’s population from consideration has grave human consequences, particularly for middle income countries such as China, Brazil and India. Although a small portion of the populations of such countries may technically afford the monopoly prices of medicines and other tools, the vast majority cannot. The USPTO must take care to include the conditions afflicting these countries and define resource-limited countries as those not ranked as high income on the World Bank’s List of Economies. The USPTO might go even further and look to creative ways to define populations in need that can exist within developed countries.

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<sup>15</sup> 21 C.F.R. § 316 (2003).

## **B. Which criteria of other public or private organizations should be followed**

A voucher proposal should not be limited to a specific list of diseases or conditions. The WHO has produced a list of seventeen neglected tropical diseases (NTD); by its own admission, the list is not exhaustive.<sup>16</sup> Furthermore, the WHO criteria not only fail to include all NTDs, but also do not account for the many other neglected diseases that burden developing nations. Perhaps of greater value than its list of neglected diseases, the WHO's examination of disease burden could provide an excellent starting point for USPTO consideration of qualifying humanitarian criteria. Disease burden and resource limitations, rather than a list of specific diseases and conditions, provide the appropriate benchmark for inclusion in USPTO's humanitarian licensing criteria. Taking a broader view of qualifying diseases and populations, would necessarily require that impacts be fairly large in order to ensure that the program is not flooded should the bar be set too low.

## **7. Efforts to increase access to a patented technology**

### **A. Actions that should be considered to determine whether a patent holder has made significant efforts**

Whether efforts have been made to increase access to patented technology may be evaluated by the allowance or encouragement of generic production and competition, as well as the level of price reductions for a given technology. Whether a technology is locally produced might also be taken into account.

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<sup>16</sup> World Health Organization, Neglected Tropical Diseases: Frequently Asked Questions, (Aug. 10, 2010) [http://www.who.int/neglected\\_diseases/faq/en/index.html](http://www.who.int/neglected_diseases/faq/en/index.html).

Regarding generic competition, the significance of a patent owner's efforts to increase access to patented technology may be determined by conformity to reasonable and non-discriminatory terms of licensing practice (RAND). Accordingly, the terms would be defined by USPTO (or another designated standard setting organization) in order to enhance competitiveness in pricing. These terms of licensing practice, and the resultant competition, will lead to increased access to technology and decreased cost to consumers and government and aid organizations making bulk purchases.

Though terms of licensing practice are not yet defined for the program, terms may be gleaned from competition law and inappropriate use of monopoly. For example, "reasonable" usually refers to licensing rates that do not increase cost or decrease competition; therefore, patent-owner licensors may have reasonable licensing packages that enable greater access to technology. Additionally, "Non-discriminatory" generally refers to the requirement that licensors treat each licensee equally with regards to conditions contained in a licensing agreement; the aim of the non-discrimination requirement is to enable a level playing field for existing competitors and entrants into the market.

Abiding by these licensing terms prevents patent owners and licensors from acting in anticompetitive ways. Actions considered to be anticompetitive include requiring restraining clauses on licensees' transactions with competitors, forcing licensees to purchase bundled licenses for undesired products in addition to the license for the desired product, and requiring a licensee to license its own intellectual property to the licensor at an unfair rate or for free.

To some extent, this may evolve over time. For instance, it would seem that licensing to the UNITAID-supported Medicines Patent Pool (subject to examination of specific licensing terms) would be considered by many groups to be a qualifying action. Given ever evolving

standards, it may behoove USPTO to leave some flexibility for creating standards as specific issues are examined. For instance, with input from various parties, licensing to the Medicines Patent Pool and the attendant licensing terms can in one proceeding examining a request for a voucher set a basic standard to evaluate future participation in patent terms and related licensing terms.

## **8. to 11. Omitted**

## **12. Non-monetary prizes or awards sponsored by the USPTO recognizing humanitarian efforts**

### **A. Non-monetary prizes and awards may encourage greater investment in the field**

Non-monetary incentives may be helpful to encourage greater equitable access to patents for needy populations. For criteria, USPTO may reference UAEM's Access Metrics Initiative (AMI) which has been developed over a number of years with technology transfer professionals, academics, civil society and others. The metrics look at policies and licensing terms used at universities that promote access.<sup>17</sup> The project is in its pilot phase and to date, 14 universities have participated in the pilot of the metrics. For example, USPTO could use such metrics to provide rewards to participating universities and institutions based on their performance on the AMI survey.

### **A. Criteria to be used for selecting recipients of prizes and awards**

In addition to criteria from the AMI survey results, other criteria to select recipients for USPTO humanitarian prizes or awards might include the following:

- (1) *Open-Access Publishing Policies at Universities.* USPTO can take steps to encourage open-access publishing policies at universities. As has been increasingly recognized in recent years, patents are not the sole key to innovations; instead, greater efforts should be made to strengthen the public domain and open methods generally. By

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<sup>17</sup> More information and the pilot metrics are available at: <http://essentialmedicine.org/projects/metrics>.



increasing open access, patents and copyrights may more effectively spread access to life-saving technologies or research resources. Aside from the specifics of humanitarian use of patents, USPTO might also consider the greater knowledge ecology in considering the broader steps that can be taken. For instance, some early stage knowledge and tools should often be patented.

- (2) *Resources for Open, Collaborative Research.* The open-source dividend has been proposed as a means of encouraging university researchers to put discoveries into the public domain as a part of a prize system. Furthermore, even if not a monetary prize, in addition to giving awards or other recognition, USPTO might offer resources to academics, researchers, administrators and technology transfer professionals on the value of open, collaborative research. Example of “resources” may be funding for symposia or acting as a repository for best practices.

## CONCLUSION

Many examples of global access policies and various innovative mechanisms can provide a solid basis for implementing the proposed USPTO program. Building upon current positive practices while continuing to augment them and learning from potentials for gaming of the system will create the most humanitarian value from the program. UAEM appreciates the opportunity to provide feedback on the USPTO program, and welcomes the opportunity to continue its participation in further development of humanitarian incentives programs.

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