PUBLIC HEALTH SERVICE

NON-EXCLUSIVE PATENT LICENSE AGREEMENT

COVER PAGE

For PHS internal use only:

License Number:

License Application Number: A-373-2010

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

United States	Application 09/720,226 – issued (7,470,506)
	Application 11/870,931 (pending)
Canada	Application 2336160 (pending)
Australia	Application 48280/99 – issued (7717880)
	Application 2004200629 (pending)
	Application 2007203321 (pending)
Japan	Application 556057/2000 (pending)
	Application 266865/2009 (pending)
EPO	Application 99931861.1 (pending)

Licensee: Medicines Patent Pool Foundation

Additional Remarks: This license agreement will provide complete rights to use the patents on a world-wide basis and to sell products covered therein in low and middle-income countries. It is equivalent to an internal commercial use license agreement in all countries where the patents are actually pending or have issued, specifically the United States, Canada, Australia, Japan and member states of the European Patent Office.

Public Benefit(s): Make and develop antiretrovirals for use in low and middle-income countries

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Licensed Products, Processes, Territory, Field of Use and Termination), Appendix C (Development Plan). The Parties to this **Agreement** are:

1) The National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**"); and

2) The person, corporation, or institution identified above and on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as "**Licensee**."

PUBLIC HEALTH SERVICE
NON-EXCLUSIVE PATENT LICENSE AGREEMENT

This **Agreement** is entered into between the National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**") through the Office of Technology Transfer, **NIH**, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 U.S.A.; and Medicines Patent Pool Foundation ("**Licensee**"), organized under the laws of Switzerland and having an office at Route de Chene 30, Geneva, Switzerland (c/o Lenz & Staehelin).

PHS and **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, **PHS** investigators and other inventors made inventions that may have commercial applicability.

1.2 By assignment of rights from **PHS** employees and license from other inventors, **HHS**, on behalf of the **Government**, owns or controls intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by **PHS**.

1.3 The Secretary of **HHS** has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions under 35 U.S.C. §§200-212, the Federal Technology Transfer Act of 1986, 15 U.S.C. §3710a, and the regulations governing the licensing of Government-owned inventions, 37 C.F.R. Part 404.

1.4 **PHS** desires to transfer these inventions to the private sector through commercial research licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 **Licensee** desires to acquire the rights to use certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.1 "**Affiliate(s)**" means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

2.2 "**Government**" means the government of the United States of America.

2.3 "**Licensed Patent Rights**" shall mean:

(a) U.S. patent applications and patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions claimed in 2.3(a):

(i) continuations-in-part of 2.3(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations; and

(iv) any reissues, reexaminations, and extensions of these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions claimed in 2.3(a): all counterpart foreign applications and patents to 2.3(a) and 2.3(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include 2.3(b) or 2.3(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter of a claim in 2.3(a).

2.4 "**Licensed Products**" means tangible materials which, in the course of manufacture, use, sale, or importation would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.5 "**Licensed Processes**" means processes which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.6 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.7 "**Licensed Fields of Use**" means the field of use identified in Appendix B.

3. GRANT OF RIGHTS

3.1 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a royalty-free nonexclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make, have made, and to use, but not to sell the **Licensed Products** and **Licensed Processes** in the **Licensed Fields of Use** for the purposes of supplying the **Licensed Products** in low and middle-income countries, as defined by the World Bank. **PHS** represents that **PHS** has the legal right, title and interest in the **Licensed Patent Rights** to enter into this **Agreement**.

3.2 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than the **Licensed Patent Rights** regardless of whether such patents are dominant or subordinate to the **Licensed Patent Rights**.

3.3 **PHS** acknowledges that information relating to the **Licensed Patent Rights** may be of assistance to **Licensee** in its commercialization efforts. Accordingly, **PHS** shall consider reasonable requests by **Licensee** for access to the inventors of the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights**, provided that such sublicenses do not have a further right of sublicense and are granted in accordance with the Development Plan as described in Appendix C. Sublicenses shall be issued without discrimination to any sublicensee with the demonstrated commitment, ability and readiness to use the sub-license.

4.2 **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to **PHS** of Paragraphs 5.1, 6.5, 7.4, 7.6, 7.8 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements.

4.3 Any sublicenses granted by **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and **PHS**, at the option of the sublicensee, upon termination of this **Agreement** under Article 7. This conversion is subject to **PHS** approval and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.

4.4 **Licensee** agrees to forward to **PHS** a complete copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of the agreement.

5. PERFORMANCE

5.1 **Licensee** shall expend reasonable efforts and resources to carry out the Development Plan as detailed in Appendix C.

5.2 **Licensee** agrees not to use the **Licensed Products** for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. **Licensee** agrees not to use the **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of this research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of this research or trials.

5.3 **Licensee** shall provide written annual reports within sixty (60) days of the end of each calendar year detailing the current status of on-going research using **Licensed Products**.

6. NEGATION OF WARRANTIES AND INDEMNIFICATION

6.1 **PHS** offers no warranties other than those expressly specified in Article 1.

6.2 **PHS** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

6.3 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS**.

6.4 **PHS** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

6.5 **Licensee** shall indemnify and hold **PHS**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by **Licensee**, its directors, employees, or third parties of any **Licensed Patent Rights**, or

(b) the design, manufacture, distribution, or use of any **Licensed Products** or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

6.6 **Licensee** agrees to require that sublicensees maintain a liability insurance program consistent with sound business practice.

7. TERM, TERMINATION AND MODIFICATION OF RIGHTS

7.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 8.8 are not fulfilled, and shall expire at the time specified in Appendix B, unless previously terminated under the terms of this Article 7.

7.2 In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 7.3 and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, **PHS** may terminate this **Agreement** by written notice.

7.3 **PHS** shall specifically have the right to terminate this **Agreement** by written notice if **Licensee**:

(a) has not demonstrated that it is executing the Development Plan submitted with its application for a license and attached herein as Appendix C or that it has not taken or cannot be expected to take, within a reasonable time, effective steps to achieve the practical application of the **Licensed Patent Rights** as contemplated by this **Agreement**; or

(b) has willfully made a false statement of or willfully omitted a material fact in its application for a license or in any report required by this **Agreement**.

7.4 **PHS** reserves the right according to 35 U.S.C. §209(d)(3) to terminate this **Agreement** if it is determined that this action is necessary to meet the requirements for public use specified by Federal regulations issued after the date of the license and these requirements are not reasonably satisfied by **Licensee**.

7.5 **Licensee** shall have a unilateral right to terminate this **Agreement** by giving **PHS** sixty (60) days written notice to that effect.

7.6 Within thirty (30) days of receipt of written notice of **PHS'** unilateral decision to terminate this **Agreement**, **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the Director of **NIH** or designee. The decision of the **NIH** Director or designee shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

7.7 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

7.8 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 7, a final report shall be submitted by **Licensee**. **Licensee** may not be granted additional **PHS** licenses if the final reporting requirement is not fulfilled.

7.9 Paragraphs 6.1-6.5, 7.6, and 7.8 of this **Agreement** shall survive termination of this **Agreement**.

8. GENERAL PROVISIONS

8.1 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

8.2 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

8.3 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

8.4 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by such other party, and shall be effective as of the date of the postmark of such notice.

8.5 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to **Licensee's Affiliate(s)** without the prior written consent of **PHS**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable.

8.6 **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological materials and other commodities. The transfer of these items may require a license from the appropriate agency of the **Government** or written assurances by **Licensee** that it shall not export these items to certain foreign countries without prior approval of the agency. **PHS** neither represents that a license is or is not required or that, if required, it shall be issued.

8.7 The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modification or termination decisions provided for in Article 7. **Licensee** agrees first to appeal any such unsettled claims or controversies to the designated **PHS** official or designee, whose decision shall be considered the final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.

8.8 The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

I. **United States**

Application 09/720,226 – issued (7,470,506)

Application 11/870,931 (pending)

II. **Canada**

Application 2336160 (pending)

III. **Australia**

Application 48280/99 – issued (7717880)

Application 2004200629 (pending)

Application 2007203321 (pending)

IV. **Japan**

Application 556057/2000 (pending)

Application 266865/2009 (pending)

V. **European Patent Office**

Application 99931861.1 (pending)

APPENDIX B – LICENSED PRODUCTS, PROCESSES, TERRITORY, FIELD OF USE AND TERMINATION

I. **Licensed Territory**:

(a) United States, Canada, Australia, Japan, Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, Great Britain, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, and Sweden.

II. **Licensed Fields of Use**:

(a) Treatment and prevention of medical conditions affecting humans

III. Termination:

(a) This **Agreement** shall expire, on a country-by-country basis within the **Licensed Territory**, on the last to expire patent containing a valid claim, unless previously terminated under Article 7.

APPENDIX C – Development Plan

Business Plan

1. Introduction

In July 2008, the UNITAID Executive Board agreed to establish, in principle, a voluntary patent pool for HIV/AIDS medicines. At its 11th session (14-15 December 2009), the Board discussed the Patent Pool Initiative Implementation Plan and decided that "there is now a sufficient basis to proceed to the next stage of the programme planned for 2010." (EB11/2009/R5) At a Special Session on the Patent Pool (5 February 2010), the Board discussed the further work on the legal structure of the Patent Pool Entity and the nature of its relationship with UNITAID and instructed the UNITAID Secretariat "...to take the necessary actions to facilitate the establishment of a patent pool entity..." (EB11/SSPP/2010/R1) Furthermore, the Board requested to review "...the Medicines Patent Pool Foundation's (MPPF) year one business plan, budget and key performance indicators" in order to inform the Memorandum of Understanding (MoU) that will govern the relationship between the Patent Pool Foundation and UNITAID.

This document provides the specifics of the Medicines Patent Pool Foundation Year One business plan, and the overall key performance indicators against which success will be measured.

2. Patent Pool Vision, Mission, and Guiding Principles

The following vision, mission and guiding principles have been set out to ensure that the Medicines Patent Pool Foundation achieves its public health goals whilst addressing the needs & concerns of licensors, licensees and other relevant parties.

Patent Pool Vision
To improve access to appropriate, affordable antiretrovirals in developing countries

Patent Pool Mission Statement
The patent pool will bring down the prices of HIV drugs, and facilitate the development and production of improved formulations (e.g. fixed dose combinations and drugs for children) by providing access to intellectual property relating to these products

Guiding Principles

1. **Public health driven:** The Patent Pool will be driven by public health needs
2. **ARV focus:** The Patent Pool will initially focus on antiretroviral (ARVs) medicines
3. **Voluntary:** The Patent Pool will operate on a voluntary basis
4. **Developing country focus:** The Patent Pool will focus on developing countries
5. **Price reductions:** The Patent Pool will focus on achieving price reductions through increased competition for production & distribution
6. **Enable product development:** The Patent Pool will enable access to patents to facilitate the development of appropriate and adapted formulations
7. **Flexible:** The Patent Pool will be sufficiently flexible and innovative to adapt to evolving health needs and opportunities, as appropriate
8. **Quality assurance:** The Patent Pool will leverage existing mechanisms (e.g. WHO pre-qualification, US FDA, EMEA, and other stringent regulatory agencies) for quality assurance
9. **Standardized licenses:** Key license terms and conditions will be standardized across all licensees / licensors to ensure efficiency & effectiveness.
10. **Non discriminatory Licenses:** Licenses will be available on a non-exclusive and non-discriminatory basis in order to enhance competition and comply with anti-trust law requirements
11. **Additional:** The Patent Pool will be additional to other mechanisms and measures to promote access to medicines
12. **Intellectual Property:** The Patent Pool will operate within the current IP framework. Patent holders will be compensated through royalties as appropriate.
13. **Independent entity:** The Medicines Patent Pool Foundation must be independent.

3. The Medicines Patent Pool Foundation Structure and Services

a. The Medicines Patent Pool Foundation Legal Status

The Medicines Patent Pool Foundation (MPPF) has been established as a Swiss Foundation and is based in Geneva, Switzerland. This will enable the organisation to benefit from a variety of factors including proximity to UNITAID, multilateral organizations (e.g. WHO, UNAIDS, WIPO, WTO), key global health actors (e.g. The Global Fund, Global Forum for Health Research), product development partnerships (e.g. DNDi), and other relevant stakeholders including NGOs. In addition, Geneva's environment is conducive to international development activities, promoted through the presence of the UN and charitable foundations, with a well recognised legal system and appropriate infrastructure.

b. The Medicines Patent Pool Foundation Functions: Technical Solution

The principal role of the Medicines Patent Pool Foundation is to negotiate and establish non-exclusive and non-discriminatory, standard, voluntary license agreements geared towards addressing public health needs. License agreements will be established between patent holders and the MPPF, and between the MPPF and sub-licensees. The MPPF will collaborate with the WHO for the identification of products of interest, and with WIPO for patent mapping and dispute resolution. In addition, the MPPF will support auditing activities by cross-referencing licensee reports with existing price reporting databases (e.g. WHO's Global Price Reporting Mechanism database).

The core functions of the Patent Pool are as follows:

Function	Description
1. Identifying Products of Interest in Relevant Countries	• Identifying existing patented products that would benefit LICs and MICs • Developing a list of patents for target products • Identifying potential FDCs/pediatric products and other innovative products
2. Recruiting Potential Licensors / Licensees of Patent Pool	• Establishing relationships with patent holders, generic manufacturers, and research institutes and encouraging them to join the patent pool • Facilitating dialogue between patent holders, generic manufacturers, and/or research institutes to encourage the development of innovative and required products
3. Developing, Contracting and Managing Licensing Agreements	• Developing Terms & Conditions for licenses • Negotiating and entering into license and sub-license agreements • Facilitating licenses and sub-licenses between patent pool licensors and licensees
4. Royalties Management	• Facilitating the collection and distribution of royalties from licensees to licensors
5. Compliance / Auditing	• Collecting and auditing reports on products developed, manufactured, and distributed using products/patents in the patent pool

6. Dispute Resolution	• Initiating dispute resolution procedures between licensors / licensees that are not in compliance with identified Terms & Conditions and/or audit reports
7. Performance Management	• Setting metrics and tracking impact of patent pool • Consolidating data for regular internal and external reporting
8. Communications	• Developing materials to communicate the impact of the patent pool with internal and external stakeholders
9. Incentive Management	• Identifying potential funding sources and other incentives to encourage patent holders and/or generic manufacturers to participate in the pool or develop improved formulations
10. Stakeholder Management	• Liaising with internal and external stakeholders to understand and address concerns or garner support for the patent pool

Table 1: Core Functions of the Patent Pool

c. Organizational Structure

The Medicines Patent Pool Foundation in year one will have 7 full-time staff members to carry out the above noted functions. These roles are as follows:

1. Executive Director
2. Administrative Assistant
3. Operations Manager
4. Policy/Communications Advisor
5. General Counsel
6. Business Development Manager
7. Finance / Administration Manager

It may be difficult to hire permanent staff with only a 12 month budget approved for patent pool operations. As such, positions may need to be filled with external consultants.

Figure 1 provides a high level overview of the roles and responsibilities of each of these positions.

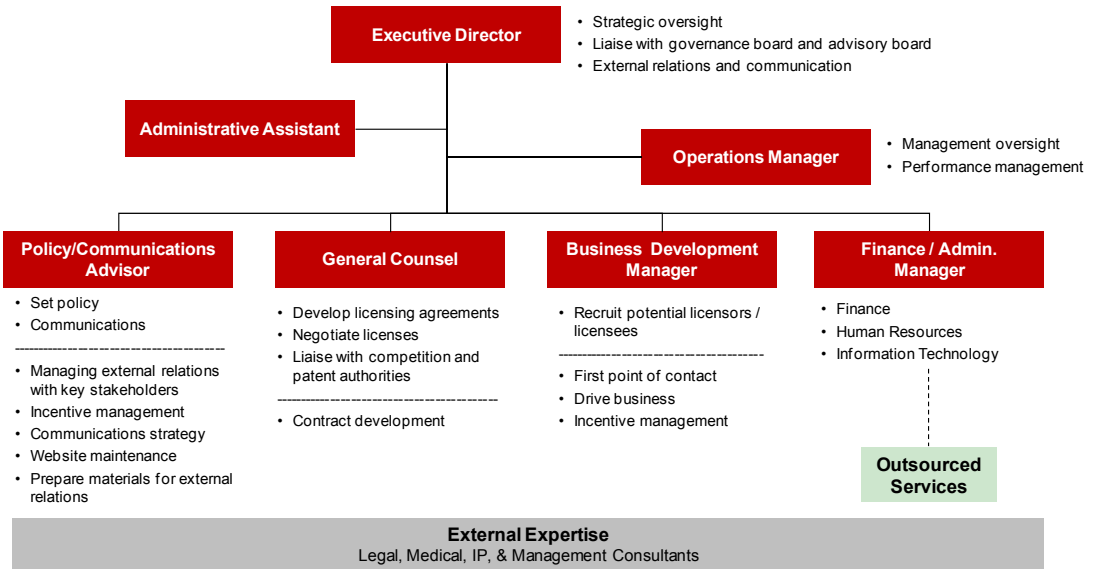

Figure 1: Organizational Structure of the Medicines Patent Pool Foundation

As demand for the Patent Pool services increases (i.e. more patent holders join the Patent Pool or new incentives are being facilitated), the number of full-time resources will scale accordingly. Additional expertise will need to be contracted on a part-time basis for specialist services such as the identification of new products of interest, provision of finance/taxation advice, legal support, and economic analysis. By keeping a relatively small core full-time staff and leveraging external specialists as required for their skills or additional capacity, the Medicines Patent Pool Foundation will be able to maintain a low cost base whilst maximizing opportunities to scale up when demand increases.

Operational management will be critical for the effectiveness of the Medicines Patent Pool Foundation. The Executive Director with senior level staff will be entrusted with decision-making authority in order to quickly respond to licensors and licensees requirements within the parameters established by the Patent Pool Governance Board. This authority includes approving licensing terms and conditions for patent holders, and sub-licensing to generic manufacturers.

d. Governance Board

Good governance is critical to the credibility and efficacy of the Patent Pool. The Medicines Patent Pool Foundation will be governed and guided by three bodies, each playing a unique but complementary role in the overall stewardship and operation of the organization:

- Governance Board
- Medicines Patent Pool Foundation Management
- Expert Advisory Group (no decision making authority)

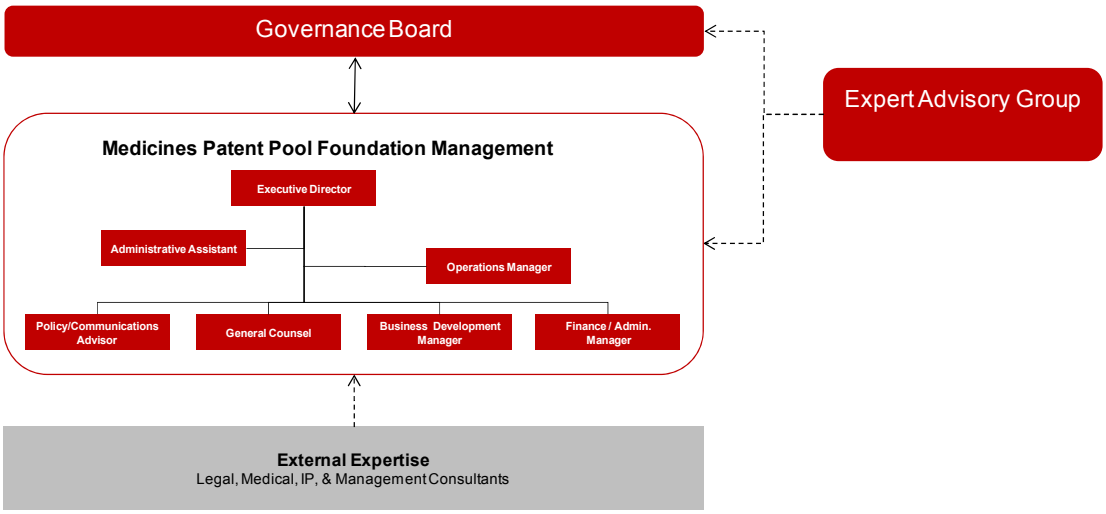

Figure 2: Role of Governance Board and Expert Advisory Group

The Governance Board will be comprised of a small number of individuals (3-7) who are trusted by the various stakeholders, and who will ensure that the Governance Board can effectively support the Management team in a timely and effective manner. Given the strategic support the organization requires and the need to respond quickly to the changing demands of licensors and licensees, the Governance Board's decision making authority will be reserved for setting the overall strategic direction, managing service scope and risks, budget setting, and organizational performance monitoring rather than getting involved in the day-to-day operational decisions. The Governance Board will provide strategic guidance by providing insight, advice, and support on key decisions, and overseeing, guiding and judging performance.

Governance Considerations during the Establishment of the Medicines Patent Pool Foundation

A Founding Board of 3 individuals has been established in order to create the Medicines Patent Pool Foundation. This will enable the MPPF to attain independent legal status in a timely manner and thus begin formal negotiations on terms and conditions with licensors/licensees. This Founding Board will play a critical role in stewarding the MPPF through its establishment, and guiding initial negotiations with patent holders and potential licensees. The Founding Board will also play a role in selecting members for the full Governance Board.

In addition to the Governance Board, an Expert Advisory Group will be established with a broad range of relevant expertise and representation across key stakeholder groups. Areas of expertise include public health, law, economics, management, and pharmaceutical sciences. Although this body will not have official decision-making authority, their input will be critical to the effective decision making of the Governance Board and Management Team. The Chair of the Advisory Group will have observer status at the Governance Board meetings.

4. Activities to Establish the Patent Pool Foundation (Year One)

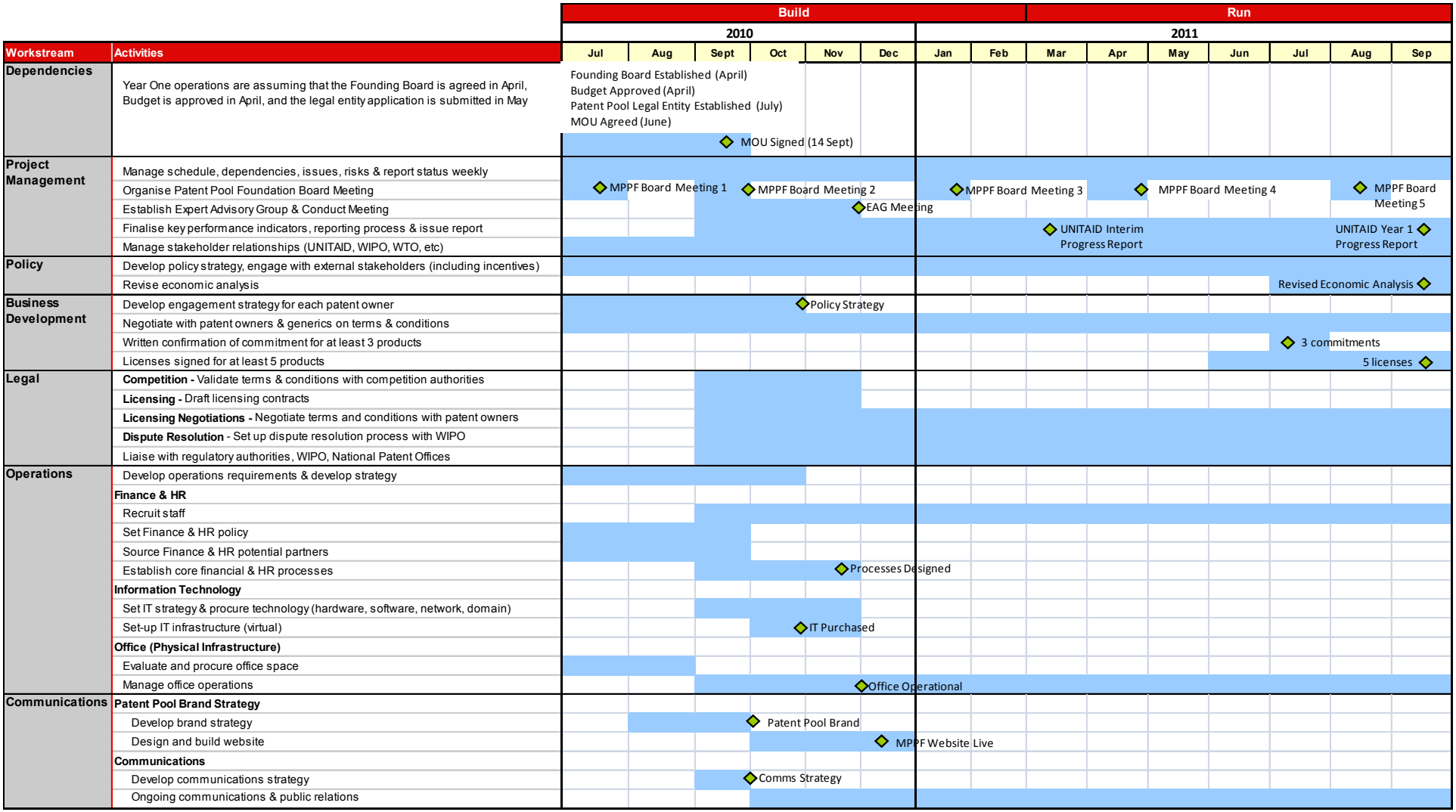

Figure 3: Workplan for Year One

5. Key Milestones

The following milestones, or key scheduled events signifying the completion of major deliverables or a set of related deliverables, have been established by UNITAID in EB11/2009/R5 in order to evaluate the performance of the Medicines Patent Pool Foundation after one year. Dates have been identified for each milestone based on the revised workplan for Year One.

- Agreement of a small Interim Board
- The establishment of such legal entity, according to agreement
- At least three patent holding entities committing in writing to license their patents to the Medicines Patent Pool Foundation
- Licence agreements concluded covering at least five products
- Preparation of a medium term funding plan incorporating and justifying provision of finance by donors and/or licensees with a view to attaining financial sustainability
- Revised economic justification based on products licensed to the pool in 2010
- Revised revenue and cost estimates for the period 2011-2014
- Definition of additional incentives

6. Key Performance Indicators

In order to facilitate results-based management, the patent pool will implement an integrated performance management framework that aligns with the objectives of the Medicines Patent Pool Foundation and organizational effectiveness. This framework consists of two areas:

- Patent Pool Strategy: The routine collection of internal strategic and operational information on the MPPF's activities, outputs, and immediate results. This information will be gathered through regular operational processes and reporting mechanisms. It will be used for internal risk management, reporting, and on-going decision making.
- Impact of the Patent Pool on Health Outcomes The periodic analysis or in-depth studies of the Patent Pool's contribution to health outcomes is not part of the MPPF's immediate core functions. As such the MPPF will rely on information and analysis from external sources.

These areas directly align with UNITAID's results frameworks, thereby allowing the MPPF to develop KPIs that support UNITAID in achieving its strategy.

Area 1: Patent Pool Strategy

In order to assess the performance of the MPPF against its strategic and operational objectives, performance indicators have been identified against key functions of the patent pool. This will allow the management team to directly measure the success of each of its core functions and report on it.

Action	Indicator	Target
Identifying Products of Interest in Relevant Countries	Target products identified	Year 1 target products identified
Identifying Potential Licensors / Licensees of Patent Pool (Recruiting)	Target licensors/licensee identified	Year 1 target products identified
	Number of licensors/licensees at each stage of the pipeline	Three patent holding entities committing in writing to license their patents to the Patent Pool
Developing / Managing Licensing Agreements (Terms & Conditions)	Number of active licensing agreements in place (disaggregated by licensor/licensee)	Licence agreements covering at least five products
Royalty Management	Number of generic manufacturers producing against each product license agreement	Target to be developed for Year 2 of operations
	Number of products produced using patent pool licenses (disaggregated by type of product)	Target to be developed for Year 2 of operations
	Total royalty earnings by licensors	Target to be developed for Year 2 of operations
Compliance / Auditing	Number of licensor audits conducted	Target to be developed for Year 2 of operations
Dispute Resolution	Number of disputes facilitated by dispute resolution body	Target to be developed for Year 2 of operations
	Proportion of disputes resolved	Target to be developed for Year 2 of operations

Performance Management	N/A	N/A
Communications / Marketing & Public Relations	Number of patent pool-related publications	N/A
Incentive Management	Number of collaborations initiated for pediatric and FDC formulations	Organizations identified for collaboration on improved formulations
Stakeholder Management	N/A	N/A

Table 2: Indicators for Performance Management

Area 2: Contributions to Health Outcomes

The Medicines Patent Pool Foundation will work with UNITAID in order to support the UNITAID monitoring and evaluation framework with respect to contributions to health outcomes made by the Patent Pool.

7. Priority ARVs for inclusion in Patent Pool

Urgently-needed ARVs that would be a priority for potential inclusion in the Pool were identified. The selected list of products (at right) is currently under final review by AIDS treatment experts. Selection criteria included: patent information; current availability (as originator or generic); registration status; quality standard (e.g. WHO Pre-qualification); adequacy of formulations; timeline (for investigational drugs); clinical information on pediatric use; price; price of alternates; potential for co-formulation; clinical or practical advantages; WHO Essential Medicines List; WHO HIV/AIDS treatment guidelines; and potential scope of use.

Compound	Company
Lopinavir (LPV)	Abbott
Ritonavir (r)	Abbott
Nevirapine (NVP)	Boehringer-Ingelheim
Atazanavir (ATV)	Bristol Myers Squibb
GS-9350	Gilead
Elvitegravir (EVG)	Gilead
Tenofovir (TDF)	Gilead
Emtricitabine (FTC)	Gilead
Efavirenz (EFV)	Merck
Raltegravir (RAL)	Merck
Vicriviroc	Merck (Schering-Plough)
Saquinavir (SQV)	Roche
Etravirine (ETR)	Tibotec / J&J
Darunavir (DRV)	Tibotec / J&J
Rilpivirine	Tibotec / J&J
Lamivudine (3TC)	Viiv (GSK)
Abacavir (ABC)	Viiv (GSK)
Fosamprenavir (FSV)	Viiv (GSK)
Maraviroc	Viiv (Pfizer)

8. Conclusions

In the face of rising drug costs, decreasing financial resources, and the broader reach of pharmaceutical patents, the Medicines Patent Pool Foundation can play a role in maximizing the reach of every dollar spent on health products. The international donor community and national governments in developing countries cannot afford to pay high prices for urgently-needed medicines. The high prices of newer-generation ARVs suggests that complementary, innovative approaches that exploit every efficiency gain are needed.

The creation and functioning of the Medicines Patent Pool Foundation will take us one step closer to achieving the shared mission of improving access to more affordable, well-adapted antiretrovirals for children and adults in developing countries. The business plan sets out clear objectives for the MPPF and identifies the minimum resources necessary to achieve these objectives. The performance of the MPPF can and should therefore be judged by investors against the key performance indicators defined.