

# The Essential Medical Inventions Licensing Agency

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## **Essential Medical Inventions Licensing Agency**

### **Working Plan – 1 June 2007**

#### **Introduction**

The 2006 report by the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) recommended voluntary and non-voluntary licensing of patents to generic drug manufacturers, in order to ensure that a competitive and more affordable market exists for medical technologies. One instrument to facilitate such licensing is the collective management of intellectual property rights, through the creation of patent pools.

The Essential Medical Inventions Licensing Agency (EMILA) will be established as a nonprofit organization that manages patent pools or licensing programs that increase access to patented medical products and vaccines in developing countries. The fundamental idea behind EMILA is to provide a professional platform to facilitate collective management of intellectual property rights and more efficient, reasonable and non-discriminatory licensing strategies to enable generic competition to supply developing country markets with more affordable medical technologies.

#### **EMILA Mission**

The mission of the EMILA is to support the creation of one or more patent pools that facilitate the competitive manufacture and sale of medical products and vaccines.

Each patent pool will negotiate licenses to patents and other intellectual property rights necessary to manufacture, register, sell, import, and export medical technologies in the developing world. This will involve obtaining “in-licenses” from patent holders, and granting “out-licenses” to entities that use the patents and other intellectual property rights to manufacture or sell products.

The pools will:

- a) Facilitate professional management of the negotiation and administration of licensing arrangements,
- b) Reduce licensing transaction costs, through a one-stop licensing strategy that enables generic manufacturers to acquire essential rights in medical technologies from multiple holders in a single transaction as an alternative to negotiating separate agreements,
- c) Establish global norms for licensing that protect individual countries, government agencies and generic manufacturers from external pressures,
- d) Develop best practices for licensing, including transparency, adequate remuneration, non-discriminatory open licensing, and requirements that the licensees address concerns regarding product quality and fiscal accountability,
- e) Provide a predictable and fair system for remuneration to patent holders, respecting national laws and trade agreements on intellectual property rights,
- f) Facilitate technology transfer to developing countries and scale up developing countries manufacturing and distribution capacities,
- g) Ensure sufficient economies of scale,

- h) Provide for the management of multiple owners and stacking of royalties, clearing blocking patents when patent thicket situations exist, and
- i) Provide a platform for collective management of non-patented technology and know-how.

### **EMILA Description**

EMILA will be a nonprofit Swiss organization. It will be funded initially by donations and grants, but will seek to develop a sustainable source of funding from fees drawn from licensing royalties.

EMILA will have members representing a wide constituency from around the globe. These members will elect an executive board that will act as a board of directors.

Management will comprise an Executive Director, responsible for the day-to-day operations of the EMILA, and the executive board. The Executive Director and the executive board will determine staffing requirements in order to carry out the EMILA mission.

EMILA will have several expert committees that will assist the Executive Director and the executive board, including an EMILA Scientific Advisory Board (SAB).

### **EMILA Strategy**

EMILA will assist various national, regional or multilateral third parties (partners) to create and manage patent pools.

The partners will determine the policy objectives for each pool, including, for example, the geographic coverage, targeted diseases or conditions, and the specific licensing terms for patent holders and patent users.

The pools may be national, regional or multilateral, and they may (or may not) be limited to specific diseases or conditions, depending upon the objectives of the partners.

Each pool will be operated as an independent licensing administrator. EMILA itself will not be a user of the patents under license, except when EMILA decides to be responsible for product registrations in a target market.

EMILA will appoint a Scientific Advisory Board (SAB) that will provide advice on medical technologies for which licenses should be sought, will determine the essentiality of patents to be included in the pool, and will provide advice on royalty allocations in cases involving multiple patents in a single product or combination therapy.

On behalf of such pools, EMILA will seek voluntary licenses from owners of relevant patents and other intellectual property rights. To the maximum extent practicable, EMILA will strive to standardize licensing terms for each pool, in order to facilitate sub-licensing. Ideally, EMILA licensees would execute a single standard contract providing access to the pooled patents. In practice, individual licenses will likely be necessary for some products.

EMILA will execute Memoranda of Understanding (MOU) with governments, donors and key procurement bodies (e.g., PEPFAR, Global Fund, UNITAID, the Gates and Clinton Foundations) in order to generate support for a patent pool, as well as to facilitate cooperation between the numerous interested parties.

Once the patented technology is licensed to EMILA, it will be licensed out to generic manufacturers or distributors on an open and non-discriminatory basis, subject to standards, such as ensuring quality and safety.

EMILA would collect royalties from generic manufacturers and pay royalties to patent owners on a pre-determined transparent and predictable formula basis that takes into account the actual use of each patent in the manufacture of products by patent pool licensees.

If EMILA fails to secure a voluntary license for a desired medical technology, EMILA will consider cooperating with governments and third parties who seek compulsory licenses from target market countries in which patents are in force.

### **EMILA Model License Terms and Conditions**

After consultations with industry, universities, health activists, academics and technology licensing experts,<sup>1</sup> Knowledge Ecology International (KEI) has drafted three model agreements:

- 1) Between patent holders and EMILA (patent in-license agreement),
- 2) Between EMILA and generic manufacturers/distributors (patent out-license agreement),  
and
- 3) An authorization to reference or rely upon health registration data.

These draft agreements are attached as Appendices A, B and C.

Each EMILA-managed pool will modify the draft agreements in order to address the policy objectives of the partner organization.

### ***The In-License***

The model standardized voluntary patent *in-license* agreement for licensing of medical products and vaccines to EMILA by patent owners is attached as Appendix A. It provides for these terms:

- 1) A nonexclusive, worldwide royalty-bearing license for the sole purpose of non-exclusively sublicensing patents essential to the manufacture, registration, exportation,

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<sup>1</sup> Persons consulted in the drafting of the model EMILA licenses included: Amy Kapczynski, Brook Baker (Northeastern University), Eric Easom, Frederick M. Abbott (Florida State University), James Love (KEI), John Frase (Florida State University/ 2007 Immediate Past-President, AUTM), Jon Merz (University of Pennsylvania), Michelle Childs (KEI), Judit Rius (KEI), Mark Rohrbaugh (NIH), Michael Whitham and Bob Cook (Whitham, Curtis, Christofferson & Cook), Polly Murphy (Scripps), Rob Weisman (Essential Action), Sandra Shotwell (Alta Biomedical), plus several anonymous persons.

importation, distribution, offering for sale, sale, and use of the product in identified developing world countries;

- 2) Patent holders retain nonexclusive rights in all countries covered by the license, and exclusive rights throughout the remainder of the world;
- 3) Licensees will grant back equivalent licenses to the EMILA on any patentable improvements made to products, and licensors will have rights of first refusal to licenses to patents on such improvements in all high-income countries;
- 4) Licensees shall pay to the EMILA a royalty based on sales of products in each country covered by the license, but no royalty shall be paid if the product is neither manufactured nor sold in a country in which patents covering the product are in force; and
- 5) The royalty will be calculated using the Tiered Royalty Method;

### ***The Out-License***

The model standardized voluntary patent out-license for licensing of medical products and vaccines to third parties by EMILA is attached as Appendix B. It provides Non-Discriminatory access to the pooled patents to qualified companies. Significant terms are:

- 1) EMILA or authorized third parties will be responsible for product registrations in all target markets; and
- 2) licensee manufacturers will be required to be certified under the WHO's Prequalification of Medicines program or by other national regulatory authorities that enforce Good Manufacturing Practices of equal or higher stringency acceptable to licensor; and
- 3) licensees will take reasonable steps to distinguish the licensed product, including not using licensor's proprietary drug names or marks; and
- 4) licensees will be required to procure product liability insurance protecting the licensor and EMILA from potential lawsuits arising from their licensed activities.
- 5) licensees will provide for cross-licensing of new patents that involve improvements on licensed products.
- 6) Licensees will provide a Development Plan and will annually report on its implementation.

### ***The Test Data Authorization***

A standardized model authorization to reference or reply upon health registration data when needed for registration of medical products and vaccines is attached as Appendix C.

## **Antitrust Review**

Patent pools and other intellectual property licensing strategies can raise antitrust issues. The EMILA model licenses have been submitted to the U.S. Federal Trade Commission (FTC) for review. A similar review will be carried out in other jurisdictions, as needed.

## **EMILA Benefits**

The benefits of EMILA to various parties can be summarized as follows:

- 1) Patients.
  - a. Lower prices, through greater competition and larger economies of scale,
  - b. Enhanced access to follow-on innovations, such as new Fixed Dose Combinations or delivery mechanisms.
  - c. Ensure that licenses are tied to appropriate standards for product quality.
- 2) Patent owners:
  - a. Ensure respect for national patent laws and trade agreements on intellectual property rights,
  - b. Provide a predictable, transparent and fair system for remuneration,
  - c. Facilitate cross licensing of new patents that involve improvements on licensed products.
  - d. Serve a more efficient strategy to license out their patented technologies,
- 3) Donors:
  - a. Ensure that the “solution” to the patent problem is focused on the rule of law,
  - b. Obtain lower prices through open competition,
  - c. For regional or multilateral pools, aggregate markets to ensure sufficient economies of scale
- 4) Generic manufacturers:
  - a. EMILA will facilitate access to patented technologies on a non discriminatory manner,
  - b. Lower costs of obtaining licenses,
  - c. For regional or multilateral pools, aggregate markets to ensure sufficient economies of scale
- 5) Governments:
  - a. Provide technical assistance on management of licenses and access to patented technologies,
  - b. For regional or multilateral pools, the pool will be perceived as the norm setting body, insulating the national government from political pressure and antagonistic reporting in the financial press.
- 6) Civil Society:
  - a. The pools provide a more effective opportunity to lobby for voluntary licenses to provide access to patented medical technologies in the developing world and to encourage socially responsible behavior.



### **Possible Partners**

EMILA will approach several potential partners who have interest in establishing pools. This will include discussions with U.N. Agencies such as WHO, UNAIDS, UNFPA and UNDP, donors such as the Global Fund, PEPFAR, UNITAID and the World Bank, and regional bodies in Africa, Asia and Latin America, as well as groups concerned about specific diseases or conditions, such as AIDS, TB, or HPV.

EMILA will offer a range of possible services or partnerships, including, for example, the design, set-up and management of a pool, or any lesser combination, depending upon the partner's interest in undertaking or contracting out tasks.

### **Possible Relationship Between EMILA and Prize Type Rewards for Innovation**

An optional feature of EMILA that could encourage voluntary licensing of patents is the possibility that licensing patents to a pool would be a requirement to qualify for innovation prizes.

The possibility of rewarding innovators with prizes or monetary rewards has been advocated by several economists and health experts and it is currently being considered in different forums, including the WHO Intergovernmental Working Group on Intellectual Property Rights, Innovation and Public Health (IGWG).

**EMILA- APPENDIX A**

***Patent License-In Agreement***

(version 3 May 2007)

License Agreement  
between the  
Essential Medical Inventions Licensing Agency  
and  
< licensor >

This License Agreement, effective on the date last executed below, is by and between the Essential Medical Inventions Licensing Agency (EMILA), a Swiss association having its principal place of business at < address >, and < licensor > (Licensor), a < corporation > having its principal place of business at < address >.

WITNESSETH:

WHEREAS EMILA aims to increase the supply of medical technologies throughout the developing world at affordable prices; and

WHEREAS EMILA seeks to facilitate access to licenses to patents necessary to the manufacture, Registration, distribution, import, export, offering for sale, sale and use of medical technologies in the developing world; and

WHEREAS EMILA wishes to license patents necessary to the manufacture, Registration, distribution, import, export, offering for sale, sale and use of < generic name > for these purposes; and

WHEREAS Licensor is willing to grant a license to its patents for the manufacture, Registration, distribution, import, export, offering for sale, sale and use of < generic name > to populations in the developing world; and

WHEREAS Licensor is willing to license EMILA to meet these mutual goals.

NOW, THEREFORE, EMILA and Licensor agree to be legally bound by the following terms and conditions:

**Article 1. DEFINITIONS**

When used in capitalized form, the following terms shall have the meanings set forth in this Section.

### **1.1 Combination Therapy**

A Combination Therapy is any co-formulated, co-packaged, bundled, or other type of combination pharmaceutical or vaccine product that includes one or more Products.

### **1.2 Licensed Patents**

Licensed Patents are those for which licenses are necessary for manufacture, Registration, distribution, import, export, offering for sale, sale or use of the Product or for implementing a Process. Licensed Patents are identified in Appendix A.

### **1.3 Improvement**

An Improvement is any discovery or invention first made and reduced to practice by a Sub-licensee that generically or specifically comprises a substantive improvement, addition, or enhancement to the Product or a Process, including without limitation know-how, technical or scientific information, processes, techniques, methodologies, formulae, devices and biological or chemical compositions of matter.

### **1.4 Licensed Country**

A Licensed Country is any country not designated by the World Bank as high income as of the date of execution of this License Agreement that will be the target market for manufacturing, Registration, export, import, distribution, offering for sale, sale and use of Product; [provided, that Licensed Country can include a high income country for the manufacturing, Registration and export of Product and/or implementation of Process solely to export, import, Registration, distribute, offer for sale, sale and use Product and/or Process in a country not designated by the World Bank as high income].

Licensed Countries shall not include any country expressly excluded by the parties hereto as delimited in Appendix B.

### **1.5 Patent**

Patent refers to any issued, pending and future letters patent and patent applications in any country that are or become owned by or licensed in whole or in part to Licensor and that claim, in whole or in part, the Product, Process or method of use.

### **1.6 Process**

Process refers to all public, proprietary or Patented methods necessary or useful for making, exporting, importing, distributing, offering for sale, selling or using the Product.

### **1.7 Product**

Product is the < generic name > pharmaceutical or vaccine product made, exported, imported, distributed, offered for sale, sold and used pursuant to a Sub-license hereunder, including but not limited to all Active Pharmaceutical Ingredients (APIs), vaccine adjuvant, components, intermediates, other ingredients, and Improvements thereto.

### **1.8 Qualified**

Qualified refers to pharmaceutical manufacturers who are, or who become within one (1) year of grant of a Sub-license hereunder, certified as manufacturers for the Product under the World Health Organization's Prequalification of Medicines program or other national regulatory authority enforcing Good Manufacturing Practices of equal or higher stringency, including specifically the regulatory bodies of the countries delimited in Appendix C.

### **1.9 Registration**

Registration refers to the process of securing all necessary licenses for manufacture, importation, exportation, distribution, offering for sale, sale and use of Product in any Licensed Country.

### **1.10 Sub-license**

A Sub-license is a grant of rights made under the terms of this License Agreement to Registration, manufacture, export, import, distribute, offer for sale, sell and use the Product and implement any Process.

### **1.11 Sub-licensee**

A Sub-licensee is a Qualified pharmaceutical manufacturer, distributor, exporter, importer, retailer, health care provider, hospital, non-governmental organization, government agency, or other entity licensed by EMILA pursuant to a Sub-license hereunder for the purposes of manufacturing, registering, importing, exporting, distributing, offering for sale, selling and using Product and implementing any Process.

### **[1.12 Field of Use**

Field of Use shall mean the treatment and prophylaxis of [specify diseases and conditions].]

## **Article 2. LICENSE**

### **2.1 Grant of License**

Licensor grants to EMILA a non-exclusive, world-wide license to Licensed Patents for the sole purpose of non-exclusive Sub-licensing for Registration, manufacture, export, import, distribution, offering for sale, sale, and/or use in Licensed Countries of Product and/or Process [in the Field of Use].

### **2.2 Licensed Patents**

Licensed Patents licensed pursuant to this License Agreement are delimited in Appendix A hereto.

### **2.3 Retention of Rights**

Licensor retains all of its rights, title, and interests to its world-wide Patents for use throughout countries not identified as Licensed Countries hereunder, and non-exclusive rights to practice and license Licensed Patents as it sees fit, in its sole discretion, throughout Licensed Countries.

## **Article 3. SUB-LICENSING**

### **3.1 Non-exclusive sub-licensing**

Subject to the terms of this License Agreement, EMILA is authorized to grant non-exclusive licenses to Qualified Sub-licensees for the manufacture, Registration, import, export, distribution, offer for sale, sale and/or use of Product and implementation of any Process in Licensed Countries.

### **3.2 Product Differentiation**

Product shall be differentiated from Licensor's < generic name > by special packaging and labeling.

### **3.3 No Use of Licensor's Marks**

Sub-licensees will not use Licensor's name, trademark, nor its proprietary trade name < Product trade name > for any purposes other than Registration; provided, that Sub-licensees will be free to market, advertise, promote, and label the Product by its chemical name or < generic name > and to use their own marks, trademarks, and trade names on Products, labels, advertising, package inserts, and all Product-related documentation.

### **3.4 Labeling**

Sub-licensees will include the following notice, translated into relevant languages as appropriate, on all labeling: "Manufactured and sold under license from the Essential Medical Inventions Licensing Agency. Not permitted for sale or use outside the territory in which license has been granted".

### **3.5 Back-licensing of Improvements**

Any patented Improvements shall be treated as Licensed Patents, and they will be subject to terms equal to those secured under this License Agreement.

[Option 1 or 2]

EMILA will require Sub-licensees to disclose to EMILA the filing of any patents on Improvements no later than 30 calendar days following the first of such filing(s), including a list of all countries in which applications have or will be filed.

EMILA will provide notice of sub-licensees' filings to Licensor within 30 calendar days of its receipt of notice from Sub-licensee, and Licensor will notify EMILA of its decision to exercise its option hereunder within 60 days of receipt thereof. If Licensor fails to provide such

notice or chooses not to file patent applications in any country covered by this option, then the rights will revert to Sub-licensee.

### Option 1

EMILA will secure an option on behalf of Licensor to a non-exclusive, non-royalty-bearing back-license for any Improvements patented by Sub-licensees for use in high-income countries as defined by the World Bank, provided that Licensor shall bear the direct costs of securing patents in any such countries it determines is desirable, in its sole discretion.

### Option 2

EMILA will secure an option on behalf of Licensor to an exclusive, royalty-bearing back-license for any Improvements patented by Sub-licensees for use in high-income countries as defined by the World Bank, provided that Licensor shall bear the direct costs of securing patents in any such countries it determines is desirable, in its sole discretion.

EMILA will coordinate negotiations between Licensor and Sub-licensee to reach reasonably agreeable terms for such back-license; in the event of failure to reach agreement before any such Improvements are commercially used by Licensor, the royalty payable by Licensor shall be determined in accordance with Article 4 hereunder.

## Article 4. ROYALTIES

### 4.1 Royalties Paid

A royalty shall be collected by EMILA from Sub-licensees for Product that is manufactured in, exported from, imported to, distributed, offered for sale, sold or used in a Licensed Country; provided there are Licensed Patents in either the country in which the Product is manufactured, the country in which it is sold, or both. When there is a patent in both the manufacturing country and the country where the product is sold, royalties shall be based upon the importing country where the product is sold.

*{Illustrative example:*

<i>Target/sold mkt patent?</i>	<i>mfg country patent?</i>	<i>royalty paid?</i>
<i>yes</i>	<i>yes</i>	<i>yes (only target mkt country)</i>
<i>no</i>	<i>yes</i>	<i>yes (only country with patent)</i>
<i>yes</i>	<i>no</i>	<i>yes (only country with patent)</i>
<i>no</i>	<i>no</i>	<i>no}</i>

#### 4.2 Royalty Calculation\*

Annual royalties collected by EMILA shall be calculated by the following formula:

$$R_{year} = R_{base} * GDPpc_i / GDPpc_{HI} * Sales_i * Base Price_{year-1}$$

where:  $R_{year}$  is the royalty payable for calendar year  $year$ ;  
 $R_{base}$  is the base royalty rate;  
 $i$  is the Licensed Country in which Product is sold;  
 $GDPpc_i$  is per capita GDP as specified by the World Bank in Licensed Country  $i$  for  $year-2$ ;  
 $GDPpc_{HI}$  is average per capita GDP in high income countries as designated by the World Bank for  $year-2$ ;  
 $Sales_i$  is the volume of Product sold by Sub-licensee in  $year$  in Licensed Country  $i$ , measured in the same units as the Base Price; and  
 $Base Price_{year-1}$  is the average U.S. wholesale price established by the Red Book as of October 1 in year-1, or when not such a product exists, the price of a Reference Product. Reference Product is a product or combination of products with similar therapeutic benefits as determined by the EMILA Medical Expert Committee.

For epidemic conditions in which disease target population in Licensed Country  $i$  exceeds 3 standard deviations above the average rate of disease target population in high income countries as estimated by the World Health Organization for year-2, the royalty rate shall be modified by the following factor:

- $TP_{HI} / TP_i$

where: TP is the Target Population Rate of the treated disease in high income (HI) countries and Licensed Country  $i$ , respectively.

*{Illustrative example without epidemic condition:*

*Consider a drug with a Base Price of USD 4,000/ year,*

*An  $R_{base}$  (base royalty rate) of 4 percent, and*

*A Licensed Country GDP per capita 10 percent of the average for high income countries.*

*The royalty per unit of sales would be  $4000 * .04 * .1 = \$16$  per year}*

#### 4.3 EMILA Fee

EMILA shall retain from collected cumulative royalties a fee of 10% of the first \$1,000,000, plus 1% of cumulative amounts in excess of \$1,000,000. At the end of each fiscal year, all EMILA revenues in excess of operating costs and expenses and reasonable operating reserve as determined by the EMILA Board of Directors will be paid to all licensors, allocated by relative contribution of each licensor's royalty to gross EMILA royalty revenues.

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\* Source: Remuneration guidelines for non-voluntary use of a patent on medical technologies. Geneva: World Health Organization, 2005;  
[http://www.who.int/medicines/areas/technical\\_cooperation/WHOTCM2005.1\\_OMS.pdf](http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf)

#### **4.4 Royalty Allocation**

In the event that Product is incorporated in a Combination Therapy or other situation arises in which patents held by third parties are determined to be necessary for Registration, manufacturing, exporting, importing, offering for sale, selling or using Product or implementing a Process, then Royalties paid to Licensor, net of EMILA fee, shall be allocated based on the relative contribution of Licensor's Licensed Patents to the Product. This allocation will be determined by EMILA's Scientific Advisory Board (SAB), subject to Licensor's approval, which will not be unreasonably withheld; provided, that if Licensor does not agree with the allocation recommendation of the SAB, the parties (including any third party owners of necessary patents) will enter into good faith negotiations to resolve the matter. If the parties fail to reach agreement, then any party (other than EMILA) may require the matter to be submitted to an independent mediator or arbitrator reasonably acceptable to all of the parties; provided, that the cost of such mediator shall be borne by the party demanding mediation; that the decision of the mediator will be final, and that the resulting royalty allocation shall be effective only from the date of the mediator's decision. The allocation recommended by the SAB shall be used for royalty allocation throughout the pendency of any negotiations and mediation, unless agreed otherwise by the parties hereto.

#### **4.5 Accounting**

The EMILA will collect all royalties on a quarterly basis, and will pay all amounts due to Licensor within 30 calendar days from receipt of royalties from Sub-licensees. Any amount payable hereunder to Licensor, which is not paid on a timely basis, shall bear a penalty rate of 1% per month.

#### **Article 5. TERMINATION**

EMILA may terminate this License Agreement upon 30 days written notice to Licensor.

EMILA shall retain the right to terminate any Sub-license for material breach of any substantive terms by a Sub-licensee, following written notice and a reasonable time in which Sub-licensee may cure the breach. If Licensor reasonably believes that Sub-licensee is in material breach, Licensor may, by written request documenting the reasons therefore, require EMILA to promptly notify the Sub-licensee of the material breach and, if the Sub-licensee fails to cure in reasonable time, terminate the Sub-license.

EMILA will have the right, but not the obligation, to bring an infringement action against Sub-Licensee or to authorize Licensor to initiate an infringement action against Sub-Licensee at Licensor's own expense and in its own name. If EMILA authorizes Licensor to bring an infringement action against Sub-licensee, EMILA will reasonably assist (at Licensor's expense) in such actions or proceedings if so requested, and will lend its name to such actions or proceedings if required by law in order for Licensor to bring such action. EMILA will have the right to participate and be represented in any such suit by its own counsel at its own expense.

Termination or Expiration of this Agreement in whole or in part for any reason shall not relieve EMILA and sub-licensee of its obligations to pay all fees and royalties that shall have accrued hereunder prior to the effective date of termination or expiration.



**Article 6. AUDIT**

EMILA will prepare annual financial statements audited by an independent certified public accountant (CPA). The statements must use generally accepted accounting principles. The independent CPA must follow generally accepted auditing standards.

EMILA shall maintain accurate books and records that will enable Licensor, or an independent auditor reasonably acceptable to EMILA, to verify EMILA's compliance with the terms of this License Agreement. Upon reasonable notice, Licensor or its agents may view books and records during EMILA's normal business hours at mutually agreed times to conduct a review or audit for the sole purpose of verifying the accuracy of EMILA's payments and compliance with this License Agreement. Records that may be viewed include records concerning the calculation, collection, and payment of royalties and the terms and conditions of all Sublicenses granted hereunder.

Financial records will be available for [specify number] years after payment to Licensor hereunder; provided, that nothing herein grants access to Licensor or its agents to records and data underlying EMILA's overall operations, including revenues, finances, costs, and expenses

**Article 7. WARRANTIES**

**7.1 Licensor Warranties**

Licensor agrees and warrants that it is the owner, assignee, or licensee of sufficient rights, title and interest in the Licensed Patents for it to grant the license granted to the EMILA in this License Agreement.

In the event that any claim, civil action or other legal proceeding is brought or threatened against EMILA or Sub-licensee based in whole or in part upon the alleged infringement of any Licensed Patent, then Licensor shall indemnify EMILA and Sub-licensee and hold EMILA and Sub-licensee harmless, from and against any and all losses, liabilities, damages, costs, and expenses (including attorneys' fees) arising out of such claim, action or proceeding. In the event that any such claim results in the interruption of EMILA or Sub-licensee's business activities, Licensor will indemnify EMILA and Sub-licensee for profits lost as a result of such interruption. EMILA and Sub-licensee shall have the right to control its own defense with respect to any such claim, action, or proceeding, without consultation of Licensor. Licensor shall notify EMILA promptly of any such claim, action, or proceeding.

**7.2 EMILA Warranties**

EMILA agrees and warrants that: a) it is duly authorized by its Articles of Incorporation and by all necessary corporate actions to enter into this License Agreement; and b) it will not grant any Sub-license hereunder that does not contain all of the substantive protections for Licensor contained in this License Agreement.

### **7.3 Exclusive Remedy**

If the warranties made by the parties in this Article 7 are not true and accurate, and the other party incurs damages, liabilities, costs or other expenses as a result, the party making such representations and warranties shall indemnify and hold the other party harmless from and against any such damages, liabilities, costs or other expenses reasonably incurred as a result.

### **7.4 Limited warranty**

EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, LICENSOR AND EMILA DO NOT GIVE ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE LICENSED PATENT.

## **Article 8. LIMITATION OF LIABILITIES**

Neither party will be liable for any direct, indirect, special, incidental or consequential damages to the other, however caused, arising under any theory of liability.

Licensor releases, acquits, and forever discharges EMILA from any and all claims of liability for infringement or alleged infringement of the Licensed Patents prior to the date of this agreement.

## **Article 9. INSURANCE AND INDEMNITIES**

EMILA shall require Sub-licensees to secure first dollar products liability insurance in the amount of U.S.\$ < limit > and to provide copies of such policies to EMILA annually along with any notices of changes in coverage. Such policies shall name EMILA and Licensor as third party insureds.

## **Article 10. MISCELLANEOUS**

### **10.1 TERM**

This License Agreement shall be effective from the date last executed below to the expiration of the last-to-expire Licensed Patent licensed under this Agreement, unless earlier terminated in accordance with Article 5 of this Agreement.

### **10.2 MERGER**

This License Agreement constitutes the entire agreement between the parties, and merges and supercedes all prior agreements, representations, statements, negotiations, and undertakings.

### **10.3 ASSIGNMENT**

This License Agreement may not be assigned by EMILA without the prior written agreement of Licensor. Licensor may assign this License Agreement to any third party, including any third party that acquires or merges with Licensor.

### **10.4 JURISDICTION**

The parties hereby agree that any dispute, controversy or claim arising under, out of or relating to this License Agreement and any subsequent amendments of this License Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be [specify place]. The language to be used in the mediation shall English.

If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within 60 days of the commencement of the mediation, it shall, upon the filing of a Request for Arbitration by either party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules. Alternatively, if, before the expiration of the said period of 60 days, either party fails to participate or to continue to participate in the mediation, the dispute, controversy or claim shall, upon the filing of a Request for Arbitration by the other party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules. The place of arbitration shall be [specify place]. The language to be used in the arbitral proceedings shall be English. The dispute, controversy or claim referred to arbitration shall be decided in accordance with the law of [specify law].

*{This clause is still under consideration}*

### **10.5 WAIVER**

The delay or failure of any party at any time to require performance of any provisions of this License Agreement will not be deemed a waiver of the right to enforce its rights at any later time. The terms of this License Agreement may be waived only by written agreement executed by the party waiving compliance.

### **10.6 SEVERABILITY**

If any provision of this License Agreement is ruled invalid by a court of competent jurisdiction or is deemed unenforceable, the remainder of this License Agreement shall not be affected.

### **10.7 THIRD PARTY BENEFICIARY**

There are no third party beneficiaries of this License Agreement.

**10.8 NOTICE**

All notices provided pursuant to this License Agreement shall be in writing, mailed via certified mail, return receipt requested, courier, or facsimile transmission with transmission confirmed, addressed as follows, or to such other address as may be designated by the parties:

Essential Medical Inventions Licensing Agency  
<address>  
<fax>

[Licensor]  
<address>  
<fax>

**10.9 CONSTRUCTION AND INTERPRETATION**

This Agreement shall be construed and interpreted without regard to any presumption or rule requiring construction or interpretation against the Party drafting or causing any instrument to be drafted. This Agreement has been fully reviewed and negotiated between the Parties and no uncertainty or ambiguity in any term or provision of this Agreement shall be construed strictly against either Party under any rule of construction or otherwise. Paragraph headings are used in this Agreement only for purposes of convenience. Licensor and EMILA acknowledge that the headings may not describe completely the subject matter of the applicable paragraph and that headings shall not be used in any manner to construe, limit, define or interpret any term or provision of this Agreement.

IN WITNESS WHEREOF the parties hereto have executed this License Agreement by their duly authorized officers.

Essential Medical Inventions Licensing Agency	[Licensor]
By: _____	By: _____
Title: _____	Title: _____
Date: _____	Date: _____

Appendix A Licensed Patents

Appendix B Exclusions from Licensed Countries

Appendix C Countries where Manufacturers may secure GMP certification in lieu of WHO Prequalification

**EMILA - APPENDIX B**

***Patent License-Out Agreement***

*(Version 3 May 2007)*

License Agreement  
between the  
Essential Medical Inventions Licensing Agency  
and  
< licensee >

This License Agreement, effective on the date last executed below, is by and between the Essential Medical Inventions Licensing Agency (EMILA), a Swiss association having its principal place of business at < address >, and < licensee > (Licensee), a < corporation > having its principal place of business at < address >.

WITNESSETH:

WHEREAS EMILA aims to increase the supply of medical technologies throughout the developing world at affordable prices; and

WHEREAS EMILA holds patent licenses from numerous Licensors enabling it to license qualified pharmaceutical manufacturers, distributors, exporters, importers, retailers, health care providers, hospitals, nongovernmental organizations, government agencies, or other entities to manufacture, register, distribute, import, export, offer for sale, sell and use patented medical technologies for these purposes; and

WHEREAS Licensee wishes to secure a license enabling the manufacture, Registration, distribution, import, export, offering for sale, sale and use of these medical technologies for populations in the developing world; and

WHEREAS EMILA is willing to grant a license to Licensee to meet these mutual goals.

NOW, THEREFORE, EMILA and Licensee agree to be legally bound by the following terms and conditions:

**Article 1. DEFINITIONS**

When used in capitalized form, the following terms shall have the meanings set forth in this Section.

### **1.1 Combination Therapy**

A Combination Therapy is any co-formulated, co-packaged, bundled, or other type of combination pharmaceutical or vaccine product that includes one or more Products.

### **1.2 Licensed Patents**

Licensed Patents are those for which licenses are necessary for, manufacture, Registration, distribution, import, export, offering for sale, sale and use of Products or for implementing a Process.

### **1.3 Improvement**

An Improvement is any discovery or invention first made and reduced to practice by Licensee that generically or specifically comprises a substantive improvement, addition, or enhancement to a Product or a Process, including without limitation know-how, technical or scientific information, processes, techniques, methodologies, formulae, devices and biological or chemical compositions of matter.

### **1.4 Licensed Country**

A Licensed Country is any country not designated by the World Bank as high income as of the date of execution of this License Agreement that will be the target market for manufacturing, Registration, export, import, distribution, offering for sale, sale and use of Product; provided, that [Licensed Country can include a high income country for the manufacturing, Registration and export of Product and/or implementation of Process solely to export, import, Registration, distribute, offer for sale, sale and use Product and/or Process in a country not designated by the World Bank as high income; and provided further, that] Licensed Country varies by Product as determined by EMILA's license.

Licensed Countries do not include the countries delimited in Appendix A for each Product.

### **1.5 Licensor**

Licensor refers to an owner or licensee, in whole or in part, of any Licensed Patent licensed to EMILA under separate agreement, and licensed by EMILA to Licensee under this License Agreement.

### **1.6 Notice**

Notice refers to written notice provided by Licensee to EMILA of its intent to manufacture, distribute, import, export, offer for sale, sell or use a Product under this License Agreement.

### **1.7 Patent**

Patent refers to any issued, pending and future letters patent and patent applications in any country that are or become licensed by a Licensor in whole or in part to EMILA and that claim, in whole or in part, a Product or a Process or method of use.

### **1.8 Process**

Process refers to all public, proprietary or Patented methods necessary or useful for making, exporting, importing, distributing, offering for sale, selling or using the Product.

### **1.9 Product**

Product refers to any one or more of the set of pharmaceutical or vaccine products to be made, exported, imported, distributed, offered for sale, sold and used pursuant to this License Agreement, including but not limited to all Active Pharmaceutical Ingredients (APIs), vaccine adjuvant, components, intermediates, other ingredients, and Improvements thereto.

### **1.10 Registration**

Registration refers to the process of securing all necessary licenses for manufacture, importation, exportation, distribution, offering for sale, sale and use of a Product in any Licensed Country.

### **[1.11 Field of Use**

Field of Use shall mean the treatment and prophylaxis of [specify disease].]

## **Article 2. LICENSE**

### **2.1 Grant of License**

EMILA grants to Licensee a non-exclusive, non-transferable, non-assignable, royalty bearing world-wide license to Licensed Patents for the sole purpose of Registration, manufacturing, importing, exporting, distributing, offering for sale, selling and using in Licensed Country any Product and/or implementing any Process [in the Field of Use].

### **2.2 Licensed Patents**

Licensed Patents licensed pursuant to this License Agreement are delimited in Appendix C hereto.

### **2.3 Retention of Rights**

Licensors retain all of its rights, title, and interests to their worldwide Patents for use throughout countries not identified as Licensed Countries hereunder, and nonexclusive rights to practice and license Patents as each sees fit, in their sole discretion, throughout Licensed Countries.

## **Article 3. LICENSEE'S OBLIGATIONS**

### **3.1 Notice**

Licensee shall provide Notice 180 days before first anticipated sale, and shall identify the Product and each Licensed Country in which Licensee anticipates sales.

### **3.2 Product Differentiation**

Each Product shall be differentiated from the Licensor's product by special packaging and labeling, as agreed upon by EMILA in consultation with each Licensor.

### **3.3 No Use of Licensor's Marks**

For each Product for which Licensee has provided Notice, Licensee will not use the Licensor's name, trademark, nor its proprietary trade name for any purposes other than Registration; provided, that Licensee may market, advertise, promote, and label the Product by its chemical name or generic name and use its own marks, trademarks, and trade names on Products, labels, advertising, package inserts, and all Product-related documentation.

### **3.4 Labeling**

Licensee shall include the following notice, translated into relevant languages as appropriate, on all labeling: "Manufactured and sold under license from the Essential Medical Inventions Licensing Agency. Not permitted for sale or use outside the territory in which license has been granted".

### **3.5 Qualification**

If Licensee is a pharmaceutical manufacturer who will manufacture a Product or implement a Process, Licensee shall be certified under the World Health Organization's Prequalification of Medicines program or other national regulatory authority enforcing Good Manufacturing Practices of equal or higher stringency for manufacture of each Product for which it has provided Notice. Alternative national regulatory bodies of the countries acceptable for each Product are delimited in Appendix B. Such certification shall be secured within one (1) year of Licensee's Notice under Article 3.1 above, and shall be maintained thereafter through the term of this License Agreement.

The Licensee may request technical assistance from the Licensor. In such case, and at the sole discretion of the Licensor, the parties may agree upon terms including appropriate compensation for such services.

### **3.6 Registration**

Licensee is solely responsible for securing all necessary Registrations for each Product for which it has provided Notice, in each Licensed Country.

The Licensee may request technical assistance from the Licensor. In such case, and at the sole discretion of the Licensor, the parties may agree upon terms including appropriate compensation for such services.



### **3.7 Back-licensing of Improvements**

Licensee shall disclose in writing to EMILA its intent to file or filing of any patents on Improvements no later than 30 calendar days following the first of such filing(s), including a list of all countries in which applications have or will be filed. Any patented Improvements shall be treated as Licensed Patents and they will be subject to terms equivalent to those secured under this License Agreement.

#### **[Insert Option 1 or 2]**

EMILA will provide notice of such filings to the appropriate Licensor within 30 calendar days of its receipt of notice from Licensee, Licensor will notify EMILA of its decision to file patent applications within 60 days of receipt thereof, and EMILA will promptly notify Licensee of Licensor's decision. If Licensor fails to provide such notice or chooses not to file patent applications in any country covered by this option, then the rights to file will revert to Licensee.

Licensee shall disclose in writing to EMILA its intent to file or filing of any patents on Improvements no later than 30 calendar days following the first of such filing(s), including a list of all countries in which applications have or will be filed. Any patented Improvements shall be treated as Licensed Patents and they will be subject to terms equivalent to those secured under this License Agreement.

#### **[Option 1**

Licensee hereby grants to each Licensor an option to take a non-exclusive, non-royalty-bearing back-license for any patentable Improvements made to that Licensor's Product throughout high-income countries as defined by the World Bank; provided, that Licensor shall bear the direct costs of securing patents in any such countries it determines is desirable, in its sole discretion. ]

#### **[Option 2**

Licensee hereby grants to each Licensor an option to take an exclusive, royalty-bearing back-license for any patentable Improvements made to that Licensor's Product throughout high-income countries as defined by the World Bank; provided, that Licensor shall bear the direct costs of securing patents in any such countries it determines is desirable, in its sole discretion.

EMILA will coordinate negotiations between Licensor and Licensee to reach reasonably agreeable terms for such back-license; in the event of failure to reach agreement before any such Improvements are commercially used by Licensor, the royalty payable by Licensor to EMILA shall be determined in accordance with Article 4 hereunder.]

### **3.8 Development Plan and Annual Report**

Licensee has agreed to non binding milestones that are attached as Appendix D ("the Development Plan").

Within three months after the end of each calendar year. Licensee shall (a) provide EMILA with a detailed report on the progress to implement the Development Plan, the amounts

of Product produced and on stock, total invoiced sales per country, Sales, samples of the labeling and package with clear identification of the brand-name or trademark used, total royalties owed for the calendar year, the countries in which the Product has been register, sent and in what quantities, the third party resellers, if any, to which Licensee has provided Product and in what quantities, and sales by each third-party reseller (the “Annual Report”); and (b) provide EMILA with a written certification of the accuracy of the contents of the Annual Report, signed by an appropriate Licensee senior officer. Licensee shall provide Annual Reports to EMILA at the address listed below.

## **Article 4. ROYALTIES**

### **4.1 Royalties Paid**

Licensee shall pay a royalty to EMILA for each Product that is manufactured in, exported from, imported to, distributed, offered for sale, sold or used in a Licensed Country; provided, that there are Patents in either the country in which the Product is manufactured, the country in which it is sold, or both. When there is a patent in both the manufacturing country and the country where the Product is sold, royalties shall be based upon the importing country where the Product is sold.

### **4.2 Royalty Calculation\***

Annual royalties paid to EMILA shall be calculated by the following formula:

$$R_{year} = R_{base} * GDPpc_i / GDPpc_{HI} * Sales_i * Base Price_{year-1}$$

where:  $R_{year}$  is the royalty payable for calendar year  $year$ ;

$R_{base}$  is the base royalty rate;

$i$  is the Licensed Country in which each Product is sold;  
 $GDPpc_i$  is per capita GDP as specified by the World Bank in Licensed Country  $i$  for  $year-2$ ;

$GDPpc_{HI}$  is average per capita GDP in high income countries as designated by the World Bank for  $year-2$ ;

$Sales_i$  is the volume of total Product sold by Licensee in  $year$  in Licensed Country  $I$ , measured in the same units as the Base Price; and

$Base Price_{year-1}$  is the average retail U.S. wholesale price established by the Red Book as of October 1 in year-1, or when not such a product exists, the price of a Reference Product. Reference Product is a product or combination of products with similar therapeutic benefits as determined by the EMILA Medical Expert Committee.

For epidemic conditions in which disease target population in Licensed Country  $i$  exceeds 3 standard deviations above the average rate of disease target population in high income countries

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\* Source: Remuneration guidelines for non-voluntary use of a patent on medical technologies. Geneva: World Health Organization, 2005;  
[http://www.who.int/medicines/areas/technical\\_cooperation/WHOTCM2005.1\\_OMS.pdf](http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf)

as estimated by the World Health Organization for year-2, the royalty rate shall be modified by the following factor:

- $TP_{HI} / TP_i$

where: TP is the Target Population Rate of the treated disease in high income (HI) countries and Licensed Country *i*, respectively.

#### **4.3 EMILA Fee**

EMILA shall retain from collected royalties allocable to each Product a fee of 10% of the first \$1,000,000, plus 1% of cumulative amounts in excess of \$1,000,000.

#### **4.5 Accounting**

Licensee shall pay all royalties for sales in each calendar quarter within 30 days from the end thereof. Any amount payable hereunder, which is not paid on a timely basis, shall bear a penalty rate of 1% per month.

#### **Article 5. TERMINATION**

EMILA may terminate this License Agreement, in whole or in part, at its sole discretion, for material breach of any substantive terms by Licensee, following written notice and a reasonable time in which Licensee may cure the breach to EMILA's satisfaction.

Nothing in this Agreement will prevent EMILA to authorize Licensor to enforce this License Agreement against Licensee at Licensor's own expense and in its own name, or to seek royalties directly from Licensee.

Licensee may terminate this License Agreement upon 60 days written notice to EMILA.

Termination or Expiration of this Agreement in whole or in part for any reason shall not relieve Licensee of its obligations to pay all fees and royalties that shall have accrued hereunder prior to the effective date of termination or expiration.

#### **Article 6. AUDIT**

Licensee will prepare annual financial statements audited by an independent certified public accountant (CPA). The statements must use generally accepted accounting principles. The independent CPA must follow generally accepted auditing standards.

Licensee shall maintain accurate books and records that will enable EMILA, or an independent auditor reasonably acceptable to Licensee, to verify Licensee's compliance with the terms of this License Agreement, including but not limited to the amount of Product produced and sold, the parties to whom the Product was sold and the countries in which sales occurred. Upon reasonable notice, EMILA or its agents may view books and records during Licensee's normal business hours at mutually agreed times to conduct a review or audit for the sole purpose of verifying the accuracy of Licensee's payments and compliance with this License Agreement.

EMILA will bear the full cost of any such audit unless such audit discloses a difference of more than five percent (5%) from the amount of royalties due. In such case, Licensee shall promptly pay EMILA any underpayment and shall bear the full cost of such audit.

Financial records will be available for [specify number] years after payment to EMILA hereunder.

## **Article 7. WARRANTIES**

### **7.1 EMILA Warranties**

EMILA agrees and warrants that it is the licensee of sufficient rights, title and interest in the Licensed Patents for it to enter into this License Agreement.

### **7.2 Licensee Warranties**

Licensee agrees and warrants that it has the corporate authority to enter into this License Agreement, that is or will become within one (1) year of grant of this License Agreement certified as manufacturers for the Product under the World Health Organization's Prequalification of Medicines program or other national regulatory authority enforcing Good Manufacturing Practices indicated by EMILA and Licensor, that it will abide by local laws of conducting business, and that it will comply with all substantive terms and conditions herein.

### **7.3 Exclusive Remedy**

If the warranties made by the parties in this Article 7 are not true and accurate, and the other party incurs damages, liabilities, costs or other expenses as a result, the party making such representations and warranties shall indemnify and hold the other party harmless from and against any such damages, liabilities, costs or other expenses reasonably incurred as a result.

### **7.4 Limited warranty**

EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, LICENSOR, EMILA AND LICENSEE DO NOT GIVE ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE LICENSED PATENT.

## **Article 8. LIMITATION OF LIABILITIES**

Neither party will be liable for any indirect, special, incidental or consequential damages to the other, however caused, arising under any theory of liability.

**Article 9. INSURANCE AND INDEMNITIES**

Licensee shall secure first dollar products liability insurance in the amount of U.S.\$< limit > and provide copies of such policies to EMILA annually along with any notice of changes in coverage. Such policies shall name EMILA and each Licensor of Products for which Licensee has provided Notice as third party insureds. Licensee shall send notice to EMILA if insurance status changes within 30 business days.

**Article 10. MISCELLANEOUS**

**10.1 TERM**

This License Agreement shall be effective from the date last executed below to the expiration of the last-to-expire Licensed Patent licensed under this Agreement, unless earlier terminated in accordance with Article 5 of this Agreement

**10.2 MERGER**

This License Agreement constitutes the entire agreement between the parties, and merges and supercedes all prior agreements, representations, statements, negotiations, and undertakings.

**10.3 ASSIGNMENT**

This License Agreement may not be assigned by Licensee without the prior written agreement of EMILA. EMILA may assign this License Agreement to any third party, including any third party that acquires or merges with EMILA.

**10.4 JURISDICTION**

The parties hereby agree that any dispute, controversy or claim arising under, out of or relating to this License Agreement and any subsequent amendments of this License Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be [specify place]. The language to be used in the mediation shall English.

If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within 60 days of the commencement of the mediation, it shall, upon the filing of a Request for Arbitration by either party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules. Alternatively, if, before the expiration of the said period of 60 days, either party fails to participate or to continue to participate in the mediation, the dispute, controversy or claim shall, upon the filing of a Request for Arbitration by the other party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules. The place of arbitration shall be [specify place]. The language to be used in the arbitral proceedings shall be English. The dispute, controversy or claim referred to arbitration shall be decided in accordance with the law of [specify].

*{This clause is still under consideration}*

#### **10.5 WAIVER**

The delay or failure of any party at any time to require performance of any provisions of this License Agreement will not be deemed a waiver of the right to enforce its rights at any later time. The terms of this License Agreement may be waived only by written agreement executed by the party waiving compliance.

#### **10.6 SEVERABILITY**

If any provision of this License Agreement is ruled invalid by a court of competent jurisdiction or is deemed unenforceable, the remainder of this License Agreement shall not be affected, so long as the remaining is not inconsistent with the obligations toward the licensor.

#### **10.7 THIRD PARTY BENEFICIARY**

Licensors of any Product for which Licensee has provided Notice, as identified in Appendix C, and their successors in interest and assignees, are third party beneficiaries of this License Agreement.

#### **10.8 WRITTEN NOTICE**

All notices provided pursuant to this License Agreement shall be in writing, mailed via certified mail, return receipt requested, courier, or facsimile transmission with transmission confirmed, addressed as follows, or to such other address as may be designated by the parties:

Essential Medical Inventions Licensing Agency  
<address>  
<fax>

[Licensee]  
<address>  
<fax>

#### **10.9 CONSTRUCTION AND INTERPRETATION**

This Agreement shall be construed and interpreted without regard to any presumption or rule requiring construction or interpretation against the Party drafting or causing any instrument to be drafted. This Agreement has been fully reviewed and negotiated between the Parties and no uncertainty or ambiguity in any term or provision of this Agreement shall be construed strictly against either Party under any rule of construction or otherwise. Paragraph headings are used in this Agreement only for purposes of convenience. Licensee and EMILA acknowledge that the headings may not describe completely the subject matter of the applicable paragraph and that headings shall not be used in any manner to construe, limit, define or interpret any term or provision of this Agreement.

*EMILA Model Out-License – 3 May 2007*

IN WITNESS WHEREOF the parties hereto have executed this License Agreement by their duly authorized officers.

Essential Medical Inventions Licensing Agency      [Licensee]

By: \_\_\_\_\_

By: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Appendix A Exclusions from Licensed Countries, by Product

Appendix B Countries where Manufacturers may secure GMP certification in lieu of WHO Prequalification, by Product

Appendix C Licensed Patents, by Product, Licensor

Appendix D Licensee Development Plan

*EMILA Model Authorization to Reference or Rely Upon Health Registration Data  
3 May 2007*

*{This proposed agreement has a limited goal, to allow EMILA and generics authorized by EMILA to overcome regulatory barriers in countries that require authorization to refer or rely on third party health registration data.*

*The agreement does not contemplate transfer of know-how or access of the first registrant's proprietary data, although nothing in this agreement prevents parties from entering into additional agreements on these topics.}*

**EMILA- APPENDIX C**

***Authorization to Reference or Rely Upon Health Registration Data***

(Version 3 may 2007)

Agreement  
between the  
< EMILA >  
and  
< FIRM >

This Agreement, effective on the date last executed below, is by and between the Essential Medical Inventions Licensing Agency (EMILA), a Swiss association having its principal place of business at < address > and <FIRM> (FIRM), a < corporation > having its principal place of business at < address >.

WITNESSETH:

WHEREAS EMILA aims to increase the supply of medicines throughout the developing world at affordable prices; and

WHEREAS FIRM has certain rights in data which have been or will be used for purposes of obtaining marketing approval of the Product in the countries listed in Annex A; (FIRM's Marketing Approvals); and

WHEREAS EMILA seeks to obtain or facilitate Registration of the Product in the developing world; and

WHEREAS EMILA seeks to facilitate tentative or conditional approval of the Product in the developed world when required in order for generic versions of the Product to be purchased, exported and/or registered in the developing world. Including obtaining tentative approval by the United States Food and Drug Administration for the purpose of permitting purchase of generic versions by the United States Global AIDS Initiative, President's Emergency Plan for AIDS Relief, and any other global health program that requires FDA approval as a condition of purchase for sale in the developing world; and

WHEREAS FIRM is willing to authorize the reference and reliance to the data included in the FIRM's Marketing Approvals for the Registration of the Product in the developing world or in



*EMILA Model Authorization to Reference or Rely Upon Health Registration Data*  
*3 May 2007*

the developed world to allow purchase, export and/or registration of generic versions of the Product as outlined above; and

NOW, THEREFORE, EMILA and FIRM agree to be legally bound by the following terms and conditions:

**Article 1. DEFINITIONS**

When used in capitalized form, the following terms shall have the meanings set forth in this Section.

**4.1 Authorized Applicant**

An Authorized Applicant is a pharmaceutical manufacturer, distributor, exporter, importer, retailer, health care provider, hospital, non-governmental organization, government agency, or other entity authorized by EMILA to pursue Registration of the Product in an Authorized Country or in the developed world to allow export, registration or purchase of generic versions of the Product to an Authorized Country.

**4.2 Authorized Country**

An Authorized Country is any country not designated by the World Bank as high -income as of the date of execution of this Agreement, which will be the target market for manufacturing, export, import, distribution, offering for sale, sale and use of Product, provided that Authorized Countries shall not include any country expressly excluded by the parties hereto as delimited in Appendix B.

**4.3 Health Registration Data (HRD)**

HRD means all preclinical, clinical, registration and manufacturing information required for Registration of the Product, including, without limitation, all biological, chemical, pharmacological, toxicological, clinical, control, manufacturing, and relevant data.

**4.4 Marketing Approvals (FIRM's)**

FIRM's Marketing Approvals refers to certain rights that FIRM has in HRD which have been or will be used for purposes of obtaining marketing approval of the Product in the countries listed in Annex A.

**4.5 Product**

Product is the < generic name > pharmaceutical, vaccine or other medicine product, including specifically all Active Pharmaceutical Ingredients (APIs), any components, intermediates, and Improvements thereto.

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**4.6 Registration**

Registration refers to the process of securing all necessary licenses for manufacture, importation, exportation, distribution, offering for sale, sale and use of Product in any Authorized Country.

**4.7 Right to Reliance or Rely**

Right to Reliance or Rely is the permission granted to EMILA, an Authorized Applicant, and the regulatory authority to rely on FIRM's HRD or FIRM's Marketing Approvals of the Product.

**4.8 Right of Reference or Refer**

Right of Reference or Refer is the permission granted to EMILA, an Authorized Applicant, and the regulatory authority to refer to the Firm's HRD or Firm's Marketing Approvals.

**Article 2. AUTHORIZATION**

FIRM authorizes EMILA, any Authorized Applicant, and the regulatory authority to refer to and rely on all the FIRM's HRD and FIRM's Marketing Approvals, for the sole purpose of Registration of the Product in an Authorized Country, should such authorization for such reference or reliance be required under national law.

FIRM authorizes EMILA, any Authorized Applicant, and the regulatory authority in a non-Authorized Country to refer to and rely on all HRD concerning Firm Marketing Approvals for the sole purpose of gaining such tentative or conditional Registration as would be necessary in order: (1) to permit export to an Authorized Country (2) to permit Registration in an Authorized Country or (3) to permit purchase of a generic version of the Product by a global health initiative, such as the U.S. Global AIDS Initiative and PEPFAR program, for use in an Authorized Country.

If further authorizations or cooperation is needed to register the Product in an Authorized or non-Authorized Country, the FIRM agrees to provide any reasonable authorizations and cooperation within 30 days of receipt of notice from EMILA.

**Article 3. NOTIFICATION**

EMILA will require Authorized Applicants to submit EMILA lists of the Authorized and non-Authorized Countries in which the Authorized Applicant has registered the Product, no later than 30 calendar days after obtaining registration. EMILA will provide notice of such registrations to FIRM, if authorization from FIRM is needed, within 30 calendar days of its receipt of notice from Authorized Applicant.

Notwithstanding this article notification obligation, the authorization contained in this agreement is self-executing, and a copy of this agreement, certified by EMILA, can be filed with drug regulatory agencies for the purpose of verifying the right of reference or reliance.

**Article 4. ROYALTY**

A royalty shall be collected by EMILA from Authorized Applicant for sales of Registered Products in an Authorized Country by the Authorized Applicant for which FIRM's authorization has been sought to refer to or rely on HRD concerning FIRM's Marketing Approvals. Annual royalties collected by EMILA shall be calculated by the formula set up in Annex C.

The EMILA will collect all royalties on a quarterly basis, and will pay all amounts due to FIRM within 30 calendar days of receipt of royalties from Authorized Applicant.

**Article 5. MISCELLANEOUS**

**5.1. DISCLAIMER**

Nothing in this agreement shall prevent parties from expressing different views on the obligations in international or national law to require authorization to rely, reference or otherwise use HRD submitted to regulatory authorities to obtain marketing authorization by competing products.

**5.2. LIMITATION OF LIABILITIES**

Neither party will be liable for any indirect, special, incidental or consequential damages to the other, however caused, arising under any theory of liability.

**5.3. JURISDICTION**

The parties hereby agree that any dispute, controversy or claim arising under, out of, or relating to this Agreement and any subsequent amendments of this Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be [specify place]. The language to be used in the mediation shall be English.

If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within 60 days of the commencement of the mediation, it shall, upon the filing of a Request for Arbitration by either party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules. Alternatively, if, before the expiration of the said period of 60 days, either party fails to participate or to continue to participate in the mediation, the dispute, controversy or claim shall, upon the filing of a Request for Arbitration by the other party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules. The place of arbitration shall be [specify place]. The language to be used in the arbitral proceedings shall be English. The dispute, controversy or claim referred to arbitration shall be decided in accordance with the law of [specify jurisdiction].

*{This clause is still under consideration}*

**5.4 SEVERABILITY**

If any provision of this Agreement is ruled invalid by a court of competent jurisdiction or is deemed unenforceable, the remainder of this Agreement shall not be affected.

IN WITNESS WHEREOF the parties hereto have executed this Agreement by their duly authorized officers.

Essential Medical Inventions Licensing Agency      [FIRM]

By: \_\_\_\_\_

By: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

**Annex A**

***FIRM's Marketing Approvals***

FIRM has obtained or will obtain marketing approvals for the Product in the following countries:

For each country list:

Country:  
Year that Marketing Approval was obtained:  
Proprietary name (trade name):  
Approved generic name(s):  
Strength(s) per dosage unit:  
Dosage form:  
Holder of the Approval:  
Restrictions on sale or distribution:

**Annex B**

***Exclusions from Authorized Countries***

**Annex C**

***Royalty***

*{The options provided in Annex C are still going through internal review because some experts that KEI consulted have expressed a difference of opinion and have suggested that royalty payments for the use of health registration data should be credited against the payments for the right to use the patent}*

Annual royalties to the FIRM shall be calculated as follows, at the discretion of the Authorized Applicant<sup>2</sup>:

OPTION A  $R_i = C * s_i / S_i * 1 / \text{Term}$ , or

OPTION B  $R_i = s_i * r$

where:  $R_i$  is the royalty payable for period  $i$ ;  
C is the risk-adjusted cost of generating HDR;

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<sup>2</sup> Source: Protection of Pharmaceutical Test Data: A Policy Proposal. Consumer Project on Technology (November 2006): <http://www.cptech.org/ip/health/data/CPTech-Test-Data.pdf>

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- $s_i$  is revenue for Product sales in the Authorized Country for period  $i$  by the Authorized Applicant;
- $S_i$  is global revenue for Product sales in period  $i$  by all parties;
- Term is the number of periods for which the law of the Authorized Country requires authorization to reference or otherwise rely upon HRD; and;
- $r$  is the percentage royalty rate, which is 2 percent for countries designated as lower-middle income or low-income by the World Bank, or 5 percent for countries designated as upper-middle income by the World Bank.

For epidemic conditions in which disease target population in Authorized Country  $j$  exceeds 3 standard deviations above the average rate of disease target population in high-income countries as estimated by the World Health Organization, the royalty rate shall be modified by the following factor:

- $TP_{HI} / TP_j$

where: TP is the Target Population of the treated disease in high income (HI) countries and Authorized Country  $j$ , respectively.

**Method for determining the risk adjusted cost for HRD.**

The risk-adjusted cost for HRD data will be based upon the actual expenditures on clinical trials and other tests, and only include outlays on the tests that are used by the Authorized Applicant to register a product in an Authorized Country. To adjust for risk, expenditures on Phase I clinical trials will be multiplied by five, expenditures on Phase II clinical trials will be multiplied by two, and expenditures on Phase III trials will be multiplied by 1.5. Expenditures on Phase I/II trials will be multiplied by 3, and expenditures on Phase II/III trials will be multiplied by 1.75.

**Allocation of royalty among different FIRMS that authorize use of HRD.**

When authorizations for HDR are obtained from more than one party, the royalty will be allocated among the parties on the basis of the relative risk-adjusted costs of the tests, as determined by agreement among the parties, or by mediation provided by EMILA.