**Compulsory Licensing: Assessing the Barriers and Secondary Effects on Global Public Health**

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**Executive Summary**

Fewer than one in three people suffering with advanced HIV in Sub-Saharan Africa received lifesaving antiretroviral drugs in 2007 (Statistical Annex: Millennium Development Goals, Targets and Indicators, 2009). To address this public health crisis, the international community has devised a relatively new mechanism, compulsory licensing, with unprecedented power to override patent protections in needy countries and bring affordable drugs to those who need them most. Compulsory licensing, however, is used infrequently due to perceived barriers and secondary effects resulting from its use. While researchers have identified these barriers and secondary effects, they have not measured and documented their impact on license use. This project will assess the magnitude of the perceived barriers and secondary effects, and the results will be published in the peer-reviewed literature. Clarity on the magnitude of these obstacles will assist policymakers to make informed decisions when considering compulsory licensing as a tool to maximize global public health. The sum of $3,000 is requested to fund this project.

**Background and Public Health Significance**

Citizens of developing countries suffer the majority of global infections, and millions die of treatable diseases (Satyanarayana, K. 2008). Bearing a disproportionate burden of illness, developing nations often cannot afford or manufacture needed drugs (Bird, 2009). Intellectual property rights prohibit competition, allowing patent holders to maintain high prices for needed drugs, and highly convex demand curves in developing countries prompt pharmaceutical companies to set prices affordable by only a fraction of the market (Flynn, 2009).

To reduce drug prices, the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) allows World Trade Organization Members to grant compulsory licenses for patented pharmaceuticals and locally manufacture the drugs while paying adequate remuneration to the patent holder (Herget, 2006 and Reichman, 2009). A compulsory license is a legal right to exploit a patent granted by a government without the permission of the patent holder (Flynn, 2009). Under the Doha Declaration, countries unable to manufacture their own drugs could contract with nations willing and able to produce needed pharmaceuticals.

Compulsory licenses, when used appropriately, have the potential to significantly improve public health by increasing the availability and affordability of pharmaceuticals to needy populations. However, barriers and secondary effects from the use or threat of compulsory licensing can minimize or even controvert the intended public health effects of the license.

**Specific Aims**

The aims/objectives of this project are:

1. to evaluate barriers to the use of compulsory licensing
(2) to examine the adverse secondary effects that may arise from the use or threat of compulsory licensing
(3) to examine the benefits of compulsory licensing on the availability and affordability of needed pharmaceuticals
(4) to examine the mechanisms intended to minimize barriers and secondary effects; and
(5) to publish the results in the peer-reviewed literature.

Research Design and Methods

Specific barriers to be assessed are: (1) hesitation of developing country officials to invoke compulsory licensing provisions for fear of reduced donor aid, retaliation by developed countries through trade sanctions, negative publicity and the threat of litigation; (2) lack of awareness, inter-governmental coordination and legal infrastructure to enact and implement compulsory licensing provisions; and (3) multiplicity of patents on processes and ingredients for a single drug.

Adverse secondary effects to be assessed are: (1) reduction in direct foreign investment by firms reacting to the use or threat of licensing; (2) reduction in patent applications by patent holders in countries using, threatening or anticipating use of compulsory licensing (parallel importation concerns); (3) unaffordable pricing structures by agencies manufacturing under license; (4) alleged improper license use (e.g. uses for commercial, non-public health purposes); (5) manufacturing of poor-quality drugs under license; and (6) disincentives for pharmaceutical companies to research conditions afflicting developing nations.

Benefits to be assessed are: (1) lives saved and quality-adjusted life years increased due to license implementation; and (2) increase in accessibility and affordability of pharmaceuticals resulting from negotiations stemming from the threat of a license.

Mechanisms intended to minimize barriers and secondary effects to be examined are: (1) legal remedies for patentee claims of inappropriate license use; and (2) legal remedies for violations of the WTO Dispute Settlement Understanding.

A comprehensive search of peer-reviewed literature and secondary sources on the subject matter of this proposal has already been conducted. Research on international trade agreements, intellectual property systems and previous uses of compulsory licensing will be completed prior to the initiation of the project to provide context and background for the policy analysis.

Methodological approach will make heavy use of regression analysis. The first step will be to quantify the presence of TRIPS compliant legislation on a per-country basis in Sub-Saharan Africa and Asia (Source: World Trade Organization). Next, instances of license use and the threat of use will be quantified (Source: WTO and Knowledge Ecology International). Third, control variables such as GDP, inflation, government credit rating, and government deficit as a percentage of GNP will be collected (Source: International Monetary Fund International Financial Statistics Database). Which control variables will ultimately be selected will be determined in the course of the regression analysis. These variables will be regressed on the number of patent applications (Source: World Intellectual Property Organization Statistics Database), direct foreign investment (Source: IMF), and international donor aid (Source: IMF). Dependent variables will be analyzed for
feedback effects on the independent variables. Qualitative research into claims of unaffordable pricing structures, improper license use and poor drug quality will be conducted to determine if these claims have basis in fact. All databases are publicly available or available through University of Minnesota student access.

The findings from this research will be compiled into a final paper, which will be submitted for publication in a peer-reviewed journal at the end of this project.

**Workplan**

a. 5/10-5/30/10 Complete research for Aims # 1-4 (25 hours)
b. 5/31/10-6/15/10 Data Analysis (35 hours)
c. 6/15/10-7/15/10 Drafting final report (35 hours)
d. 7/15/10-7/30/10 Finalizing paper and submitting for publication (25 hours)

**Biography**

After graduating from St. Olaf College with majors in Physics and Mathematics, Angela Morley received her Juris Doctorate, *magna cum laude*, from William Mitchell College of Law. Before graduating in the top 10% of her law school class, Ms. Morley received CALI awards for the top grade in Public Health Law, Estates and Trusts and Family Law. Ms. Morley is now pursuing a Master of Public Health at the University of Minnesota School of Public Health. While studying the School of Public Health, Ms. Morley is working as a Research Assistant and Office Manager at the Minnesota Center for Health Care Ethics. Her professional research interests include issues at the intersection of health, policy and ethics. Ms. Morley is committed to improving global public health through her research and advocacy efforts.

**References**


United Nations (2009). Statistical Annex: Millennium Development Goals, Targets and Indicators. (Indicator 6.5) Available at: