Consortium on Law and Values in Health, Environment & the Life Sciences
2012-13 Student Proposal Cover Page

Applicant Information

<table>
<thead>
<tr>
<th>Applicant name:</th>
<th>Roma Patel</th>
<th>Email: <a href="mailto:Pate0247@umn.edu">Pate0247@umn.edu</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Project title:</td>
<td>The Doha Declaration: Two Steps Forward, One Step Back?</td>
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<tr>
<td>Department:</td>
<td>Public Health Administration and Policy</td>
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<td>College:</td>
<td>SPH</td>
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<tr>
<td>Degree program:</td>
<td>JDP</td>
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<tr>
<td>Faculty advisor name &amp; email:</td>
<td>Ira Moscovice <a href="mailto:mosco001@umn.edu">mosco001@umn.edu</a></td>
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<td>Dept. Head:</td>
<td>Any Le</td>
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<tr>
<td>Dept. Head’s email:</td>
<td><a href="mailto:Lexx0122@umn.edu">Lexx0122@umn.edu</a></td>
<td></td>
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<tr>
<td>Dean:</td>
<td>John Finnegan</td>
<td></td>
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<tr>
<td>Dean’s email:</td>
<td><a href="mailto:sphdean@umn.edu">sphdean@umn.edu</a></td>
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</tbody>
</table>

How did you hear about this funding opportunity?
- [ ] VIP email
- [ ] The Brief
- [ ] Advisor
- [ ] Dept. email/newsletter
- [ ] OVPR website
- [x] Other

How did you hear about this funding opportunity?
- [ ] Other

Funding

| Total amount of funding requested: | $6,988.00 |

Executive summary (maximum 200 words)

I am requesting a grant of $6,988 to conduct research in conjunction with the World Health Organization’s Department of Public Health Innovation and Intellectual Property. The nature of my research involves improving access to essential medicines in developing nations. My objective is to conduct a policy analysis of the Doha Declaration and to determine the scope and magnitude of the difficulties implementing it. The Doha Declaration is an amendment to the TRIPS Agreement, both are products of the WTO and WHO. I will pay particular attention to Article 6 of the Declaration which facilitates access to medicines for countries with none or insufficient pharmaceutical manufacturing capacity. This project strives to strengthen the relationship between intellectual property law, trade practices and global public health goals by determining changes that need to be made to a widely accepted international trade agreement. I plan to publish my findings in a public health and/or law journal, my work will also serve as the basis for my masters thesis.

Approvals

Check all appropriate approvals required for your proposal. Approvals must be obtained prior to receipt of funding. If you have applied for approval but have not yet received it, indicate that below.

<table>
<thead>
<tr>
<th>IRB</th>
<th>Yes</th>
<th>No</th>
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<tr>
<td>Other</td>
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</table>

Checklist

- [ ] The proposal is 1000 words or less excluding budget, biographies, references and citations.
- [ ] The proposal includes a work plan with a specific timeline using months or quarters to identify work to be done and completion dates.
- [ ] The proposal includes a 1-2 paragraph biography of the applicant and all co-investigators.
- [ ] The budget form is complete including the funds sought for this project, other pending applications for this project, and the amount/source of matching or other funds.
- [ ] The applicant's faculty advisor is copied on the application email. Professional students w/o advisors check NA.
- [ ] All necessary approvals are pending or received.
The Doha Declaration: Two Steps Forward and One Step Back?

Roma Patel

Summary of Research:
Between 2001-2009, essential medicines were, on average, available in only 42 per cent of public sector facilities, while they were available in 64 per cent of private sector facilities in developing nations. Of the medication available to patients, the median prices in public sector markets were approximately 2.7 times higher than international reference prices and 6.2 times higher in the private sector (MGD Gap Task Force Report, 2011). It has been 19 years since the advent of the TRIPS Agreement and 12 years since the Doha Declaration was instituted, yet access to affordable essential medicines continues to be an elusive and burdensome problem for many developing countries. This research seeks to determine what specific challenges TRIPS compliant nations face in implementing the DOHA declaration, with a particular focus on Article 6 and conduct a comprehensive assessment of barriers that exist beyond the Doha’s scope.

Background:

Historically, the limited availability and high price of essential medicines were attributed to the lack of consistent patent law and trade practices in the global market. The Agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPS) introduced intellectual property law standards into the global trading system for the first time. Developing countries that did not previously acknowledge product patents in areas such as pharmaceuticals had to modify their laws to become TRIPS compliant and grant patents on medicines. In order to balance the rights of pharmaceutical patent holders with international public health needs the TRIPS Agreement offers flexibilities to developing countries. These flexibilities allow for the use of compulsory licensing, parallel imports, patent right exceptions and the application of a developing country’s own rigorous criteria for patentability (South Centre, 2011). The TRIPS agreement still remains the most comprehensive international covenant on intellectual property. However, many developing nations proposed for a narrow interpretation of TRIPS, this led the World Trade Organization to adopt the Doha Declaration in 2001—a statement that aims to clarify the scope of TRIPS (Correa, 2002). The Doha Declaration provides articles safeguarding public health as a priority and allows developing countries to circumvent certain patent rights to access essential medicines. For example, the Doha Declaration gives member states the right to determine what constitutes a national emergency or other circumstance of extreme urgency with regard to public health—a required component for compulsory licensing (Alsegard, 2004).

Article 6 facilitates access to medicines for countries with none or insufficient pharmaceutical manufacturing capacity (Doha Declaration, 2001). However, only one instance of Article 6’s use has taken place. In fact, since it’s inception there have been very few instances of countries invoking the TRIPS flexibilities. (MacMillan, 2010). This suggests there are deterrents against the utilization of the TRIPS flexibilities, Article 6 in particular.

Methods:
Specific research objectives are to: (1) understand the full use of TRIPS flexibilities afforded to member states, (2) enumerate cases where TRIPS flexibilities, specifically medication and medical devices, were invoked by developing countries, (3) record amendments made to the national legislation of developing countries to become TRIPS compliant, (4) document instances of pressure from commercial manufacturers, PhRMA, NGOs and developed countries to thwart efforts to use flexibilities, (5) assess lack of technological and legal assistance from intergovernmental organizations and developed nations to implement the TRIPS Agreement, (6) understand the restraints on declaring public health emergencies i.e. limiting the conditions to only certain infectious diseases, (7) understand how US Free Trade Agreements and EU Economic Partnership Agreements impact Doha, (8) focus on specific difficulties of Article 6. The ultimate goal of this project is to determine the scope and magnitude of these challenges.

The bulk of my research will be conducted in conjunction with the World Health Organization’s Department of Public Health, Innovation and Intellectual Property in Geneva. In addition to a breadth of literature from intergovernmental organizations, trade publications, law reviews, legal journals, public health journals, trade agreements, statues and litigation stemming from TRIPS; I should have access (to be granted) to transcripts of negotiations from the WTO’s Ministerial Conference of 2001, the Doha Development Round and the Uruguay Round. I will also conduct oral interviews with members of the WTO, WIPO, WHA and WHO. The culmination of this information should serve as a generous foundation to conduct my policy analysis.

Finally, I will use the information from the research objectives to consider the future implications of Doha’s utilization, the efficacy of compulsory licensing and parallel imports, the realistic chances for a developing country to achieve a level of sustainable manufacturing capabilities—especially in politically unstable climates. Additionally, my analysis will serve to answer what other barriers exist to the access of medications if the Doha Declaration is somehow comprehensibly globally incorporated in intellectual property and trade practices by member states.

**Contribution to Law, Public Health and Policy:**

The TRIPS Agreement and Doha Declaration have already established a nexus between the law and public health objectives. However political, economic and philosophical implications attenuate this relationship. This project aims to shed light on the future policy decisions that will need to be made by countries seeking to import medication and medical devices for its people, private sector stakeholders and intergovernmental organizations that strive to balance competing interests. Changes to patent law and trade practices are not only necessary but inevitable for the aims of global public health to thrive. My research will culminate in the production of my thesis for the M.P.H. program in Public Health Policy and Administration as well as the creation of a publication: an article for submission to a public health and/or law journal. Barriers in accessing essential medications are unacceptable. It’s time to deliver.

**Time Line:**
May 15-June 1: Conduct an in depth peer literature review
June 1: Travel to Geneva to work in conjunction with the World Health Organization’s Department of Public Health, Innovation and Intellectual Property.

June 2-July 31: Achieve objectives 1-8 and conduct oral interviews.

August 1-August 20: Analyze results, draft report.

August 21-September 2: Finalize report and submit for publication.

Biography:

Roma Patel is a second year JDP student at the University of Minnesota Law School and School of Public Health, concentrating on Public Health Administration and Policy—with a focus on Management. After she graduated from Carleton College in 2010 with a B.A. in English she spent a year working at a non-profit organization in Baltimore. She began law school at Case Western Reserve University where she served on the Dean’s Advisory Committee. Her first year of law school included a Bioethics and Health Law course that sparked her interest in disparities in health and access to medication. In the spring of 2012 she was awarded the Case Western Reserve University Law-Medicine Center’s Health Law Grant. During the summer of 2012 Roma served as a law clerk for the Attorney General of Maryland in the Health Advocacy Unit. There she mediated consumer complaints with insurers and health providers, researched current health policy and legislative issues, worked on an amicus brief that was submitted to the Supreme Court of Maryland, and participated in the Maryland Healthcare Commission’s work groups on implementing the Affordable Care Act. Roma transferred to the University of Minnesota for her first year of public health and second year of law school. She was nominated as the Maynard Pirsig Moot Court Program’s “Best Oralist” and participated in the Honors Oral Argument Competition. Roma serves on the steering committee of Common Grounds, a graduate student led non-profit organization that serves the community through interdisciplinary consulting projects. She also has significant research experience from Duke University School of Medicine and The University of Minnesota Medical School.

References:


Ford, N., Wilson, D., Costa Chaves, G., Lotrowska, M., & Kijtiwatchakul, K. (2007). Sustain in access to antiretroviral therapy in the less developed world:


Killick, J. & Schulz, A. Parralell trade in Europe—the tide is turning. *Informa Law*, 2(1).


### Project Title: The Doha Declaration: Two Steps Forward, One Step Back?

**Instructions:** Provide justification along with costs.

<table>
<thead>
<tr>
<th>Category</th>
<th>Description &amp; justification</th>
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<th>Amount</th>
<th>Source</th>
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<td>Salary = 285 hrs x 17.50/hr = 4987.50 I will research a breadth of literature, conduct oral interviews, analyze policy, go through negotiant transcripts and draft a final report for publication.</td>
<td>$4,988</td>
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<td>2 Other personnel</td>
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<td>3 Speaker honoraria</td>
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**Budget Guidelines**

1. Stipend justification. You must justify the amount of stipend you are requesting by identifying the number of hours you plan to work on the project and the hourly wage used for research assistants in your department. Include fringe benefits.

2. Identify all other personnel to be paid from this grant including interpreters, travel guides, etc. and justify their salary by identifying the number of hours they will work and the hourly wage. What is the hourly wage based on?

3. For colloquia, identify the number of speakers and the amount of honoraria you will provide.

4. Supplies and services. List out all supplies and their estimated costs. Explain in line 7 or in the body of your proposal what the supplies will be used for.

5. Equipment costs are allowable only if the justification clearly shows that the equipment is necessary for the project. Include explanation of what will happen to equipment at completion of project.

6. Travel costs must include a description of the purpose of the travel, start and stop dates of travel, transportation costs, housing costs, and allowable per diem (use University rates found at http://travel/umn.edu).