INTL 190: Global Access to Modern Medicine
Fall 2018
Thursdays 9 – 11:50 AM
Rm 1328 Robinson Bldg. Complex

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Overview

More than two billion people lack access to essential medicines. Each year, about 10 million people die from diseases where current vaccines and medicines could have saved their lives. Many in the developing world cannot afford the high prices pharmaceutical companies charge for lifesaving medicines. The problem of inequitable access to medicines is of growing concern in an age where there are available methods of prevention, treatment, and cures.

This course will explore the connections between human rights, international law, trade, intellectual property, and global health, with a particular focus on how pharmaceuticals and medical technologies can effectively reach the world's poor and marginalized populations. We will research the historical context, legal issues, and current policy debates impacting drug development and access to medicines. We will analyze the development of a global standard in patent protection brought about by the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the flexibilities countries can use to protect the public health of their people. We will examine the incentives and business models of pharmaceutical companies, as well as alternative methods for addressing global health needs. In doing so, students will gain in-depth and interdisciplinary knowledge of (1) international trade and patent law, (2) policy options for research, development, and commercialization of biopharmaceutical technologies, and (3) a human rights-based approach to health.

Students will become familiar with key actors, including the World Trade Organization (WTO), World Health Organization (WHO), World Intellectual Property Organization (WIPO), pharmaceutical companies, non-governmental organizations, activist groups, and key national governments. We will critically examine controversial issues concerning patent rights, drug pricing, public health, human rights, and discuss the different roles and responsibilities of key stakeholders.

Requirements and Evaluation

As a capstone research seminar, this course is designed to support you in producing a high-quality analytical paper. My objectives are for you to (1) explore a topic that deeply interests you, and (2) develop practical skills that will help you succeed in your post-graduate endeavors. Research paper assignments therefore are scaffolded throughout the quarter to give you time and support to dig deep into your sources, formulate an original and manageable thesis, get meaningful feedback and assistance from your peers and me, and rewrite multiple drafts into a professional final report.

While your final paper is a substantial learning component, this seminar is designed to give you interdisciplinary background knowledge of world trade, intellectual property, human rights, and global health issues, as well as tools for engaging in significant legal and policy analysis. It is critical that you promptly attend each class having done all the reading, thought about the issues, and are prepared to participate with questions and comments.

The grading breakdown is as follows:

Class attendance and participation: 15%
Student-led discussion: 10%
Paper topic & outline: 10%
Paper draft and peer feedback: 10%
Research presentation: 10%
Final research paper: 45%

Important Due Dates

1-page description of research topic: October 10th
Paper outline: October 24th
Draft paper for peer review: November 14th
Research presentation: November 29th & December 6th
Final paper: December 10th

Class Attendance and Participation

Prompt attendance to each class session is mandatory. Those arriving after the class start time may be given half credit for attendance. Authorized absences from class sessions may be provided on a case-by-case basis; this will happen rarely and must be approved by me in writing.

Participation will be graded according to the degree you contribute regularly to class discussions in a way that demonstrates you have read the material and have thoughtfully considered the issues presented.

Student-Led Discussion

You and your group will be co-instructors and your primary objective is to lead an engaging and fruitful discussion that is informational, interpretive/analytical, and evokes debate.

Your class contribution must include:

- A presentation of key concepts from the readings, media, and case studies;
- Conversation with your classmates about major takeaways; and
- A facilitated discussion of your own questions and those presented in the syllabus.

Beyond these basic expectations, you are encouraged to use creative exercises, simulate role plays, prepare a structured debate, or any other teaching methods you think will enhance student understanding of the material.

In facilitating the discussion, you should explore the main problems identified in the assigned readings and media, different perspectives from which to approach the problems, the principal incentives and solutions of various stakeholders, and connections that can be made to other course topics.

Most importantly, you are expected to lead an engaging discussion. Pose challenging content-specific questions that encourage your classmates to take a position and reflect on their own assumptions. For example: "Explain why ___", "Explain how ___", "Why is ____ happening?", "What was the author's main point?", "Are you convinced?", "What do you think causes ____ and why?", "How does ___ relate to what we have learned before?", "What is another way to look at ____?", "What would happen if _____?", "Why is this important?"

At the end of class, you will grade yourself and your classmates, and your classmates will do the same for you. I will incorporate these grades with my own assessment.

Two days before your scheduled student-led discussion (Tuesday at NOON) you must send to me via email your discussion questions and a description of any planned creative exercise or activity. I will send feedback to you as soon as possible to ensure everyone is set up for a successful class.

Research Paper Requirements

My goal is for you to research a specific topic in detail and compose a comprehensive paper. In the process, you will polish your writing skills by organizing a vast amount of information into a clear and concise thesis supported by a thorough and logical analysis of credible sources. The paper should not be a recitation of facts, nor a sermon of your opinion. Rather, you are expected to produce an argument that is both empirical and analytical.

The final product for this class is a research paper of approximately 20-25 double-spaced pages in length, with Times New Roman, 12 pt font and standard 1" margins, with a cover page, introduction, conclusion, complete citations, and a bibliography. You may use any academically recognized bibliographic style (Chicago, MLA, APA, Bluebook, etc.), as long as you consistently use the same style throughout your research paper.

The due date for the final paper is **Monday, December 10th**. You are required to turn in both a hard copy to my mailbox and an exact copy in Word (DOC or DOCX) or Adobe Portable Document (PDF) format to Turnitin via Ted/Blackboard by 11:59 p.m. PST that evening.

The topic of your research paper must touch on some aspect of global access to modern medicine. Attached to this syllabus are suggested paper topics.

Research Paper Assignments:

The initial research paper assignments will be graded on the following scale: ✔+ (exceeds expectations), ✔(meets expectations), ✔- (below expectations), INC. (not acceptable).

Description of research topic: In about one page, single-spaced, describe the topic you are

planning to explore for your final paper and explain why you chose this topic. Submit an electronic copy to Turnitin the night before our third class session (Wednesday, October 10th by 11:59 p.m. PST that evening).

Paper outline (including bibliography): You are expected to have an introduction, clear and concise thesis statement, 3 body paragraphs, and a detailed outline (including citations to sources) of your research paper. This assignment is designed to help you organize your research, construct a successful argument, and draw attention to areas where you need to do more research. I am interested in seeing how you are laying out your claim and integrating your source materials. I will review your outline and provide substantive comments and suggestions. This assignment is due the fifth week of the course. Submit an electronic copy to Turnitin the night before our class session (Wednesday, October 24th by 11:59 p.m. PST that evening).

Draft paper for peer review: Submit an electronic copy of a 10 – 12-page draft of your research paper to Turnitin the night before our eighth class session (Wednesday, November 14th by 11:59 p.m. PST that evening) and bring an identical copy to class the next day (Thursday, November 15th). The hard copy will be used in a writing workshop where you will have the opportunity to discuss your paper and get meaningful feedback from a classmate. I will review the electronic copies and you will have the opportunity to discuss your progress with me during office hours or by appointment.

Research presentation: During our final two class sessions, you will have the opportunity to share your research with your classmates and get any last-minute feedback. Presentations should be about 8-10 minutes in length. The goals here are to: (1) share and learn about everyone's research and interests, (2) cultivate oral presentation skills, (3) provide a final opportunity for peer feedback prior to turning in the final paper, and (4) advance our collective understanding of the interplay of various issues concerning global access to modern medicines. During each student's presentation, classmates will be expected to provide questions and constructive feedback on a form that will be given to the presenter. If time permits, students are encouraged to ask questions of the presenter.

Final paper: Due by NOON (12:00 p.m. PST) on **Monday, December 10th, 2018**. See above for requirements and guidance.

I will provide a grading rubric for the final paper. You will be graded on a 4.0 scale on (1) integration of knowledge from the course, (2) topic focus, (3) depth of discussion, (4) cohesiveness, (5) spelling & grammar, and (6) sources and citations.

Academic Integrity Policy

From UCSD's Policy on Integrity of Scholarship: "Integrity of scholarship is essential for an academic community. The University expects that both faculty and students will honor this principle and in so doing protect the validity of University intellectual work. For students, this means that all academic work will be done by the individual to whom it is assigned, without unauthorized aid of any kind."

If you violate this policy, you will automatically fail the class. Also, I am professionally and ethically obligated to report integrity violations to the Academic Integrity Office. Students found

to have violated academic integrity will face administrative sanctions imposed by the University. See the University Sanctioning Guidelines here: http://academicintegrity.ucsd.edu/_files/Sanctioning-Guidelines.pdf

To avoid any possible integrity violation, remember that your written work must be entirely your own and you must cite all material taken from an outside source, including direct quotations, paraphrased or summarized text, and information that is not common knowledge. The Policy on Integrity of Scholarship has additional standards by which you are expected to complete your academic work, but I also expect you to use good ethical judgment as these lists do not include everything that could violate the spirit of academic integrity. If you have any questions about specifics, please discuss your concerns with me for clarification.

Course Materials

Textbook purchases can be expensive, so I have made course materials available in the most affordable way possible. There is a required course packet available through Harvard Business Publishing for $4.25. Students can access the additional readings on the Internet at no cost. I have explained on the syllabus how to access them, or, when possible, will make them available on our course TED/Blackboard page. Note that some of the readings can only be accessed for free when you are logged into the UCSD VPN system, because they are from academic journals that would otherwise require a subscription. In addition to the readings, students are required to view relevant audio-visual materials (documentaries, video clips, news stories).

Structure of Class

This is a 4-unit seminar and we are scheduled to meet for nearly three hours every Thursday from 9 am – 11:50 pm. We will take a short break about half way through each class session. Classes will include brief instructor lectures, student-led discussions based on the assigned materials, and additional enrichment activities.

Class Sessions by Week (subject to change)

Week 1 (September 27th) Course overview + Introduction to global health, world trade law, and intellectual property

I will provide an overview of the course that includes going over the syllabus and course requirements. I will also introduce key concepts and themes that we will revisit throughout the quarter. I will present information about the current state of global health needs with a particular focus on the developing world. We will discuss global health concepts, current concerns in global health, and a human rights-based approach to health. Further, we will begin to explore the overlap between intellectual property rights, trade, and access to medicines.

Assigned readings: Syllabus

Week 2 (October 4th) **Background on the connections and tensions between intellectual property, trade, human rights, and access to medicines**

Pharmaceuticals have become essential in the fight against disease. For certain diseases or symptoms, there may be only one effective treatment. When a pharmaceutical company develops a drug under patent, it has a monopoly on the production and sale of the drug with a goal to maximize profits. But many in the developing world cannot afford the high prices pharmaceutical companies charge for lifesaving medicines.

The connections and conflicts between intellectual property and human rights came to the limelight in the late nineties when millions of people in developing countries were dying (about 8,000 people per day) from HIV/AIDS when effective medicines existed, but were not affordable. How did international intellectual property rules prevent people in developing countries, particularly in Africa, from accessing affordable lifesaving medicines? What actions did countries take to make affordable HIV/AIDS treatment available in Africa? What was the response of pharmaceutical companies? Why? How did the movement for HIV/AIDS treatment reframe global understandings of the right to medicine? Was this movement effective? Why/how?

The reading from Paul Farmer's *Pathologies of Power* translates global health statistics into individual experiences of suffering. What mechanisms produce such suffering? What is Farmer's analytical model for understanding suffering in a global context? What does Farmer mean by "structural violence"? How does structural violence operate in terms of access to health care? What accepted political and economic forces limit access to medicines in the developing world? How might these forces be understood as a form of structural violence? How can structural violence be addressed?

Assigned media:

- Watch the 1 hr, 24 min-documentary *Fire in the Blood*. Available using a UCSD IP address (via VPN) at https://ucsd.kanopy.com/video/fire-blood-0 The documentary can also be viewed on Netflix, or at the library media desk, Geisel Floor1 West FVLDV 12595-1.

Assigned readings:

- Charan Devereaux, Robert Z. Lawrence & Michael D. Watkins, *TRIPS Part II: International Trade Meets Public Health: TRIPS and Access to Medicines (abridged)*, HARVARD KENNEDY SCHOOL OF GOVERNMENT CASE STUDY (2007) (HKS Case Number 1736.3) (available as a Harvard Business Publishing Reader for $4.25 online at this unique link: https://hbsp.harvard.edu/import/572555)
- Sarah Boseley, *Jean Pierre Garnier – Head of Glaxo – He Will Drop the Prices of his Drugs to the Poorest Countries*, THE GUARDIAN, (Feb. 18, 2003), available at https://www.theguardian.com/world/2003/feb/18/aids.sarahboseley11
- PAUL FARMER, PATHOLOGIES OF POWER: HEALTH, HUMAN RIGHTS, AND THE NEW WAR ON THE POOR, 29-50 (2003), Electronic version available here: http://www.mathcs.duq.edu/~packer/Courses/Psi4105/Farmer%2003%20Pathologies%20of%20Power%20Ch%201.pdf

Optional media:

- Mary Bassett, *Why Your Doctor Should Care About Social Justice*, TEDMED 2015, available at https://www.ted.com/talks/mary_bassett_why_your_doctor_should_care_about_social_justice#t-815643
- *'Could you patent the sun?'* NY TIMES RETRO REPORT (Dec. 11, 2016), available at https://www.nytimes.com/video/us/100000004811585/could-you-patent-the-sun.html

Optional readings:

- ELLEN 'T HOEN, PRIVATE PATENTS AND PUBLIC HEALTH 6-12 (2016), available at http://apps.who.int/medicinedocs/en/d/Js22475en/ (access the pdf version of the book and read *How the HIV Pandemic Changed Everything*, pp. 6-12).
- HOLGER HESTERMEYER, HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES (2007), Chapter 1: Background of the Debate, pp. 1-17. Electronic version available here: http://www.isus-stiftung.de/attachments/article/60/Background_of_the_Debate.pdf
- William W. Fisher III & Cyrill P. Rigamonti, *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy*, HARVARD LAW SCHOOL (2005), available at https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf
- Mariana Roldão Santos, *Access to Essential Medicines*, THE HIPPOCRATIC POST (Dec. 30, 2016), available at https://www.hippocraticpost.com/oyw/access-essential-medicines/
- Ellen 't Hoen, Jonathan Berger, Alexandra Calmy & Suerie Moon, *Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All*, 14 JOURNAL OF THE INTERNATIONAL AIDS SOCIETY 15 (2011), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078828/
- Amy Kapczynski & Jonathan M. Berger, *The Story of the TAC Case: The Potential and Limits of Socio-Economic Rights Litigation in South Africa*, in HUMAN RIGHTS ADVOCACY STORIES (Deena R. Hurwitz & Margaret L. Satterthwaite, eds., 2009), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1323522
- Duncan Matthews, *NGO Coalitions and the Global Access to Medicines Campaign: The Impact of Intellectual Property Rights on Developing Countries* in GLOBAL MATTERS FOR NON-GOVERNMENTAL PUBLIC ACTION (Jude Howell ed., 2012), available at https://ebookcentral.proquest.com/lib/ucsd/detail.action?docID=1058297 (Note: you need to be logged into the UCSD Library VPN to access this source.)
- Dean T Jamison, et al., *Global Health 2035: A World Converging Within a Generation*, 382 THE LANCET COMMISSIONS 1898 (Dec. 7, 2013), available at http://globalhealth2035.org/sites/default/files/report/global-health-2035.pdf
- Kofi Annan, Secretary General, United Nations; Interview with the BBC (28 Nov. 2003), transcript available at http://news.bbc.co.uk/2/hi/africa/3245014.stm

Week 3 (October 11th) Drug development, patents, and TRIPS

***Reminder*: 1-page description of research topic is DUE on Turnitin by Wednesday, October 10th by 11:59 p.m. PST that evening.**

Drug development is a critical pillar for global health. It provides new therapeutics to address unmet medical needs. But as science has progressed, research and development of new drugs

has become more challenging and expensive. Drug development is a time and resource demanding process with a low success rate. What steps must be followed to bring a drug to market? What are the scientific and social challenges to drug development? How much does research and development cost? What exactly makes drug development so expensive? Who is paying for these costs? How do pharmaceutical companies price their products? Pharmaceutical companies claim that patent protection is necessary for biomedical innovation. What are intellectual property rights? What are patents? What is the rationale behind a patent system? What is patentable? How do patents impact innovation and access to medical technologies?

Before the introduction of the TRIPS agreement, there were no global requirements for national patent systems. What was the state of national patent systems before TRIPS? What forces led to the development and acceptance of the TRIPS agreement? How did intellectual property come to be on the trade agenda? What does TRIPS require of national patent systems? How does TRIPS impact access to medicines?

Assigned readings:

- U.S. Food and Drug Administration, *The Drug Development Process*, available at https://www.fda.gov/forpatients/approvals/drugs/default.htm (Read "More Information" for all 5 steps)
- *Wyden-Grassley Sovaldi Investigation Finds Revenue-Driven Pricing Strategy Behind $84,000 Hepatitis Drug*, Press Release of United States Senate Committee on Finance (Dec. 1, 2015), available at https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug
- *Globalization, TRIPS and Access to Pharmaceuticals*, WHO POLICY PERSPECTIVES ON MEDICINES (March 2001), available at http://www.searo.who.int/entity/intellectual_property/globalization-trips-and-access-to-pharmaceuticals-perspectives-on-medicines-No3-who-2001.pdf?ua=1
- Peter Drahos & John Braithwaite, *Who Owns the Knowledge Economy? Political Organizing Behind TRIPS*, THE CORNER HOUSE, (Sept. 2004), available at http://www.thecornerhouse.org.uk/pdf/briefing/32trips.pdf (Read pp. 7-17, skim 17-24, 24-32).
- James Love, *Perspectives on Cancer Drug Development Costs in JAMA*, HARVARD LAW BILL OF HEALTH (Sept. 13, 1017), available at http://blogs.harvard.edu/billofhealth/2017/09/13/perspectives-on-cancer-drug-development-costs-in-jama/?view=ev_full
- Amy Waxmen, *Busting the Billion-Dollar Myth: How to Slash the Cost of Drug Development*, NATURE (Aug. 24, 2016), available at http://www.nature.com/news/busting-the-billion-dollar-myth-how-to-slash-the-cost-of-drug-development-1.20469
- Cynthia Koons, *The Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG BUSINESSWEEK (Sept. 7, 2017), available at https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=health-care

- Jacob Bell, *AbbVie goes 3-0 in Delaying Humira Rivals*, BIOPHARMADIVE (July 18, 2018), available at https://www.biopharmadive.com/news/abbvie-goes-3-0-in-delaying-humira-rivals/528095/
- Jonathan Saltzman & Robert Weisman, *At a UMass Lab, a Eureka Moment*, THE BOSTON GLOBE (Dec. 17, 2017), available at https://www.bostonglobe.com/business/2017/12/16/spinrazasidecopy/CgWVLcXzZNI3b8nPAyWzHL/story.html

Optional readings:

- Legal Text of the TRIPS Agreement: https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm
- *Drug Industry: Profits, Research and Development, Spending, and Merger and Acquisition Deals*, United States Government Accountability Office Report to Congressional Requesters (Nov. 2017), available at https://www.gao.gov/assets/690/688472.pdf?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top-stories
- Sudhir Krishnaswamy, *Introduction to Patent Law*, in INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES: PAPERS AND PERSPECTIVES 25-38 (WHO-SEARO, 2010), available at http://apps.who.int/medicinedocs/documents/s17521en/s17521en.pdf
- Brook K. Baker, *Patents, Pricing, and Access to Essential Medicines in Developing Countries*, 11(7) AMERICAN MED. ASS'N JOURNAL OF ETHICS 527 (July 2009), available at http://journalofethics.ama-assn.org/2009/07/pdf/pfor1-0907.pdf
- Ellen 't Hoen, *Access to Cancer Treatment*: *A Study of Medicine Pricing Issues with Recommendations for Improving Access to Cancer Medication*, OXFAM POLICY BRIEF (May 2014), available at https://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/rr-access-cancer-treatment-inequality-040215-en.pdf
- Michele Boldrin & David K Levine, *The Pharmaceutical Industry* in AGAINST INTELLECTUAL MONOPOLY (2008), available at http://www.dklevine.com/papers/ip.ch.9.m1004.pdf
- Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, 177(11) JAMA INTERNAL MED. 1569 (Sept. 11, 2017), available at http://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2653012
- Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 JOURNAL OF HEALTH ECONOMICS 20 (May 2016), available at http://www.sciencedirect.com/science/article/pii/S0167629616000291?via%3Dihub
- Aaron E. Carroll, *$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions*, N.Y. TIMES (Nov. 18, 2014), available at https://www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html
- K.M. Gopakumar, *Twenty Years of TRIPS Agreement and Access to Medicine: A Development Perspective*, 55(3) INDIAN JOURNAL OF INTERNATIONAL LAW 367 (2015), available at https://doi.org/10.1007/s40901-016-0022-7
- Mohammed el Said & Amy Kapczynski, *Access to Medicines: The Role of Intellectual Property Law and Policy*, Working Paper prepared for the Third Meeting of

the Technical Advisory Group of the Global Commission on HIV and the Law, 7-9 July 2011, available at https://hivlawcommission.org/wp-content/uploads/2017/06/ACCESS-TO-MEDICINES-THE-ROLE-OF-INTELLECTUAL-PROPERTY-LAW-AND-POLICY.pdf

- Sushil Vachani & N. Craig Smith, *Socially Responsible Pricing: Lessons from the Pricing of AIDS Drugs in Developing Countries*, 47 CALIFORNIA MANAGEMENT REVIEW 117 (Fall 2004), available at http://journals.sagepub.com/doi/abs/10.2307/41166289
- Judy Stone, *New Pharma Rankings on Global Access to Medicine Released*, FORBES (Nov. 13, 2016), available at https://www.forbes.com/sites/judystone/2016/11/13/new-pharma-rankings-on-global-access-to-medicine/#cc2ecf436b48

Week 4 (October 18th) TRIPS flexibilities (+ case studies on India and Thailand)

The TRIPS agreement requires all WTO member states to implement minimum standards for patent protection. But TRIPS also sets forth specific flexibilities that can help countries protect the public health of their citizens. What are these flexibilities? How can a country implement a TRIPS flexibility? What is the Doha Declaration? What events led to the Doha Declaration? How useful are the TRIPS flexibilities to least developed countries?

What countries have used TRIPS flexibilities to increase access to medicines for their people? What circumstances fueled the country to use a TRIPS flexibility? What policy considerations does a country make in deciding whether to exercise a TRIPS flexibility? What were the foreign policy consequences of the country's decision? Do the TRIPS flexibilities sufficiently allow for countries to protect the public health of their people?

We will go deep into two case studies: (1) Novartis' challenge to section 3(d) of the India Patent Act in *Novartis v. Union of India & Others*, and (2) Thailand's 2006/2007 compulsory licensing experience.

Assigned readings:

- ELLEN 'T HOEN, PRIVATE PATENTS AND PUBLIC HEALTH (2016), available at http://apps.who.int/medicinedocs/en/d/Js22475en/ (access the pdf version of the book and read pp. 31-35, 49-73).
- Ravinder Gabble & Jillian Clare Kohler, *"To Patent or Not to Patent? The Case of Novartis' Cancer Drug Glivec in India,"*10(3) GLOBAL HEALTH (2014), available at https://globalizationandhealth.biomedcentral.com/track/pdf/10.1186/1744-8603-10-3?site=globalizationandhealth.biomedcentral.com
- Mishka Glaser & Ann Marie Murphy, *Patients versus Patents: Thailand and the Politics of Access to Pharmaceutical Products*, 27(1) JOURNAL OF THIRD WORLD STUDIES 215 (March 1, 2010), available at http://search.ebscohost.com/login.aspx?direct=true&db=sih&AN=53153493&site=ehost-live (Note: you need to be logged into the UCSD Library VPN to access this source. Download and read full text.)
- *FOIA Document: In 2007, US Ambassador Ralph Boyce was Pleased that Abbott Withdrew Life Saving Drugs from Market in Thailand*, KNOWLEDGE ECOLOGY INTERNATIONAL (March 7, 2010), available at https://www.keionline.org/21244/

Optional readings:

- *Equitable Access to Essential Medicines: A Framework for Collective Action*, WHO POLICY PERSPECTIVES ON MEDICINES (March 2004), available at http://apps.who.int/medicinedocs/pdf/s4962e/s4962e.pdf
- Carlos M. Correa, *Intellectual Property Rights and Public Health: The General Context and Main TRIPS-Compliant Flexibilities* in INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES: PAPERS AND PERSPECTIVES 11-24 (WHO-SEARO, 2010), available at http://apps.who.int/medicinedocs/documents/s17521en/s17521en.pdf
- *POST-TRIPS Examples of Compulsory Licensing for Pharmaceuticals Worldwide (chart)*, PUBLIC CITIZEN, available at https://www.citizen.org/sites/default/files/compulsory-licenses-chart-short-version.pdf
- Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9(1) PLOS MEDICINE (Jan. 2012), available at http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001154
- Stephanie Strom & Matt Fleishcer-Black, *Drug Maker's Vow to Donate Cancer Medicine Falls Short*, N.Y. TIMES (June 5, 2003), available at http://www.nytimes.com/2003/06/05/business/drug-maker-s-vow-to-donate-cancer-medicine-falls-short.html?pagewanted=all&src=pm
- Zoee Lynn Turrill, *Finding the Patent Balance: The Novartis Glivec Case and the TRIPS Compliance of India's Section 3(d) Efficacy Standard*, 44 GEO. J. INT'L L. 1555 (2012-2013), available at https://heinonline.org/HOL/Page?handle=hein.journals/geojintl44&div=48&g_sent=1&casa_token=&collection=journals (Note: you need to be logged into the UCSD Library VPN to access this source.)
- Amy Kapczynski, *Engineered in India: Patent Law 2.0*, 369 NEW ENG. J. MED. 497 (2013), available at http://www.nejm.org/doi/full/10.1056/NEJMp1304400#t=article
- *Using TRIPS Flexibilities to Improve Access to HIV Treatment: Policy Brief*, GLOBAL COMMISSION ON HIV AND THE LAW (Sept 2011), available at https://hivlawcommission.org/wp-content/uploads/2017/06/Using-TRIPS-flexibilities-to-improve-access-to-HIV-treatment-Policy-brief.pdf
- Feroz Ali & Sudarsan Rajagopal, *How India Rejects Bad Patents*, THE HINDU (Dec. 27, 2017), available at http://www.thehindu.com/todays-paper/tp-opinion/how-india-rejects-bad-patents/article22283269.ece
- David Singh Grewal & Amy Kapczynski, *Resist Pressure at Any Price*, BUSINESS TODAY (India)(Jan 17, 2016), available at http://www.businesstoday.in/magazine/cover-story/health-for-all-resist-pressure-at-any-price/story/227501.html
- Sarah Jane Tribble, *Louisiana Proposes Tapping a Federal Law to Slash Hepatitis C Drug Prices*, KAISER HEALTH NEWS (May 4, 2017), available at http://khn.org/news/louisiana-proposes-tapping-a-federal-law-to-slash-hepatitis-c-drug-prices/
- Joshua Sharfstein, Joy Lee & Rena Conti, *We Have a Cure for Hepatitis C. But the Neediest Can't Afford It. Louisiana Wants to Change That*, VOX (Sept. 27, 2017), available at https://www.vox.com/science-and-health/2017/9/27/16350562/hepatitis-c-drug-prices-louisiana
- Amy Kapczynski & Aaron Kesselheim, *Why 'Government Patent Use' to Lower Drug Costs Won't Stifle Innovation*, HEALTH AFFAIRS BLOG (July 28, 2016), available at

http://healthaffairs.org/blog/2016/07/28/why-government-patent-use-to-lower-drug-costs-wont-stifle-innovation/

- Henry Grabowski, *Government Appropriation of Breakthrough Drug Patents Would Deter Biopharmaceutical R&D and Innovation*, HEALTH AFFAIRS BLOG (July 20, 2016), available at http://healthaffairs.org/blog/2016/06/20/government-appropriation-of-breakthrough-drug-patent-rights-would-deter-biopharmaceutical-rd-and-innovation/
- DND*i* Welcomes Malaysia's Move to Secure Access to More Affordable Treatments for Hepatitis C (Sept. 20, 2017), available at https://www.dndi.org/2017/media-centre/press-releases/dndi-welcomes-malaysia-move-access-affordable-treatments-hepc/
- Ellen 't Hoen, *The Power of TRIPS Flexibilities in Medicines Procurement*, Medicines Law and Policy Blog, (April 9, 2018), available at https://medicineslawandpolicy.org/2018/04/the-power-of-trips-flexibilities-in-medicines-procurement/
- Andrew Goldman, *FOIA Documents. In 2015 Novartis Asked U.S. Dep't of Commerce to Pressure Colombia Against Compulsory License on Glivec*, KEI INTERNATIONAL (June 8, 2017), available at https://www.keionline.org/node/2802
- Germán Velásquez, *Guidelines on Patentability and Access to Medicines*, SOUTH CENTRE RESEARCH PAPER 61 (March 2015), available at https://www.southcentre.int/wp-content/uploads/2015/03/RP61_Guidelines-on-Patentability-and-A2M_rev_EN.pdf
- Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHICAGO JOURNAL OF INTERNATIONAL LAW 27 (2002), available at http://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=1171&context=cjil
- Adun Mohara, et al., *Impact of the Introduction of Government Use Licenses on the Drug Expenditure on Seven Medicines in Thailand*, 15 VALUE IN HEALTH JOURNAL 595 (2012), available at http://www.valueinhealthjournal.com/article/S1098-3015(11)03553-4/pdf
- Timeline for US-Thailand Compulsory License Dispute (April 2009), available at http://infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf

Optional media:

- Compulsory Licensing Workshop - Panel Discussion, 28 U.S.C. 1498 (Feb. 24, 2017), available at https://www.youtube.com/watch?v=Za9RbL0jtds&t=1802s

Week 5 (October 25th) Free trade agreements and TRIPS-plus measures

***Reminder*: Paper outline is DUE to Turnitin the night before our class session Wednesday, October 24th by 11:59 p.m. PST that evening.**

Since the TRIPS agreement went into effect there has been a wave of international free trade agreements (FTAs) negotiated outside of the WTO that require countries adopt heighted intellectual property protection for medicines than those required by TRIPS. These "TRIPS-plus" measures can have a significant impact on access to medicines for people in middle- and low-income countries.

How have industry and Western governments sought to deepen, lengthen and strengthen intellectual property rights? What are the various TRIPS-plus measures that have been included in FTAs? Why are pharmaceutical companies interested in data exclusivity? How are TRIPS flexibilities being constrained? How do campaigns against counterfeit medicine fit in with the

TRIPS-plus agenda? Are TRIPS-plus provisions consistent with human rights and additional obligations of states?

Assigned readings:

- Carlos María Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, BULLETIN OF THE WORLD HEALTH ORGANIZATION (May 2006), available at http://www.who.int/bulletin/volumes/84/5/399.pdf
- *Data Exclusivity and other "TRIPS-plus" measures*, WHO-SEARO Briefing Note on Access to Medicines (March 2006), available at http://www.searo.who.int/entity/intellectual_property/data-exclusively-and-others-measures-briefing-note-on-access-to-medicines-who-2006.pdf
- Vidya Krishnan, *WHO Settles India, EU Medicines Dispute*, THE HINDU (Nov. 26, 2016), available at http://www.thehindu.com/news/national/WHO-settles-India-EU-medicine-dispute/article16703181.ece
- Michael Grunwald, *Under Trump, U.S. Companies Face a Rough Road on Trade*, POLITICO MAGAZINE (Nov. 21, 2017), available at https://www.politico.com/magazine/story/2017/11/21/trump-nafta-trans-pacific-partnership-companies-trade-215851
- Alexandra Stanley, Sankari Venkat Krishnan, Miles Simpson, *Intellectual Property and Access to Medicines: Implications of NAFTA Renegotiations*, INTERNATIONAL ECONOMIC LAW PRACTICUM AT GEORGETOWN UNIVERSITY LAW CENTER (May 13, 2018), available at https://georgetown.app.box.com/s/lfe1ryokgjps0pdevtjhowiwl4y3j6sy (Read the Executive Summary and Introduction, pp. 1- 9)

Optional readings:

- Karin Timmermans, *Monopolizing Clinical Trial Data: Implications and Trends* in INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES: PAPERS AND PERSPECTIVES 117-29 (WHO-SEARO, 2010), available at http://apps.who.int/medicinedocs/documents/s17521en/s17521en.pdf
- K.M. Gopakumar & Sanya R. Smith, *IPR Provisions in FTAs: Implications for Access to Medicines* in INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES: PAPERS AND PERSPECTIVES 141-49 (WHO-SEARO 2010), available at http://apps.who.int/medicinedocs/documents/s17521en/s17521en.pdf
- *Fight over Generic Drug Seizure Takes Centre Stage at TRIPS Council Meeting*, INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT (March 11, 2009), available at https://www.ictsd.org/bridges-news/bridges/news/fight-over-generic-drug-seizure-takes-centre-stage-at-trips-council
- Health Action International-Africa, *The Anti-Counterfeit Bill 2008: Concerns on Access to Medicines for Kenyans* (2008), available at http://kelinkenya.org/wp-content/uploads/2010/10/anti_counterfeit_bill_factsheet.pdf
- Jing Chen, Xiaoyan Nie, Peng Yao & Luwen Shi, *TRIPS-Plus and Access to Medicines in China*, 34(2) JOURNAL OF PUBLIC HEALTH POLICY 226 (May 2013), available at https://link.springer.com/article/10.1057%2Fjphp.2013.13
- William Aldis, Cecilia Oh, Kajal Bhardwaj & Karin Timmermans, *The Trans-Pacific Partnership Agreement: A Test for Health Diplomacy*, JOURNAL OF HEALTH DIPLOMACY (June 12, 2013), available at http://www.ghd-net.org/sites/default/files/The%20Trans-

Pacific%20Partnership%20Agreement%20-%20A%20Test%20For%20Health%20Diplomacy.pdf

- Amy Kapczynski, Bhavan N. Sampat, Ken Shadlen, *Trade Agreements, Patents, and Drug Prices: Continuing the Debate*, YALE LAW & ECONOMICS RESEARCH PAPER NO. 572 (Mar. 2017), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2933574
- *MSF Welcomes Suspension of Harmful Intellectual Property Measures in New TPP Trade Deal*, MSF Press Release (Nov. 14, 2017), available at http://www.doctorswithoutborders.org/article/msf-welcomes-suspension-harmful-intellectual-property-measures-new-tpp-trade-deal
- Hafiz Aziz ur Rehman, *India, TRIPS-Plus Free Trade Agreements and the Future of Access to Essential Medicines*, 19(3) INFORMATION & COMMUNICATIONS TECH. LAW 267 (2010), available at http://www.tandfonline.com/doi/abs/10.1080/13600834.2010.533457 (Note: you need to be logged into the UCSD Library VPN to access this source.)

Week 6 (November 1st) Discussion of solutions: how to promote innovation and access

Guest speaker: Jennifer Dent, President of BIO Ventures for Global Health, will speak with us via videoconference. BIO Ventures for Global Health works at the crossroads of the private and public sectors to advance research and improve global health. In addition to the assignments listed below, explore their website: https://bvgh.org/ Come prepared with questions.

This class will explore solutions to increasing global access to medicines. The two main issues can be broken down as follows:

Equitable global access to existing medicines. Thus far, we have examined how a system that allows companies to price medicine based on what the market will bear can make essential medicines unaffordable. Different approaches to increasing access to existing medicines include: competition from generics, price differentiation, parallel imports, corporate donations, patent pools (i.e., the Medicines Patent Pool). How effective are these? What are the pros and cons?

Development of medicines to treat diseases that largely impact developing countries. Pharmaceutical and technology companies are not directing research and development resources to diseases that largely affect those in the developing world (known as "neglected diseases") because there is not sufficient return on investment. This is known as the 10/90 gap: 10% of spending on health research worldwide concerns health problems that affect 90% of the world's population. What alternative systems could spur biomedical innovation in areas neglected by the current market-based system? Some strategies include: a prize system (i.e., the Health Impact Fund), a research and development treaty, open source model for drug discovery and development, delinkage. How effective are these? What are the pros and cons?

Additional questions: What alternative methods of incentivizing research and development promote both innovation and wider access to medicines? Is the patent system established by TRIPS the most efficient way to ensure that critical medical innovations are available to those who need them? Are there ways of ensuring the justifiable rights of inventors, international human rights law, trade rules, and public health? How could the international community collaborate to address global public health issues?

Assigned media:

- BIO Ventures for Global Health, African Access Initiative (March 30, 2018), available at https://www.youtube.com/watch?v=0Iyg-gWMrPQ
- Ellen 't Hoen, *Pool Medical Patents, Save Lives*, TEDxZurich (Nov. 2012), available at https://www.ted.com/talks/ellen_t_hoen_pool_medical_patents_save_lives
- Thomas Pogge, *Medicine for the 99 percent*, TEDxCanberra (Sept. 2011), available at https://www.ted.com/talks/thomas_pogge_medicine_for_the_99_percent

Assigned readings:

- ELLEN 'T HOEN, PRIVATE PATENTS AND PUBLIC HEALTH (2016), available at http://apps.who.int/medicinedocs/en/d/Js22475en/ (access the pdf version of the book and read pp. 119-133).
- Jennifer Dent, et al., *Africa's Emerging Cancer Crisis*, BIO VENTURES FOR GLOBAL HEALTH and AFRICAN ORGANISATION FOR RESEARCH AND TRAINING IN CANCER (June 2017), available at https://bvgh.org/wp-content/uploads/2017/07/Africas-Emerging-Cancer-Crisis-A-Call-to-Action.pdf
- *Impact Story: Medicines Patent Pool*, UNITAID (Dec. 2017), available at https://unitaid.eu/assets/impact-story_medicines-patent-pool.pdf
- Report of the United Nations Secretary General's High Level Panel on Access to Medicines, *Promoting Innovation and Access to Health Technologies* (Sept. 2016), available at https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf (Read Executive Summary, pp. 7-11). Fact Sheet available at https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d74b232994ca43043e01b4/1473727274910/HLP+Factsheet.pdf
- Clarke B. Cole & Jayasree K. Iyer, *Ensuring Sustained Incentives for Pharmaceutical Companies to Develop Medicine for the Poor*, ACCESS TO MEDICINE FOUNDATION (June 6, 2016), available at https://accesstomedicinefoundation.org/media/atmf/2016-Ensuring-sustained-incentives-for-pharma-to-develop-medicine-for-the-poor.pdf
- Donald G. McNeil Jr., *As Cancer Tears Through Africa, Drug Makers Draw Up an Action Plan*, N.Y. TIMES (Oct. 7, 2017), available at https://www.nytimes.com/2017/10/07/health/africa-cancer-drugs.html?_r=0
- Suerie Moon, Jorge Bermudez & Ellen 't Hoen, *Innovation and Access to Medicines for Neglected Populations: Could a Treaty Address a Broken Pharmaceutical R&D System?*, 9(5) PLOS MEDICINE (May 2012), available at http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001218

Optional readings:

- *High Priced Medicines and Lack of Needs-Driven Innovation: A Global Crisis that Fuels Inequality*, OXFAM ISSUE BRIEFING (Sept. 2017), available at https://reliefweb.int/sites/reliefweb.int/files/resources/ib-high-priced-medicines-innovation-220917-en.pdf
- Fran Quigley, *Escaping Big Pharma's Pricing with Patent-Free Drugs*, N.Y. TIMES (July 18, 2017), available at https://www.nytimes.com/2017/07/18/opinion/escaping-big-pharmas-pricing-with-patent-free-drugs.html?_r=0

- WHO–WIPO–WTO, *Promoting Access to Medical Technologies and Innovation* (2012), available at http://www.who.int/phi/PAMTI_WHO-WIPO-WTO.pdf
- Dugie Standeford, *Disparity in Access to Medicines Spurs "Humanitarian" Patent Licensing*, INTELLECTUAL PROPERTY WATCH (Sept. 28, 2017), available at http://www.ip-watch.org/2017/09/28/disparity-access-medicines-spurs-humanitarian-patent-licensing/
- Alexander Schuhmacher, Oliver Glassmann & Markus Hinder, *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 JOURNAL OF TRANSLATIONAL MEDICINES 105 (2016), available at https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4
- *Lives on the Edge: Time to Align Medical Research and Development with People's Health Needs*, MSF REPORT (Sept. 2016), available at https://www.msfaccess.org/content/report-lives-edge-time-align-medical-research-and-development-people%E2%80%99s-health-needs
- Veronika J Wirtz, et al., *Essential Medicines for Universal Health Coverage*, 389 THE LANCET COMMISSIONS 403 (Jan. 28, 2017), available at http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)31599-9.pdf
- Joseph Stiglitz, *Intellectual Property Laws Demand a 21st Century Solution*, THE GUARDIAN (Oct. 18, 2017), available at https://www.theguardian.com/business/2017/oct/18/intellectual-property-laws-demand-a-21st-century-solution
- Alexander Gaffney, Michael Mezher & Zachary Brennan, *Regulatory Explainer: Everything You Need to Know about FDA's Priority Review Voucher*, REGULATORY PROFESSIONALS SOCIETY (Oct. 2, 2017), available at http://www.raps.org/Regulatory-Focus/News/2015/07/02/21722/Regulatory-Explainer-Everything-You-Need-to-Know-About-FDA%E2%80%99s-Priority-Review-Vouchers/
- Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102(6) CORNELL LAW REVIEW 1539 (Nov. 2017), available at http://cornelllawreview.org/articles/order-without-intellectual-property-law-open-science-in-influenza/
- *An Economic Perspective on Delinking the Cost of R&D from the Price of Medicines*, UNITAID (2016), available at https://www.keionline.org/sites/default/files/Delinkage_economic-perspective_Feb2016.pdf

Optional media:

- Ernest Madu, *World-Class Health Care*, TEDGlobal, (June 2007), available at https://www.ted.com/talks/ernest_madu_on_world_class_health_care#t-835882
- Infinite Vision – Dr. Govindapa Venkataswamy (documentary), available at https://www.youtube.com/watch?v=MA5Dzlf7JEE

Week 7 (November 8th) Human rights-based approach to access to medicines

What are human rights? Is there a human right to access essential medicines? Is private intellectual property a human right? How are conflicting rights resolved? To what extent is access to medicines as a human right accommodated within the WTO system?

Who is governed by human rights law? How can human rights language be used to increase social responsibility for actors that are not directly governed by human rights law (e.g., pharmaceutical corporations)?

How has human rights law been useful in promoting public health? How has human rights law contributed to increased disparities? Is the right to health an individual or group right? What is the connection between the global political economy and human rights advocacy?

What is the role of human rights law in ensuring fair political processes (e.g., transparency, inclusiveness, non-discrimination)? What is the role of human rights law in providing for fair outcomes (e.g., access to essential medicines)? How can human rights law be used to develop better health-related laws and policies?

Assigned readings:

- Hans Hogerzeil, *Essential Medicines and Human Rights – What Can They Learn from Each Other?* 84 WHO BULLETIN 371-75 (2006) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627335/pdf/1671054 6.pdf
- Mark Heywood, *South Africa's Treatment Action Campaign: Combining Law and Social Mobilization to Realize the Right to Health*, 1 JOURNAL OF HUMAN RIGHTS PRACTICE 14 (March 2009), available at https://academic.oup.com/jhrp/article/1/1/14/2188684
- Amy Kapczynski, *The Right to Medicines in an Age of Neoliberalism, forthcoming*, HUMANITY JOURNAL (to be distributed by professor)
- Global Health Justice Partnership, *A Human Rights Approach to Intellectual Property and Access to Medicines* (Sept 2013), available at https://law.yale.edu/system/files/area/center/ghjp/documents/ghjp_ip_and_access_to_meds.pdf (Read Executive Summary, pp. 1-2, Introduction 6-10, Conclusion, 49-51)

Optional readings:

- YA Vawda & BK Baker, *Achieving Social Justice in the Human Rights/Intellectual Property Debate: Realising the Goal of Access to Medicines*, 13 AFRICAN JOURNAL ON HUMAN RIGHTS 57 (2013), available at www.ahrlj.up.ac.za/issues/2013/volume-13-no-1-2013
- Hans V. Hogerzeil & Zafar Mirza, *The World Medicines Situation 2011: Access to Essential Medicines as part of the Right to Health*, WHO (2011), available at http://apps.who.int/medicinedocs/documents/s18772en/s18772en.pdf?ua=1
- United Nations Human Rights Office of the High Commissioner, *Guiding Principles on Business and Human Rights* (2011), available at http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf

Week 8 (November 15th) Writing workshop: peer review of draft

***Reminder*: Draft of research paper is DUE to Turnitin the night before our class session Wednesday, November 14th by 11:59 p.m. PST that evening. BRING AN IDENTICAL HARD COPY TO CLASS FOR THE WRITING WORKSHOP.**

Spend all of your outside class time prior to this session producing a solid draft of your research paper. As discussed above under course requirements, you are expected to bring a 10 – 12-page draft of your research paper to class. We will discuss the grading rubric in detail, as well as my

expectations for the final version. We will do writing exercises to illustrate how to transform your working draft into a high-quality analytical research paper. You will engage in one-on-one peer review with at least one of your classmates, and are expected to provide meaningful feedback to your peers. I will hold additional office hours during this week for anyone who would like to discuss their papers in more detail with me.

Week 9 (November 29th) **Research presentations**

Week 10 (December 6th) **Research presentations & concluding remarks**

***Reminder*: Final paper is DUE by NOON on Monday, December 10th.**

INTL 190: Global Access to Modern Medicine
Fall 2018
Thursdays 9 AM – 11:50 AM
Rm 1328 Robinson Bldg. Complex

Suggested Research Paper Topics

The topic of your research paper must touch on some aspect of global access to modern medicine. I want you to pick a topic that deeply interests you. Think about what drew you to this capstone course over all the others.

To get your mind brainstorming on a topic, I have listed possible areas of inquiry. This list is not exhaustive and is intended only to help you think about what issue you are excited to explore. Similarly, the questions listed below are designed to ensure your research is comprehensive, but do not reflect what should ultimately be included in your final paper. Rather, you will build upon these initial questions to compose a narrow, clear, concise, and analytical thesis.

I have divided the suggested topics into three categories.

Country-specific topic: You may want to explore the impact TRIPS and/or other trade agreements have had on a specific country. Countries to consider include: India, Malaysia, Indonesia, Thailand, China, Egypt, South Africa, Zimbabwe, Ghana, Brazil, Ecuador, Argentina, Chile, Colombia.

Questions to consider include:

- What are the country's public health needs regarding access to medicines?
- What type of patent system did the country have before TRIPS?
- Is the country a signatory to TRIPS?
- What changes have been made to domestic law as a result of TRIPS?
- What additional obligations has the country had to undertake as a result of TRIPS?
- How has TRIPS impacted (1) the country's pharmaceutical imports and/or exports, (2) the country's domestic pharmaceutical industry, and (3) domestic access to a specific drug of need (e.g., antiretrovirals)?
- Has the country implemented TRIPS flexibilities (e.g., compulsory licenses, government use, parallel imports, etc.)? If so, under what conditions? What was the response from originator patent-holding companies? What was the response from foreign governments? What has been the public health impact?
- Has the country entered into any bilateral or regional free trade agreements that have included heightened patent requirements for pharmaceuticals? Have these additional requirements affected the country's ability to provide affordable medicine to its people?

Disease/medicine-specific topic: You could explore historical and emerging issues regarding access to medicines for certain diseases, such as HIV/AIDS, tuberculosis, malaria, certain types of cancer, hepatitis C, or other neglected diseases. You could analyze challenges to increasing access to new technologies, such as CAR T-cell therapy.

Questions to consider include:

- What costs and efforts have gone into the research and development of medicines to treat the disease?

- How have prices been set for these medicines in different countries?
- What are the barriers to accessing these medicines in different countries?
- Have any countries used TRIPS flexibilities to make these medicines available to their people?
- What key actors have been involved in policy debates surrounding access to these medicines?
- If effective medicines have not yet been developed to treat this disease, what can be done to incentivize innovation?
- What policy recommendations do you have for ensuring affordable and accessible medicines reach all the people who need it?

Looking Towards Policy Solutions: Your research could seek to answer larger questions about the impact of TRIPS and access to medicines issues, or alternative ways of addressing public health needs in developing countries. Examples include:

- Is the TRIPS agreement fair to developing countries?
- Do the TRIPS flexibilities sufficiently protect access to medicines?
- How can developing countries work together to deploy TRIPS flexibilities?
- What is the impact of the 2001 Doha Declaration on TRIPS and Public Health?
- Are there other measures beyond TRIPS flexibilities developing countries can legally undertake to protect the public health of their people?
- Is there a more effective research and development model for medicines?
- Should medicine be treated as a public good, like education or infrastructure? How would this shift the current approach to developing and providing essential medicines?
- What are the right policy incentives that would not make pharmaceutical companies upset and would allow developing countries to increase access to affordable medicines?
- How can universities influence the way lifesaving medical technologies are developed, distributed, and made accessible to the world?
- What alternative non-IP mechanisms (e.g., anti-counterfeiting campaigns, requirements for data exclusivity) have been pursued by pharmaceutical companies to protect their interests?
- What non-TRIPS mechanisms (e.g., patent pooling) have been used to ensure affordable and accessible medicines? How successful have these been?
- Is human rights law effective in ensuring equitable global access to medicines?

To start, a basic google search will provide more information about these various topics. Also, take a look at the optional readings listed under each class session. These will provide more in-depth information and analysis on the general topics we discuss in class.

Additional useful and credible websites to explore include:
PubMed Central: https://www.ncbi.nlm.nih.gov/pmc/
Access to Medicines Index: http://accesstomedicineindex.org/
WHO's Essential Medicines and Health Products Information Portal: http://apps.who.int/medicinedocs/en/
Knowledge Ecology International: https://www.keionline.org/
Universities Allied for Essential Medicine: https://uaem.org/
MSF Access Campaign: https://www.msfaccess.org/
BIO Ventures for Global Health: https://bvgh.org/

STUDENT-LED DISCUSSION EVALUATION

Date:

Presenters:

Please answer the questions using the following metrics:
✔+ (exceeds expectations), ✔(meets expectations), ✔- (below expectations),
INC. (not acceptable)

How prepared were the presenters for today's discussion?	
How clearly and effectively did the presenters explain the main points of the assignment?	
How would you rate the overall teaching methods used by the presenters? In answering this question, consider: Were students engaged and motivated? Were a variety of methods used? All voices heard and respected?	
How would you rate the quality of the discussion questions asked? In answering this question, consider: Were questions challenging? Thought-provoking? Understandable? Referred to the readings? Encouraged participation? Encouraged students to refer to readings?	
How would you rate the group's facilitation skills? In answering this question, consider: active listening, paraphrasing, summarizing, redirecting questions	
How would you rate the group's communication skills? In answering this question, consider: eye contact, voice (pitch, volume, speed, pausing), gestures, visuals, or other aides	
What overall grade would you give the presenters?	

Additional comments: