

DRAFT

Intellectual Property & Access to Medicines in Eastern and Central Europe

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Anastasia Mindrul, Mohyla
Zoriana Skaletska, Mohyla
Raminta Stuikyte, Harm Reduction Network

Dates: September 14-18, 2009
Place: Mohyla University, Kiev Ukraine

Synopsis

This course is designed with the purpose of teaching access to medicines activists and lawyers about principles of local and international intellectual property law that impact access to medicines.

The focus of the course will be on how to use the “flexibilities” and “balancing features” of these laws, including compulsory licensing, parallel importation, patent oppositions and others, that can reduce the negative impact of patent monopolies on access to needed treatments. Significant time in the course will be spent in country team strategy discussions to evaluate how the information in the course can assist local strategies to increase access to medicines in the region, particularly in campaigns to improve access to antiretroviral medication for HIV and for pegylated interferon treatments for HCV.

Throughout the course, we will use laws and policies of Ukraine as a regional case study.

Electronic copies of the materials for this course, and extra materials including laws and policies of other countries in the EECA, are included on the course's website. <https://pijip.updatelog.com>. Your username is the first letter of your first name followed by your last name. The passwords for all students is set to "password." If you cannot log in this way, use the username "student" followed by the password "password."

Please review the syllabus, particularly to familiarize yourself with the readings and exercises throughout the course.

Topic (time)	Lead Facilitator	Presentation/ Discussion	Reading/ Assignment	Logistics Notes
SUNDAY				
Pre-course			<p>1. Read Sisule Musungu, Background Paper on the Potential Impact of WTO Accession and Partnership and Cooperation Agreements on Public Health in the CI</p> <p>2. Download a copy of your patent law (copies are available at https://pijip.updatelog.com, username student, password – “password”]</p> <p>3. What is the lowest price in your country for a one year supply (or one full course) of the following treatments, brand or generic –</p> <p><u>HIV/AIDS</u></p> <ol style="list-style-type: none"> 1. combivir (ZDV/Zidovudine +3TC/ lamivudine) + efavirenz 2. Kaletra+ ddl /Didanosine+ ABC/abacavir <p><u>HCV</u></p> <ol style="list-style-type: none"> 1. Pegylated Interferon 2. Non-peg interferon 	<p>Send Sisule background paper to all participants.</p> <p>Give all students web address and passwords for basecamp site.</p>
Sunday Dinner 6:30pm			Sit for dinner with your country teams. Discuss findings of of the pre-course assignment.	Dinner at Hotel Rus [Ask hotel for reserved tables

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			Appoint a spokesperson to introduce the members of your country team. See introductions below.	sufficient for each country group to sit together. Place cards indicating which countries are at which tables.]
MONDAY Introductions 9-10:30am	Sean	Review course coverage: -analyzing patent laws -TRIPS flexibilities -compulsory licenses. -group planning Schedule -group work sections, after lunch, end of day -Last day Introductions	Country teams introduce: -participants/organizations -major access to medicines campaigns - IP barriers to access to medicines in your country	Transport from Hotel Rus to Mohilya 8:30am? Have coffee in instruction room before first session.
Coffee Break				
Introduction to IP & access to Medicines 10:30-12	Sean	Sean: Patents and monopolies AEM Economics exercise AEM Timeline 1970s, India 1994, WTO 1996, Brazil 1999, South Africa 2001, Doha 2005, India -MSF Pricing chart -Report back on price findings from countries.	Read: ABIA Publication [or a chapter from T' Hoen]	
LUNCH 12:30-1:30pm				
Q&A & Recap 1:30 – 2pm				Serve coffee outside room each day.
Focusing on HCV and HIV 2-3:30pm	Raminta (to organize)	- Prevalence statistics -reatment options	OSI Hep. C Report (from Kiev meeting March 2009)	

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	presentations by local organizations]	-Cost and supply problems in EECA -Who is getting access? -How are patents contributing to access problems? What do we know about the possible supply channels? What are the possible patent barriers? <u>Hep C in EECA</u> [EECA HCV activist, 30 min.] <u>HEP C Supply</u> [Peter] <u>Access to HIV treatments in Russia</u> Raminta or HIV treatment activist		
Coffee Break, 3:30				
Rights to Medicines 3:45-5:00	Dima, Peter, Raminta, Sean	Short informal presentations What duties are there on governments to provide access to necessary medications, e.g. for HCV and HIV? How are access movements working to secure or expand rights to medicines? How could these duties be interpreted to require use of IP flexibilities? What strategies have been used in other countries?	UN Special Rapporteur Report on Health as a Human Right, June 2009 African Commission on Human and People's Rights (ACHPR) Resolution on the Right to Health and Access to Medicines	
Country Team Meetings 5-5:45			Review country team assignments for rest of the course. Discuss final objective of the meeting: to develop a strategy to address access to medicines issues in your country.	Arrange for small rooms or break out spaces for all "country team meetings"
Reception				Casual venue near

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6pm				Mohilya. Transport back to hotel Rus @ 8:30pm
TUESDAY				
Recap and Q&A 9-9:30				
TRIPS Basics 9:30-10:30	Sean	-Short summary of history of TRIPS, regime shifting -Patents extended to all products and processes -Flexibilities -Doha declaration -Compulsory licenses, parallel imports, paragraph 6 -WTO accession and TRIPS +	TRIPS Patent Section Doha Declaration UK and Canadian Statutes on Meds and Compulsory Licenses Paris Convention Art. 5(a)	
Coffee break				
Art. 27, Patentability 10:45-11:15	Brook	-Art. 1. -Article 7 & 8 -27(2) and (3) -Close read of article 27(a) -Indian sec. 3(d) -Non-novel inventions, Kaletra patent landscape	India Patent Act sec. 3(d) B. Baker Powerpoint, Patentability standards	
Patent Oppositions in India 11:15-11:45	Peter	-India pre and post grant oppositions -Description of some of the major successes of oppositions in India - Peg interferon opposition		
Patent Oppositions in Ukraine /EECA law 11:45-12:15	Mohilya	-What is the process for challenging a patent application either before or after the grant of the patent in Ukraine (and other EECA) laws? -Who can file a challenge? -What role can an NGO play? -How much capacity does the patent	Law of Ukraine 3687 (Inventions and Utility Models)	

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		office have?		
Discussion 12:15-12:30				
LUNCH				
Country team meetings 1:30-2pm			Discuss the viability of patent opposition strategies in your country. What allies do you have? Is this a wise use of your advocacy resources? What information would you need to determine whether this is a viable strategy?	
TRIPS and Compulsory Licenses 2-3:15	Sean or Brook	Explanation of compulsory licensing Exercise on Article 31	Examples of compulsory licenses: Brazil, Thailand	
Break				
Ukraine Compulsory License Regulation 3:30-4	Mohilya	Who can request a CL? How would an access to medicines campaign ask for a CL? What are the procedures? What has to be shown to get a CL for a health reason?	Ukraine Regulation on Compulsory Licenses	
Exercise 4-5	Peter	-Group discussion on how to use the Ukraine compulsory license procedures for Kaletra. -Create a strategy chart listing procedural steps, partners, targets, tactics, etc.		
Team Meetings 5			Discuss any variations on the compulsory licensing strategy for Kaletra you would need in your country. Review your compulsory license section of your patent	Transport back to Hotel Rus @ 6pm

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			act. Is they anything different you need to consider?	
WEDNESDAY				
Q&A and Recap		What are the quality control issues we are facing in our countries? Do people trust generic drugs? Are generics of high quality? What are the legitimate supply problems? What are the wrong assumptions people may have?		
IP & Drug Registration 9:45-10:30	Brook	-recap of the basics on registration and brand v. generic. -Hatch Waxman and the shift to reliance on data to register drugs. -Data protection/ exclusivity as part of the U.S. bargain. -Internationalization of data protection: FTAs, WTO accession	B. Baker, Basics of Registration B. Baker Powerpoint, Overcoming Registration Barriers B. Baker, Powerpoint, Generics and Registration	Docuiments need translation
Generic Biologic Registration Pathways 10:30-11:00	Peter	Review of EU and U.S. pathways for generic registration. Review of global best practices for registration	Giogeneric registration bill in U.S. EU biogeneric legislation	
Registration in Ukraine/EECA 11:00-11:30	Mohilya	How does the drug registration process in Ukraine and other EECA countries work? What are the data protection rules in Ukraine law and the WTO accession agreement? Does the registration process work well to ensure quality? How are generics registered? What does a generic medicine need to prove to get marketing approval? How would a generic version of a biologic drug gain marketing approval?	Ukraine Registration Law 123 96 VR	
BREAK,				

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Discussion on Quality Assurance 11:45--12:30		How are the registration/quality control systems working in our countries and how can we improve them? How can we register a generic peg interferon in the EECA? What information do we need?		
LUNCH				
Country Team Meetings 1:30-2pm			What more do you need to know to implement a compulsory licensing strategy for peg interferon?	
Parallel importation and TRIPS 2-2:30	Sean	What is parallel importation? What are the TRIPS/Doha rules on PI?		
Parallel Importation in EECA 2:30-3:00	Mohilya	What are the rules for parallel importation in Ukraine and within the EECA?		
Discussion 3-3:30		What should be the exhaustion/parallel importation rules in the EECA? How could parallel importation help solve pricing problems?		
Break				
Paragraph 6 Importation 3:45-4:30	Brook	Paragraph 6 and August 30 decision and TRIPS amendment. How might the process be of use in HCV/HIV access issues?		
Discussion 4:30-5		How can we use importation rules to access supplies or quality medicines?		
Team meetings			Discuss quality assurance and importation issues and how you would seek to access quality supplies of drugs in	Transport to hotel Rus @ 6pm

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			your campaigns.	
THURSDAY				
Q&A and Recap 9-9:30				
TRIPS Plus Trade Agreements 9:30-10:30	Brook	-US/EU agenda in bilaterals, -301, -WTO accession agreements -Data Exclusivity -Regulatory linkage -Patent Term extensions	Excerpts U.S. – Columbia & Chile FTAs EU-Ukraine FTA EFTA – Macedonia FTA B. Baker Powerpoint, FTA and new trade policy	
Exercise: TRIPS Plus WTO Accession agreements 10:30-11:30	Sean		Read the excerpts of the Ukraine accession agreement. What “TRIPS plus” provisions do you find? What questions do you have?	
Coffee break				
Discussion 11:45-12:30		How have groups in other countries opposed TRIPS Plus provisions? How have north-south linkages been used? What could EECA activists do to resist TRIPS plus WTO accession agreements where they have not joined yet? What could be done to resist implementation of existing TRIPS plus accession agreements?		
LUNCH				
Team Meetings 1:30-2			Discuss strategies for intervening in the WTO accession or implementation debate in your country. What links should be made	

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			with US/international ngos in an accession campaign? ACTA One Pager	
Enforcement Agenda 2:00-3:30	Sean/Peter/ Brook	ACTA 301 Anti-counterfeiting legislation		
Break				
Open Session 3:45-5	Mohyla	TBA – Tour of Live with Mohyla		Work with Mohyla to plan
Team Meetings 5			Discuss strategies for intervening in the accession or implementation debate in your country.	
GALA DINNER	Mohilya to plan			Work with Mohilya team to decide place and transport arrangements
FRIDAY				
Strategy development Exercise 9-11am		Meet in groups and develop a strategy chart on how you may use the information in this course to address an access to medicines problem in your country. Consult with lecturers freely.		separate small meeting rooms for each team. It would also be good to give the teams access to printers.
11-1pm		Report Back: each team present your ideas to the larger group and seek information, advice and input.		
Lunch				
Meetings with OSI and/or instructors 2:30-4pm @ Hotel Rus		Schedule meetings on poster chart calendars		Create poster chart calendars with 30 minute meetings for each lecturer or OSI representative.