

Expanding Developing Nations'
Access to Brand Name Drugs by
Understanding Impediments to
Compulsory Licensing

APHA Annual Meeting
October 31, 2011

Angela M. Morley, JD, MPH
Research Associate and Associate Director of Operations,
Minnesota Center for Health Care Ethics

Presenter Disclosures

Angela M. Morley

The following personal financial
relationships with commercial interests
relevant to this presentation existed during
the past 12 months:

No relationships to disclose

Acknowledgments

- The presenter gratefully acknowledges the significant contributions of Dr. Roger Feldman, University of Minnesota School of Public Health, to this project.
- The presenter thanks the University of Minnesota Consortium on Law and Values in Health, Environment and the Life Sciences for generous financial support of this project.



The Gap and the Goal

The Public Health Problem

- **High prices of brand name drugs in developing countries can severely inhibit vulnerable populations' access to lifesaving medicines**

The Goal

- Maximize access to essential medicines through effective use of intellectual property laws, in particular, compulsory licensing

Agenda

- Part 1: Review IP and trade law influencing access to medicines: TRIPS and compulsory licensing
- Part 2: Identify claims that explain rarity of compulsory licenses (mechanisms designed to improve access to drugs)
- Part 3: Evaluate the legitimacy and magnitude of potential barriers to and secondary effects of compulsory licensing
- Part 4: Quantitative study of the interrelation between compulsory licensing and (1) direct foreign investment and (2) pharmaceutical technology transfer

Part 1

Review intellectual property and trade law influencing access to medicines: TRIPS and compulsory licensing

United States Patent (10) Patent No.: US 8,006,297 B2
 Johnson et al. (45) Date of Patent: Aug. 23, 2011

1. METHOD AND SYSTEM FOR COMBINED SECURITY PROTOCOL AND PACKET FILTER OFFLOAD AND ONLOAD	6,716,980 B1	3/2004	Hiro et al.
	6,757,701 B1	6/2004	Dennis et al.
	6,800,801 B1	12/2004	Van Nieu et al.
	6,858,881 B2	2/2005	Shankar et al.
	6,882,100 B1	6/2005	Shankar et al.

Part 1: Patents

- "The basic idea of patents is a good one: an inventor is granted a limited monopoly over a technology in return for disclosing the details of its workings, so that others can build upon the invention. Advanced technologies are thus made widely available, rather than remaining trade secrets, spurring further innovation. In some industries, notably pharmaceuticals, it is doubtful that the huge investments needed to develop new products would be made without the prospect of patent protection."
 - **Patent medicine. Why America's patent system needs to be reformed, and how to do it. August 20, 2011**
 - *The Economist* Available at: <http://www.economist.com/node/21526370>

Part 1: Compulsory Licenses

- **THE COMPULSORY LICENSE**
 - "When the authorities license companies or individuals other than the patent owner to use the rights of the patent — to make, use, sell or import a product under patent without the permission of the patent owner." World Trade Organization. Available at: http://www.wto.org/english/thewto_e/iglossary_e/compulsory_licensing_e.htm.
- **FREQUENCY**
 - Rarely issued, occasionally threatened by governments in negotiations for discounted drugs
- *"In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose. [5] Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: ... (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." Doha Declaration*

Part 1: The "TRIP(s)" to Doha

- **AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) OF 1994**
 - International law required WTO members to implement robust patent protections in exchange for expanded access to developed trade markets; Compulsory licensing permitted
- **DOHA DECLARATION OF 2001**
 - Reiterated the public health potential of the compulsory license

DOHA WTO MINISTERIAL 2001: TRIPS
WT/MIN(01)/DEC/2
20 November 2001
Declaration on the TRIPS agreement and public health
Adopted on 14 November 2001
World Trade Organization
http://www.wto.org/english/press/pr/min01_min01_01minded_trips_e.htm

Part 2

Identify claims in the literature attempting to explain compulsory license rarity: Peer-reviewed literature search for cited barriers to and secondary effects of compulsory licensing

Part 2: Identifying Potential Barriers

- Information and infrastructure challenges within developing countries
 - *Lack of awareness of the right to issue compulsory licenses*
 - *Lack of legal infrastructure (i.e. compulsory licensing statutes)*
 - *Insufficient intra-governmental coordination and communication required for implementation*

Part 2: Identifying Potential Secondary Effects

- Nations may be dissuaded from licensing due to two potential classifications of secondary effects:
 - (1) Fears, founded or unfounded, of adverse consequences imposed by international community in response to licensing
 - (2) Outcomes that negate or diminish the public health impact of compulsory licensing

Part 2: Identifying Potential Secondary Effects

(1) Potential adverse responses to licensing:

- *Legal challenges*
 - Costly, high-profile litigation over complexities of implementation or as obstructive or retaliatory measure
- *Trade retaliation*
 - Indirect retaliation by developed nations protective of their pharmaceutical industries
- *Reduced international aid*
 - Reductions in international governmental foreign aid resulting from negative perceptions of licensing nations' governments

Part 2: Identifying Potential Secondary Effects

(1) Potential adverse responses to licensing (cont'd):

- *Reduced direct foreign investment*
 - Multinational companies viewing licensing as unfriendly to business and diverting investment elsewhere
- *Decreased pharmaceutical innovation*
 - Reduced technology transfer and reduced innovation for neglected diseases
 - Pharmaceutical profitability threatened by licensing → fewer patent applications filed in licensing nation, reduced investment in neglected diseases

Part 2: Identifying Potential Secondary Effects

(2) Outcomes that negate or diminish the public health impact of compulsory licensing

- *Parallel importation*
 - Resale of licensed drugs to wealthier markets diverting supply from needy populations
- *Shadow pricing*
 - Generic manufacturers producing under compulsory license selling licensed drugs just below brand-name prices
- *Other improper compulsory license use*
 - Licensing for commercial purposes and for reasons other than to improve the public's health

Part 3

Evaluate the legitimacy and magnitude of potential barriers to and secondary effects of compulsory licensing

Part 3: Evaluating Potential Barriers

- *Lack of awareness of the right to issue compulsory licenses*
 - Currently not a significant barrier...extensive awareness of the right to license; prevalence of licensing statutes
- *Lack of legal infrastructure (i.e. compulsory licensing statutes)*
 - Currently not a significant barrier... prevalence of licensing statutes; successful implementation examples; access to statutory language
- *Insufficient intra-governmental coordination and communication for implementation*
 - Likely a true, present and potentially significant barrier, evidenced by case study

Part 3: Evaluating Potential Secondary Effects

- *Legal challenges*
 - Potential but avoidable...narrowly tailored licensing statutes and reasonable implementation prevent legal challenges; access to legal remedies to resolve disputes and minimize frivolous suits
- *Trade retaliation*
 - Possibly a true, present and significant secondary effect... significant economic pressure has been exerted in response to past use of compulsory licensing

Part 3: Evaluating Potential Secondary Effects

- *Reduced international aid*
 - Insufficient evidence to evaluate
- *Reduced direct foreign investment (DFI)*
 - IP strength and DFI relation inconclusive in literature; some evidence of a correlation and some evidence of a negative association between IP strength and DFI

Part 3: Evaluating Potential Secondary Effects

- *Decreased pharmaceutical innovation (reduced technology transfer and innovation for neglected diseases)*
 - Insignificant secondary effect...Profit loss from licensing negligible in light of profit for global diseases, minimal expenditure on neglected diseases pre & post licensing
- *Parallel importation, shadow pricing and improper license use*
 - Potential but avoidable, with mandates that licensed use is predominantly for domestic market, price ceilings and prohibitions on exports and resale

Part 4

Quantitative study on the interrelation between compulsory licensing, direct foreign investment (DFI) and patent applications filed nationally

Part 4: Quantitative Study

- The Question:
 - *Does a nation's use of compulsory licensing negatively impact the nation's economic prosperity - i.e., negatively impact direct foreign investment into the nation or patent applications filed within the nation?*



Part 4: Quantitative Study

HYPOTHESIS

- Speculation in the literature that nations issuing compulsory licenses will experience reduced influx of direct foreign investment and fewer patent application filings

hear-say [heer-sey] [Show IPA](#)

noun

1. unverified, unofficial information gained or acquired from another and not part of one's direct knowledge: *I pay no attention to hearsay.*
2. an item of idle or unverified information or gossip; rumor: *a malicious hearsay.*

Part 4: Quantitative Study

METHODS

Dependent Variables:

- (1) Real 2003 annual direct foreign investment ("DFI") and
Defined as capital directly invested into the reporting country, including equity capital and reinvested earnings; Source: IMF International Financial Statistics Database
- (2) annual patent applications filed

Patent applications by patent office, broken down by resident and non-resident (1883-2008)
Source: WIPO Statistics Database, December 2009

from 1980-2008 in Brazil, China, Ecuador, Indonesia, Malaysia, Mozambique, South Africa, Swaziland, Thailand and Zambia

Part 4: Quantitative Study

METHODS, CONT'D

Independent Variables

Annual number of compulsory licenses issued and annual number of threats to issue licenses in 10 countries from 1980-2008

Control Variable

Real Annual 2003 GDP Purchase Power Parity in USD per capita

Part 4: Quantitative Study

METHODS, CONT'D

Model: Stata 11.0

- Country-level regression for each dependent variable
- Pooled, cross-sectional time series regression analysis for each dependent variable

RESULTS

- Descriptive Statistics and Correlation Matrix

Table 2. Descriptive Statistics

VAR	Mean	St. Dev.	Min	Max
DFI	9,027.7	19,206.5	(5,159.1)	134,111.6
PA	12,655.0	35,512.3	88.0	289,838.0
PPP	1.0	1.4	0.0	16.4

Table 3. Correlation Matrix

VAR	DFI	PA	PPP
DFI	1.000		
PA	0.897	1.000	
PPP	(0.114)	(0.100)	1.000

Part 4: Quantitative Study

RESULTS, CONT'D

Regression results for DFI

- 10 regressions of DFI against compulsory licensing
 - only for one country, Thailand, was compulsory license use a statistically significant predictor for DFI in the positive direction (p<.05)

Regression results for patent applications

- 7 regressions of patent application filings against compulsory licensing
 - in no case was licensing or the threat of a license a statistically significant predictor of the number of patent applications filed

Part 4: Quantitative Study

RESULTS, CONT'D

- Pooled regression analyses revealed that compulsory license use or threat was not a statistically significant predictor of direct foreign investment into or of patent applications filed within a nation

CONCLUSION

- *Results do not support the hypothesis that nations issuing or threatening to issue compulsory licenses will experience a reduction in direct foreign investment or patent application filings*

Public Health Impact of Project

- If known barriers to compulsory licensing are overcome, and known secondary effects are mitigated with advance planning,
- Then developing nations can successfully exercise their right to issue compulsory licenses for essential medications and *maximize global public health*

Thank you

- Questions?
- Comments?

Article 25.

- (1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.
United Nations Universal Declaration of Human Rights
