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Price negotiations of ARVs

Using game theory to explain the “Brazilian Model”

Eduardo Urias
urias@merit.unu.edu
UNU-MERIT, Maastricht,
The Netherlands

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Presentation outline

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5. Episodes of price negotiation in Brazil
6. Pattern matching to test the hypothesis
7. Discussion & Recommendations
8. Conclusions

Context and motivation (1)

- Patent monopoly tends to result in higher drug prices

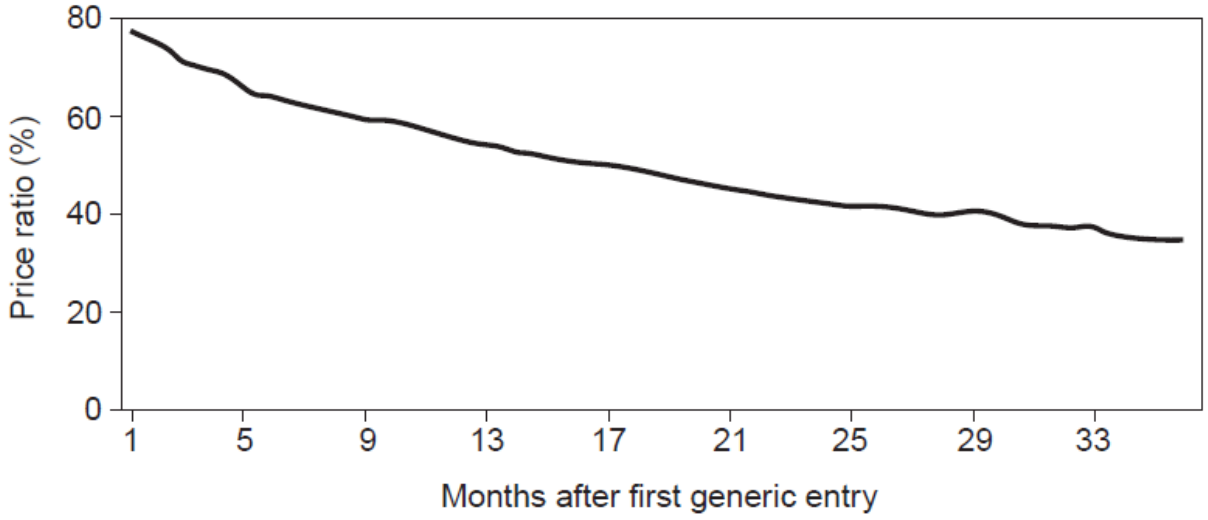


Figure 2b. Average generic-to-brand price ratio.

Context and motivation (2)

- Higher prices may prevent access to life-saving drugs
  - Raltegravir PPPY in Brazil (2010): $6,944
  - GDP per capita in Brazil (2010): $11,200

Context and motivation (3)

- Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)
  - Launched in 1995
  - The most comprehensive multilateral agreement on intellectual property to date
  - Minimum standards for the regulation of intellectual property rights in WTO Members.
  - Flexibilities to cope with the negative impact of patents on access
    - Compulsory license is one of them

Context and motivation (4)

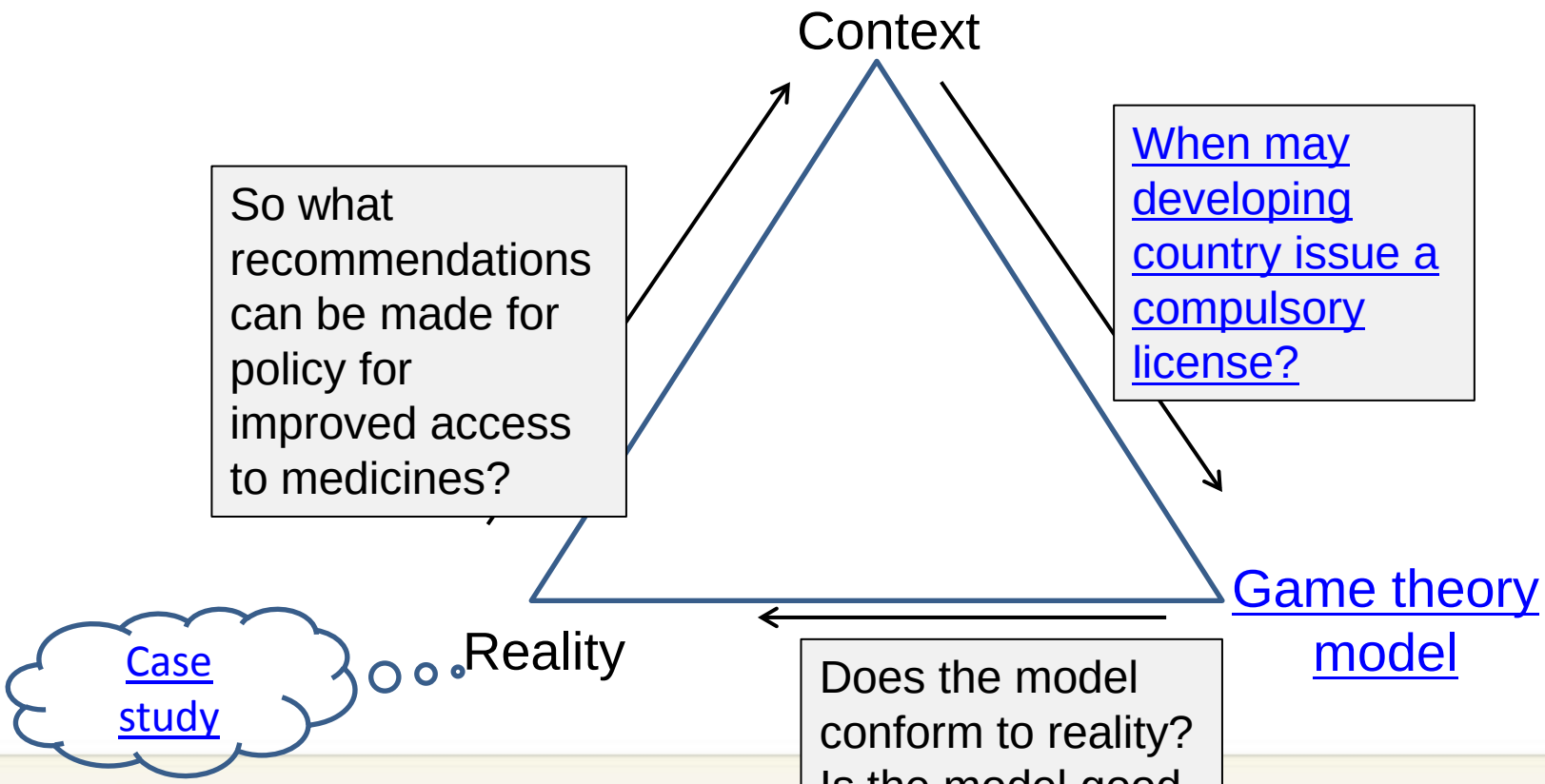
- Compulsory license **threat** used as leverage in price negotiation

- Brazil is the most prominent example of such strategy

Research Questions

1. What are the drivers of bargaining outcomes of price negotiations between multinationals and public agencies of developing countries?
2. What is the individual and joint influence of these drivers in determining the type of outcome?
3. From answers to the above, what can we say about the use of compulsory licensing as tool to promote access to medicines?

Methodology



The Brazilian Universal Access Program

- Program was formalized in 1996, but its origins date back 1985 (in SP)
- Strategy based on two main pillars
  - Production of off-patented ARVs in state-owned labs (since 1994)
  - Compulsory license threat as leverage in price negotiations with patent holders
- Brazilian strategy has been referred to as the ‘‘Brazilian model’’ for AIDS treatment by the WHO

Episodes of price negotiation of ARVs in Brazil

Episode	Drug	Outcome	Predicted outcome
1A	Efavirenz (200 mg)	D	D
1B	Nelfinavir	D	D
2A	Efavirenz (600 mg)	D	D
2B	Lopinavir + Ritonavir	D	D
2C	Nelfinavir	D	D
3A	Lopinavir + Ritonavir	D	D
3B	Efavirenz (600 mg)	SQ	SQ
3C	Tenofovir	D	SQ

Episodes of price negotiation of ARVs in Brazil

Episode	Drug	Outcome	Predicted outcome
4	Atazanavir (200mg)	D	SQ
5	Efavirenz (600 mg)	CL	CL
6A	Tenofovir	D	SQ
6B	Tenofovir	D	SQ
7A	Raltegravir	VL / D	SQ
7B	Atazanavir (200mg/300 mg)	VL / D	SQ

Pattern matching to test the hypothesis

- Hypothesis 1 
  - A compulsory license is never issued under complete information.

	Compulsory License	Other Outcomes
Complete Information	0	2
Incomplete Information	1	5
Information irrelevant	0	8

Pattern matching to test the hypothesis

- Hypothesis 2
  - The price will not change whenever a generic version of the drug cannot be imported and there is no sufficient local manufacturing capacity for the drug.

Episode	Technological capacity	Observed Outcome	Predicted Outcome
1A	Yes	D	D
2A/B/C	Yes	D	D
3A/B	Yes	D	D
4	No	D	SQ
5	Yes	CL	CL
6A/B	No	D	SQ
7A/B	No	VL / D	SQ

Pattern matching to test the hypothesis

- Hypothesis 3 ✓
  - For a given value of the expected reprisal, *for higher levels of local capacity to procure drugs from alternative sources, it more likely that the negotiated price will be lower.*

Episodes where a minimum level of manufacturing capacity was present									
Episode	1A	1B	2A	2B	2C	3A	3A	5	Average
$\frac{P_2}{P_{CL}}$	1.9	1.5	1.8	1.9	1.5	1.5	1.8	2.4	1.8
Episodes where a minimum level of manufacturing capacity was absent									
Episode	3C	4A	4B	6A	6B	7A	7B	7C	Average
$\frac{P_2}{P_{CL}}$	4.6	6.3	4.8	7.8	6.1	3.8	4.1	8.1	5.7

Recommendations

- Support technological capacity building
  - Industrial policy
  - Public procurement
  - Use of other flexibilities, such as experimental use

- Avoid Undeserved Patents and Unsound Patent Policy
  - Capacity building in “patent bureaucracy”
  - Encourage pre-grant opposition
  - Anti-evergreening regulation

Conclusions

- Compulsory licensing (threat) can be effective
- IPR matters only if there is sufficient manufacturing capacity or alternative sources
- Real contexts provided a better understanding of the main drivers and obstacles to the use of compulsory license
  - Many other variables at play (e.g. drug stocks, adequacy of IP and regulatory frameworks, “spillovers”, simultaneous negotiations)
  - Other sources of informational constraints (e.g. actual level of technological capacity)
  - Other players (e.g. Ministry of Finance; civil society)
- Many countries cannot replicate the “Brazilian model”
  - There is a need for institutional changes to facilitate CL for exports

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Thank you!

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Discussion

- Episode 5 is the only instance of compulsory license issuance
  - Although necessary conditions can be tested in a single instance (see Dion 1998; Nock, Michel, and Photos 2007; Dul and Hak 2008), we cannot be sure that the underlying proposition can be generalized for other instances of compulsory license.

Discussion

- Hypothesis 2 and the measurement for the underlying variables account for manufacturing capacity at the drug level.
  - This may suggest that the existence of a “general capacity to manufacture” is already sufficient for obtaining price reductions
  - But, according to hypothesis 3, higher price reductions are expected when there is technological capacity for the concerned drug