

FTA USA-Peru and access to medicines



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You have to be crazy
to oppose
the FTA !!!!!

Current Protection of IP in Peru

- 20 years of patent protection
- Compulsory licensing
- Paralell imports
- **No** patent for plants and animals
- **No** patent for therapeutic and diagnosis methods
- **No** patent for second uses
- Data Protection for at least 5 years from dishonest use

USA Propossal

- Second use patents
- Patents for therapeutics and diagnosis methods
- Compensation for the delay of more that 5 years on granting the patent
- Compensation for unreasonable delay of marketing approval
- Exclusive use of data on efficacy and safety of medicines for at least 5 years
- Linkage between marketing approval and patenting

**How did the
negotiation go ?**

Let's negotiate. I propose **A**.

Then, I propose **B**.

So, I propose **C**.

I propose **Z**.

I propose **Z**.

I propose **Z**.

Okay, **Z**
It was a tough negotiation,
but successful.



Results (1)

- Compensation for the delay of more than 5 years on granting the patent
- Compensation for unreasonable delay of marketing approval
- Exclusive use of data on efficacy and safety of medicines for at least 5 years
- Linkage between marketing approval and patenting

Results (2)

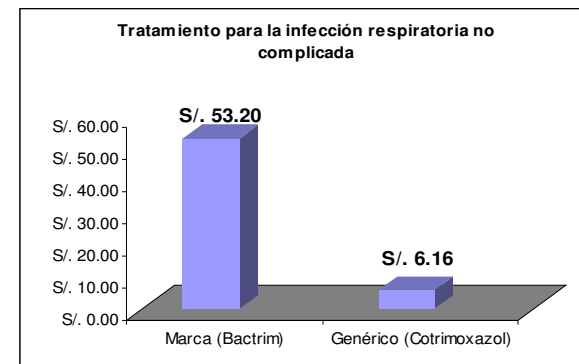
- Compensation for delays on granting patents (five years)
- Compensation for “unreasonable reduction” of the effective patent’s life. (marketing approval)
- Linkage between patenting and marketing approval

Results (3)

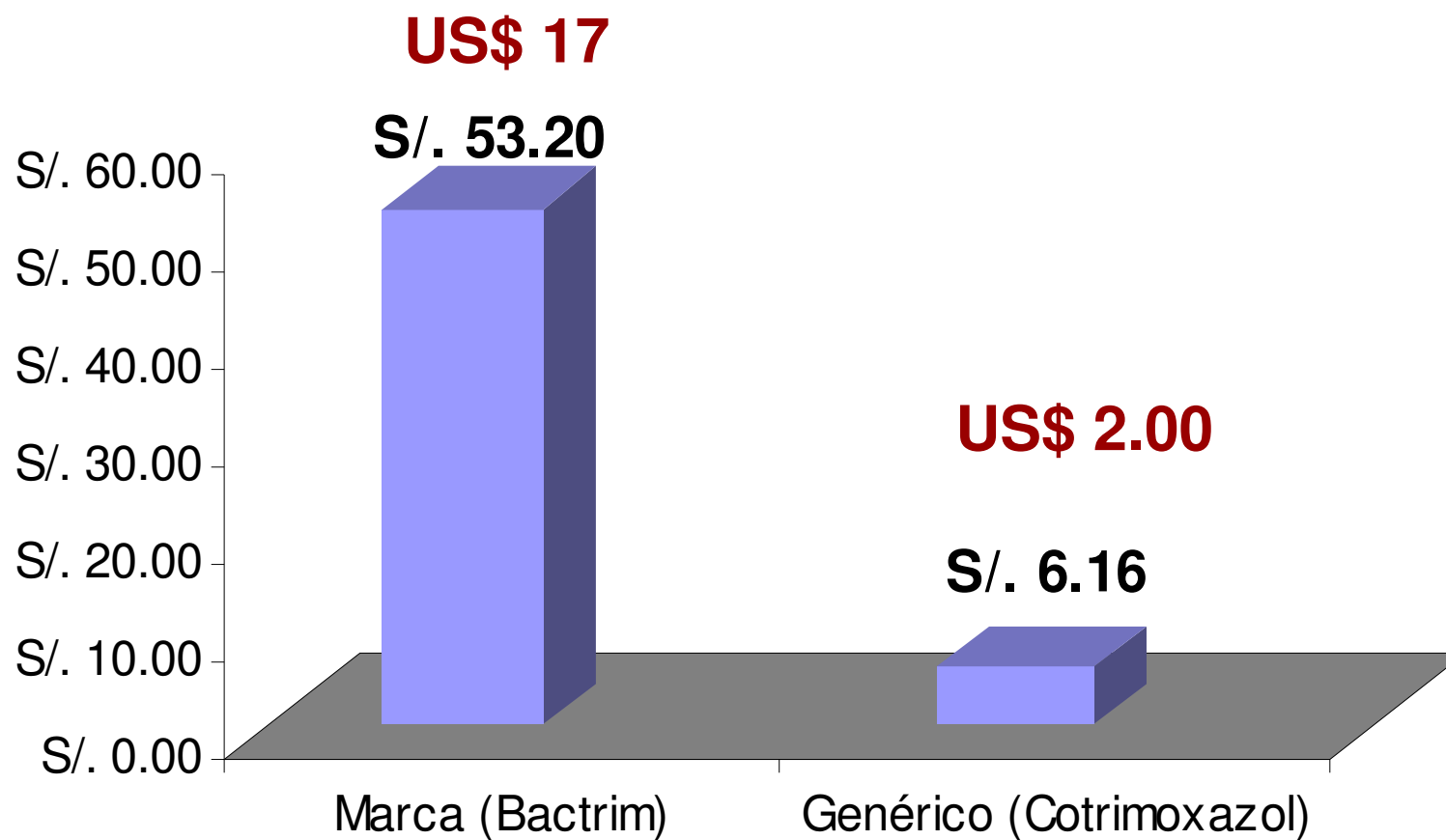
- Data exclusivity (at least 5 years)
- “Information” related to efficacy and safety
- New chemical entity?

¿What will be the effects?

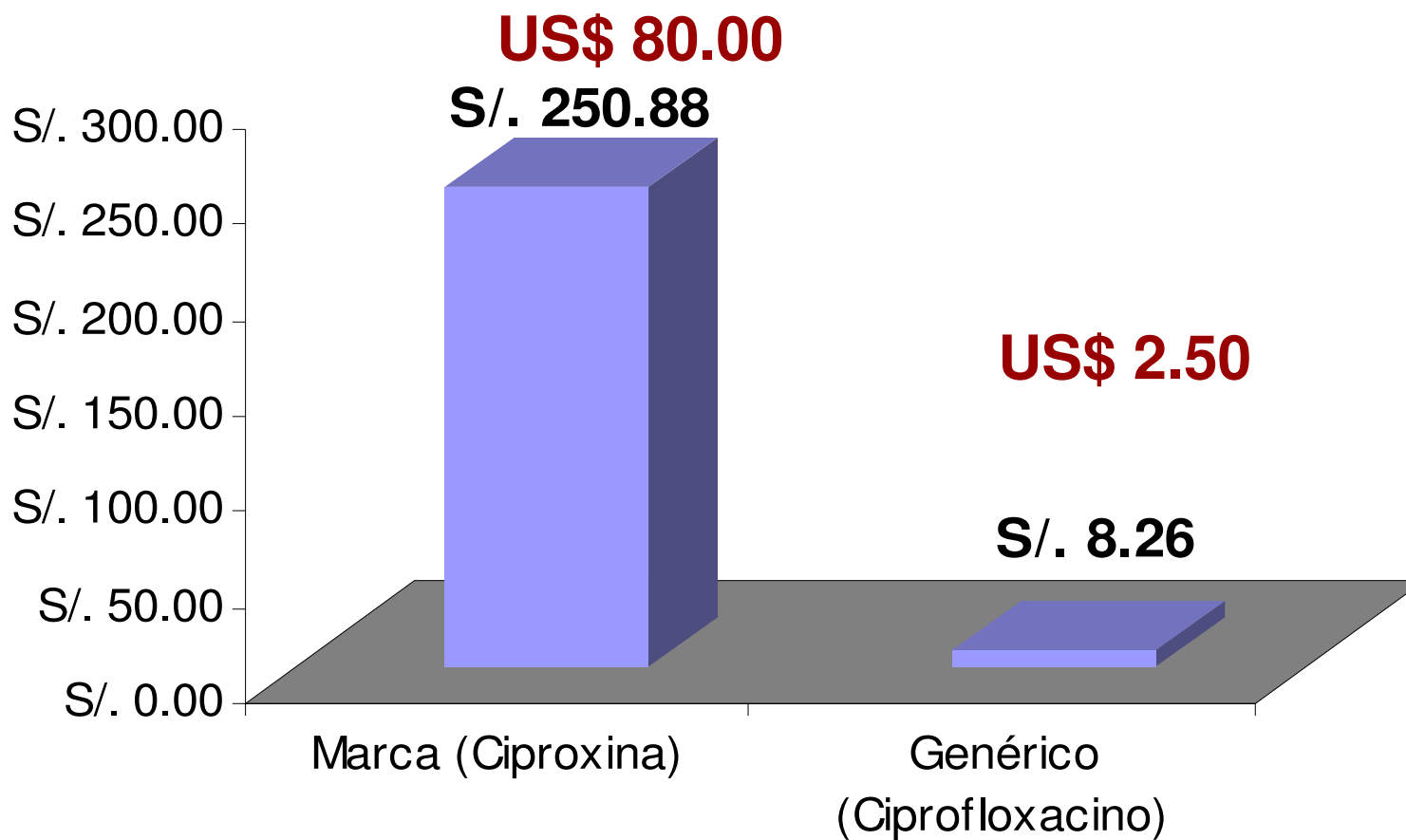
- A greater concentration (monopolies) at the pharmaceutical market
- Delay of the introduction of generics versions
- Reduction of competition
- Increase of medicine prices



Tratamiento para la infección respiratoria no complicada



Tratamiento para la infección urinaria no complicada



What is at risk?

- Coverage of public health services: exclusion of some population segments and restrictions due to the higher costs of attention (medicines)
- Currently the Public Insurance System (for those on poverty) does not cover for example cancer ... nor all the poor people.

What is at risk?

- Comply commitments of Peruvian State regarding the right to health:
 - Constitutional mandates
 - International Covenant on Economic, Social and Cultural rights
 - Milenium objectives

Impact on access to medication

A the first year of the FTA

- US\$ 34 millions additional on medicines
- US\$ 29 millions out of pocket

Source: MOH, Peru, 2005

Impact on access to medicines

- First 5 years: **700** to **900** thousand will not get the medication they need
- 2011 to 2017: US\$ **130** millions will be spend additionally at least and US\$ **169 at most**
- Prices will increase on an average of **99%** for 2017. Original brand name: **132%**

Source: MOH, Peru, 2005

There is more!... “FTA plus”

- Peru has to change legislation on patents
- Perú has to change legislation on medicines
- USA will lobby for second uses patents and other provisions to benefit the big industry: the watch list.

“.... A preferential deal is needed taking into consideration the level of development of the country... Higher standards to those established at the TRIPS could mean ... to limit the availability of medicines with prices affordable for the people”

“ Acknowledgment the asymmetries of the negotiators (countries)”

“The right to health has primacy over the property rights”

“Peru is not allowed to transgress the andean legislation through bilateral agreements”

(INDECOPI, Institute for Defense of Competition and Intellectual Property, Peru "***Los Intereses Nacionales en Propiedad Intelectual y los Tratados de Libre Comercio: Marco Referencial***" 11.03.2005).

"I am concerned that the US-Peru free trade negotiations could lead to higher protection of patents than is currently required under the rules of the World Trade Organization. **Higher protection of patents could restrict Governments from taking action to protect the right to health in the future.**"

"Any standards introduced under the FTA on intellectual property protection – and patents more specifically – **should include an express safeguard recognizing the right and duty of countries to protect human life and health**"

(Paul Hunt; Special Rapporteur of UN on Right to Health)

