Barking Up the Wrong Tree?

Patents, TRIPS Flexibilities and Public Health in Argentina

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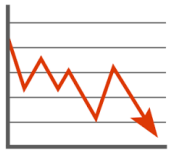
1. Introduction

- ❑ TRIPS Agreement and Minimum Standards for IP Protection
- ❑ Public Health and TRIPS Flexibilities

2. Pharma Patents in AR: the AR PTO's 2012 Guidelines

- ❑ Background and Outline
- ❑ Exclusions from Patentability

3. Results: The Experience after 7 Years



- ❑ Impact on Patent Filing and Grants
- ❑ Impact on Public Health and Drug Prices
- ❑ Collateral Damages

4. Barking Up the Wrong Tree?

- ❑ Why did the Guidelines Fail?
- ❑ Alternative Legal Tools

5. Conclusion

1. Introduction

TRIPS Agreement and Minimum Standards

- Protection available for all inventions in all fields of tech, without discrimination
- 3 substantial requirements (novelty, inventive step, industrial application)
- Limited exceptions

1. Introduction

Public Health and TRIPS Flexibilities

- Tension between IP protection and public health during TRIPS negotiation
- How much freedom do Member States have when implementing TRIPS?
- Doha Declaration (2001)
  - Acknowledged tension
  - TRIPS provisions "*provide flexibility*" (e.g., interpretation of legal provisions, compulsory licensing, exhaustion)

1. Introduction
Types of Flexibilities

In the process of the acquisition of the right

e.g.:

- formal requirements
- substantial requirements

Scope of the patent right

e.g.:

- experimental exceptions
- exhaustion

Use and enforcement of the right

e.g.:

- remedies
- prevent abusive practices

2. Pharma Patents in AR: the AR PTO's 2012 Guidelines

Background and Outline

- 1995: AR amended its patent law to comply with TRIPS
- 2003: AR PTO Patentability Guidelines (similar to EPO)
- 2012: New Patenting Guidelines which severely restrict patentability of pharma and chemical inventions
  - Invoked Doha and *flexible* nature of TRIPS provisions
  - Purpose: avoid *evergreening* and reduce drug prices

In practice, all incremental inventions now excluded from patentability

2. Pharma Patents in AR: the AR PTO's 2012 Guidelines

Exclusions from Patentability

- Set of presumptions and instructions on how *novelty*, *inventive step* and *patentable subject matter* should be interpreted

Exclusions from patentability

- ✘ polymorphs
- ✘ salts, esters
- ✘ compositions and formulations
- ✘ metabolites, prodrugs
- ✘ second medical uses
- ✘ selection inventions
- etc.

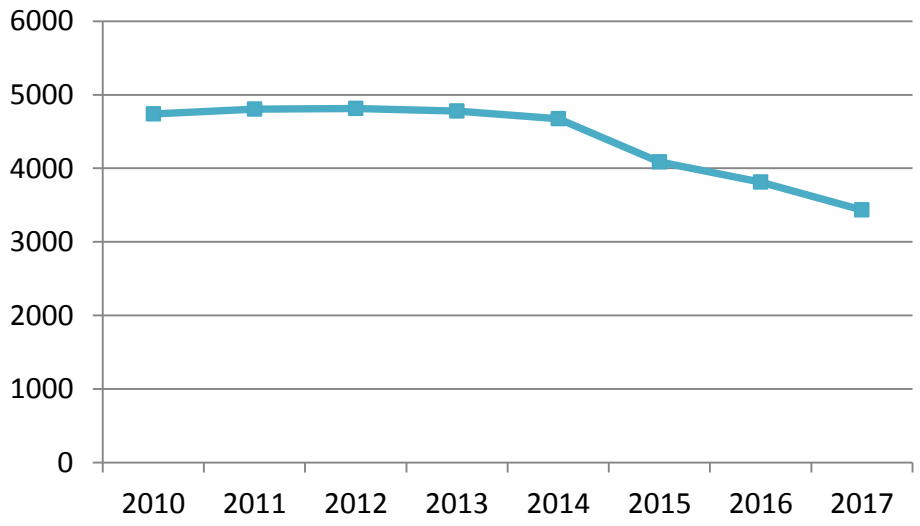
- Raising the bar or building a wall?

- Is it really a case of TRIPS flexibilities?

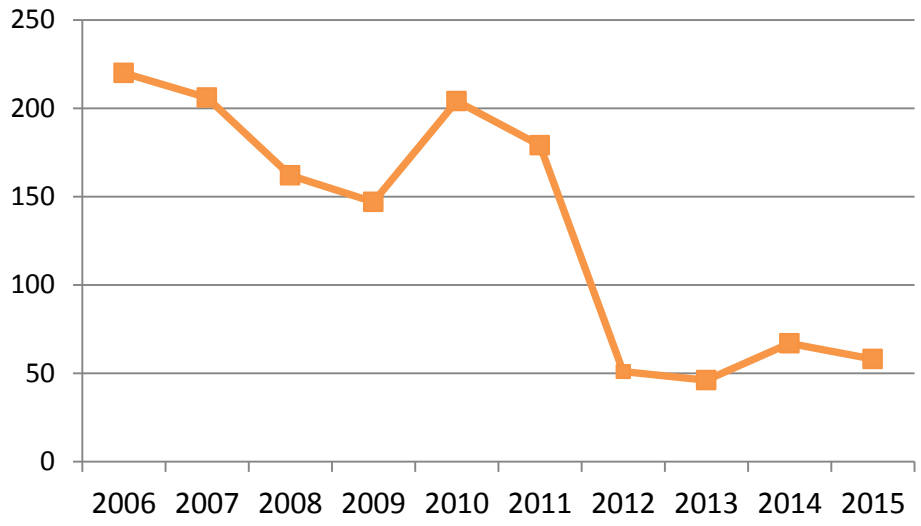
3. Results: The Experience after 7 Years

Impact on Patent Filing and Grants

Less patent applications



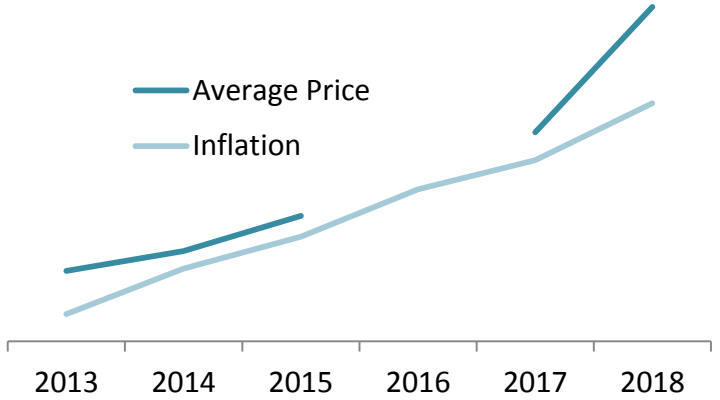
Less patents granted
in pharma and chemistry



3. Results: The Experience after 7 Years

Impact on Public Health and Drug Prices

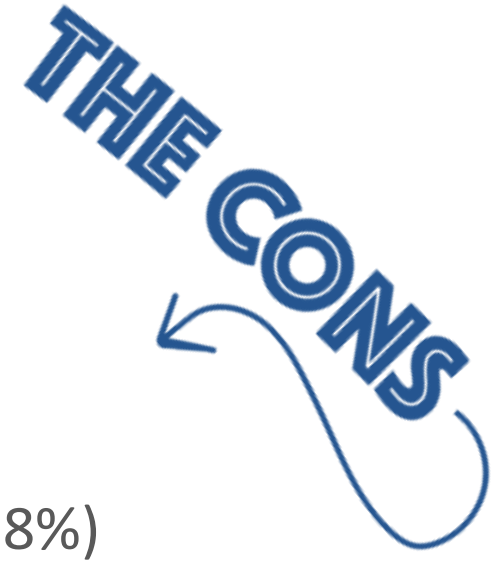
- No indications of price reductions
- No improvements in access to medicine
- Minor changes in market share (+2.1% for Gx)
- No impact on employment or balance of trade



The 2012 Guidelines are failing to achieve any of their goals

3. Results: The Experience after 7 Years

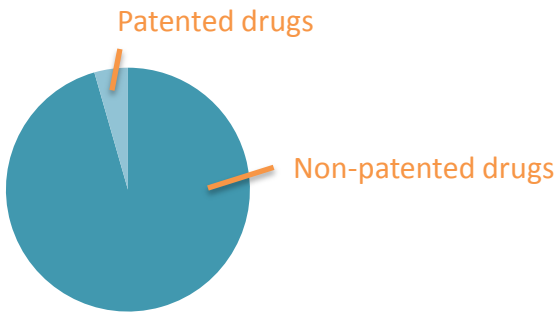
Collateral Damages



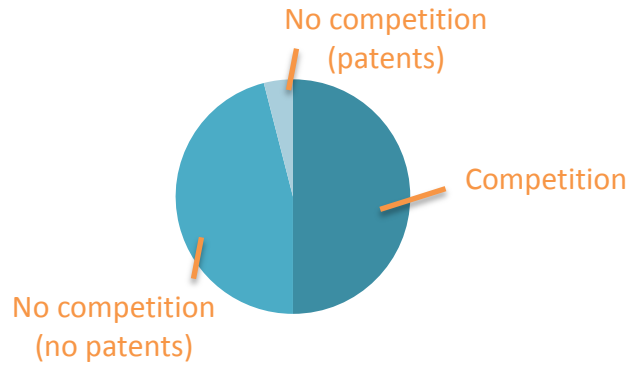
- Impact on local R&D
  - Local innovation neglected
  - Reductions in local R&D expenditures (from 3.6% to 2.8%)
- Impact on other unrelated industries
  - Patentability restrictions in, e.g., chemistry and animal health
- TRIPS violation and exposure to WTO disputes
- Impact on international affairs and foreign investments

4. Barking Up the Wrong Tree?
Why did the Guidelines Fail?

- Very few drugs were actually covered by patents in AR
  - ➢ Between 2% and 6% of drugs on the market



- Despite of that, only 50% of drugs on the market have competition
  - ➢ For expensive drugs, even less (30%)



- New market players do not bring drug prices down


Alternative

4. Barking Up the Wrong Tree?
Alternative Legal Tools

- Competition law
  - Vertical Integration
  - Other market entry barriers?
  - Collusion
- Regulatory improvements
  - Health insurance companies
  - Transparent public biddings
  - Drug prescriptions
  - Bioequivalence studies
- Compliance
- Other TRIPS Flexibilities
  - Compulsory licenses

5. Conclusion

- AR 2012 Guidelines did not reduce drug prices, did not improve access to medicine in any other way and seem to be doing more harm than good
- Discussions on IP seem to be diverting the attention from other legal tools (competition law, compliance and key health regulations) which could indeed be effective for improving public health
- When discussing public health issues, IP should not be deemed as a starting point but rather as one of many alternative legal tools

Thank You!

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