



# **The Egyptian Patent Office Approach to the Examination of Pharmaceutical Patents**

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# Objectives

- Highlight the importance of TRIPS Flexibilities regarding patent examination
- Describe the examination of pharmaceutical patents in Egypt: Law and Practice
- Discuss how adopting the appropriate examination standards could support a well- functioning patent system in the pharmaceutical field



# TRIPS Flexibilities and Patent Examination

## Patentability Criteria

- Universal Criteria
- National Standards

## Option to Exclude Subject Matter

- To protect public order
- Methods for treatment
- Plants and animals

## Disclosure Levels

- Enablement
- Best Mode

# Balance

**Patent Holder**  
**Private Rights**



**Society**  
**Public Rights**

# **Examination of Pharmaceutical Patent Applications in Egypt**

Law and Practice



# Disclosure level

- **Enablement**

Clear and complete to enable a person skilled in the art to carry out the invention

- **Best Mode**

The best mode known by the inventor to carry out the invention

Art. 13 of the EG IP Law 82/2002

# Non-Patentable Subject Matter

Art. 2 of the EG IP Law 82/2002

- Contrary to public order or morality
- Prejudicial to the environment, or life and health of human, animal or plant

- Discoveries, scientific theories, mathematical methods, programs and schemes

- Diagnostic, therapeutic and surgical methods for humans and animals

- Plants and animals
- Essentially biological processes

- Organs, tissues, living cells, natural biological substances, nucleic acid and genome

# Novelty

- Absolute
- Implicit / explicit disclosure



Art. 1&3 of the EG IP Law 82/2002





# Inventive Step

- Significant degree of progress
- Prior art includes common knowledge
- Person skilled in the art



Art. 1 of the EG IP Law 82/2002



# EGPO Pharmaceutical Patent Examination Section

Background and  
Education  
(Pharmacy and Law)

Continuous Training  
(Search Skills, Subst.  
Examination, Public  
Perspective)

Databases  
(Advanced / Field  
Specific)

Self-learning and  
Group work

Quality Team

Guidelines

# The Choice of the Appropriate Patentability Standards

What to Consider?



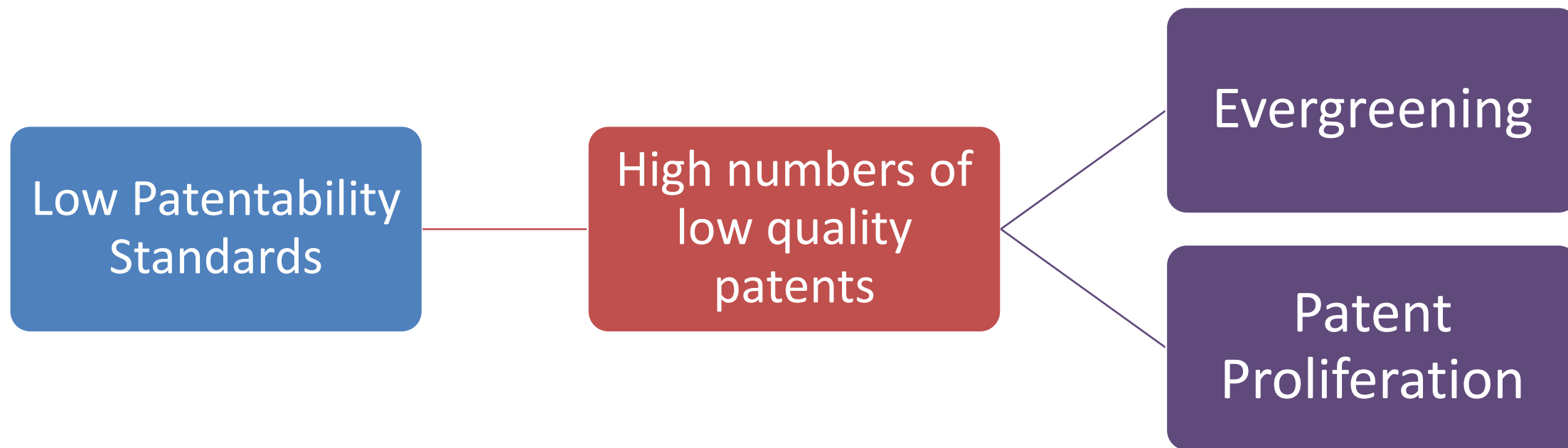
# Pharmaceutical Patent Quality

## Pharmaceutical Patents

- **Should**
  - Foster innovation and R&D
  - Achieve patent system intended socioeconomic goals
- **Should NOT**
  - Impede medicine availability and affordability
  - Stifle competition
  - Deter local generic manufacturing



# Lax Examination Does Not Lead to High Quality Patents



# Sofosbuvir





# Efficient Utilization of TRIPS Patent Flexibilities



# Questions





**Thank You**