WHO, WIPO, WTO Technical Workshop on Patentability Criteria

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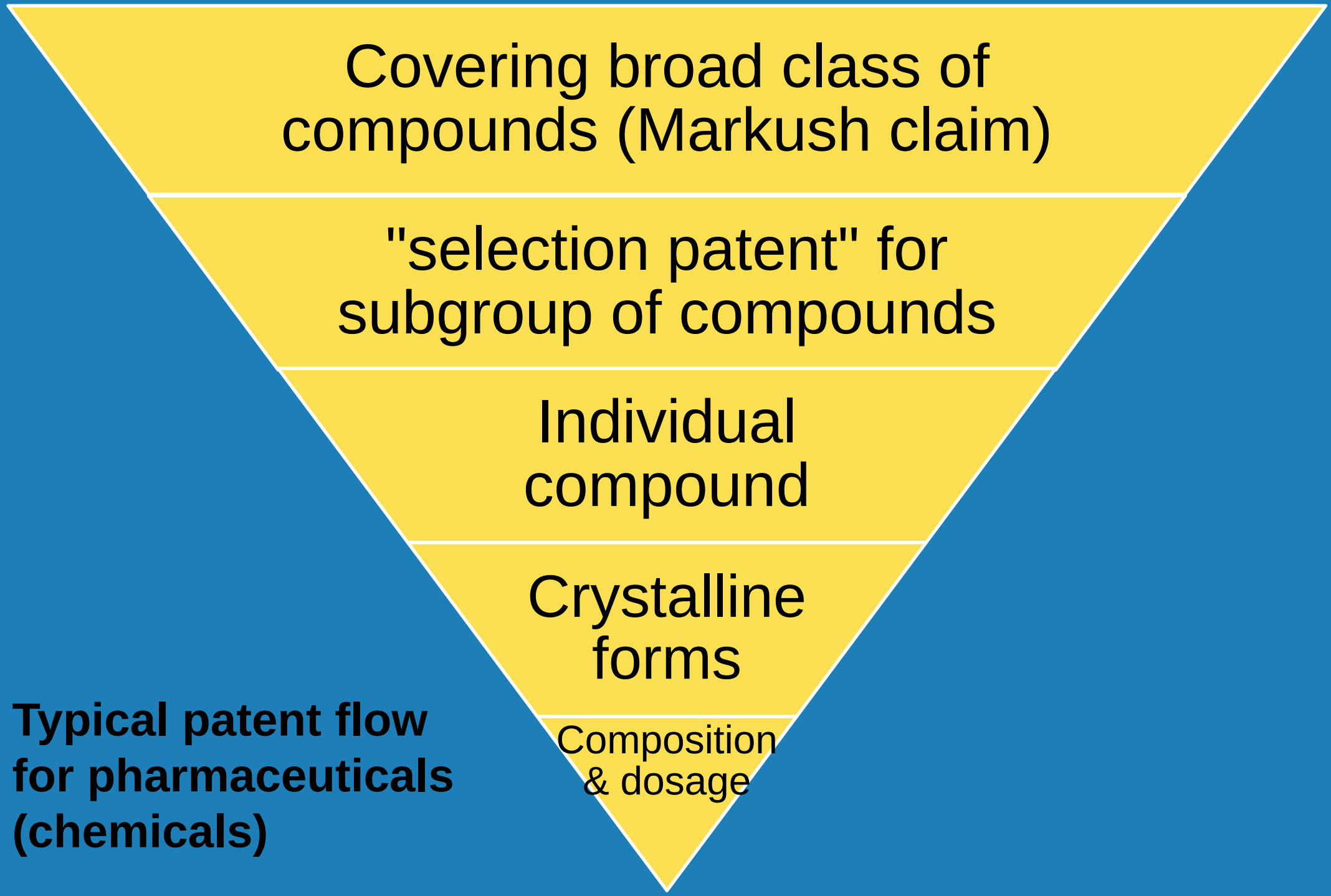
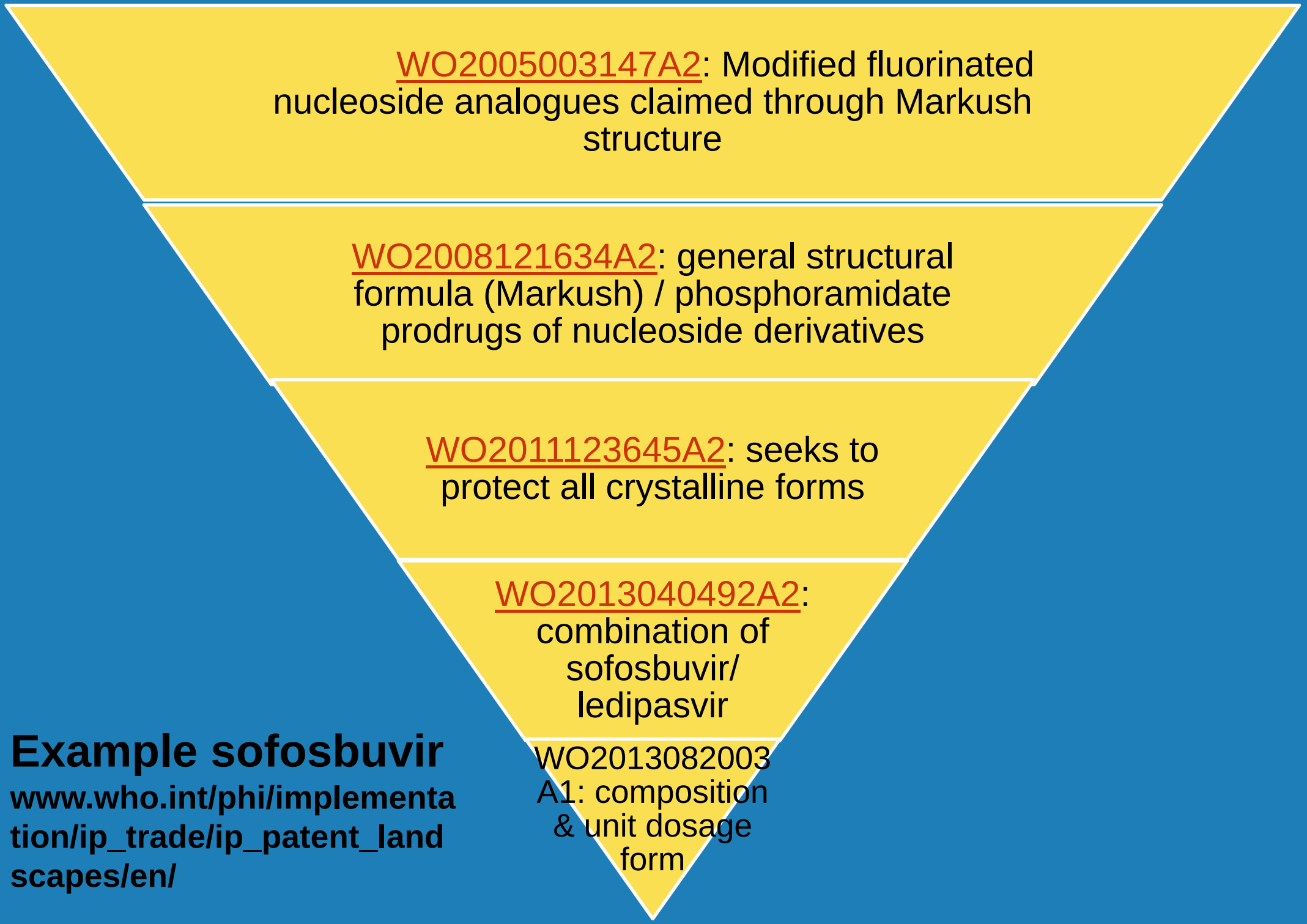


Typical patent flow for pharmaceuticals (chemicals)



Example sofosbuvir

www.who.int/phi/implementation/ip_trade/ip_patent_landscapes/en/

Sofosbuvir: Expected expiry without patent term extension(s)

Market Authorization
US: 2013
Sof/ledipasvir: 2014

2024
- Broad compound patent (Markush)
- WO2005003147A2

2028
- Compound patent on prodrug
- WO2008121634A2

2031
- Crystalline forms
- WO2011123645A22

2032
- Combination with ledipasvir
- WO2013040492A

2032
- Composition & dosage
- WO2013082003A1

Incremental innovation vs life cycle management

Incremental advances for public health can include:

- **Combinations & new dosage forms with improved efficacy:** co-formulation of antiretroviral drugs
- **Formulations with better product characteristics:** vaccines stored in fridge rather than freezer
- **New routes of delivery:** tablets or nasal spray vs injections
- **Paediatric formulations:** dispersible flavored tablet of artemether-lumefantrine

"…a key element of life cycle management strategies is to extent patent protection for as long as possible by filing secondary patents to keep generics off the market." (Burdon and Sloper 2003)

Prilosec – Nexium (omeprazole/esomeprazole)

Proton pump inhibitor that inhibits gastric acid secretion

"It has surprisingly been found that the magnesium salt of S-omeprazole occurs in a number of structurally different forms. It is an object of the present invention to provide a substantially pure magnesium salt of S-omeprazole tri-hydrate…." (US 6,369,085 B1)

Nexium = single-isomer version of Prilosec

Omeprazole vs. esomeprazole

US Patent No.	Filing Date	Expiry	Description
US 4255431	Apr 5, 1979	**2001**	Original compound patent
US 6369085	May 5, 1998	**2018**	Novel form of S-omeprazole

Marketing: US$500 mill/year following launch (New Yorker 2004)
Revenue 2006: >US$ 5 billion

Vernaz et al.: €5,2 mill 2000 - 2008 extra costs in Geneva Hospitals

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Rituximab: subcutaneous vs. intravenous

Benefits: 5 minutes injection vs. several hours

- Patients' preferences (Pivot et al. 2013)
- Savings in healthcare professional time and costs (Rule et al 2014)

- Intravenous patent expires in 2013
- Subcutaneous patent expires in 2030

Is every switch from IV to subcutaneous inventive?

Would companies do this step if they would not get a patent?

Where to draw the line?

Opposing trends:

- Argentina, India and Philippines follow new approaches in the pharmaceutical area to limit secondary patents
  Brazil and South Africa consider similar rules

- US through trade agreements endeavours to expand patentability, eg secondary uses, methods of use and to prevent limitation of secondary patents

- **Definition of patentability criteria can impact health budgets**
- **What is incremental innovation and what is "life cycle management"?**
- **Do all incremental improvements merit a 20 year patent?**

ICTSD, UNCTAD, WHO, Guidelines for the examination of pharmaceutical patents: developing a public health perspective

http://www.who.int/phi/publications/category/en/

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