



# Second Medical Use Patents

**Reward fit for purpose?**

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Fordham IP Conference

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# Originator

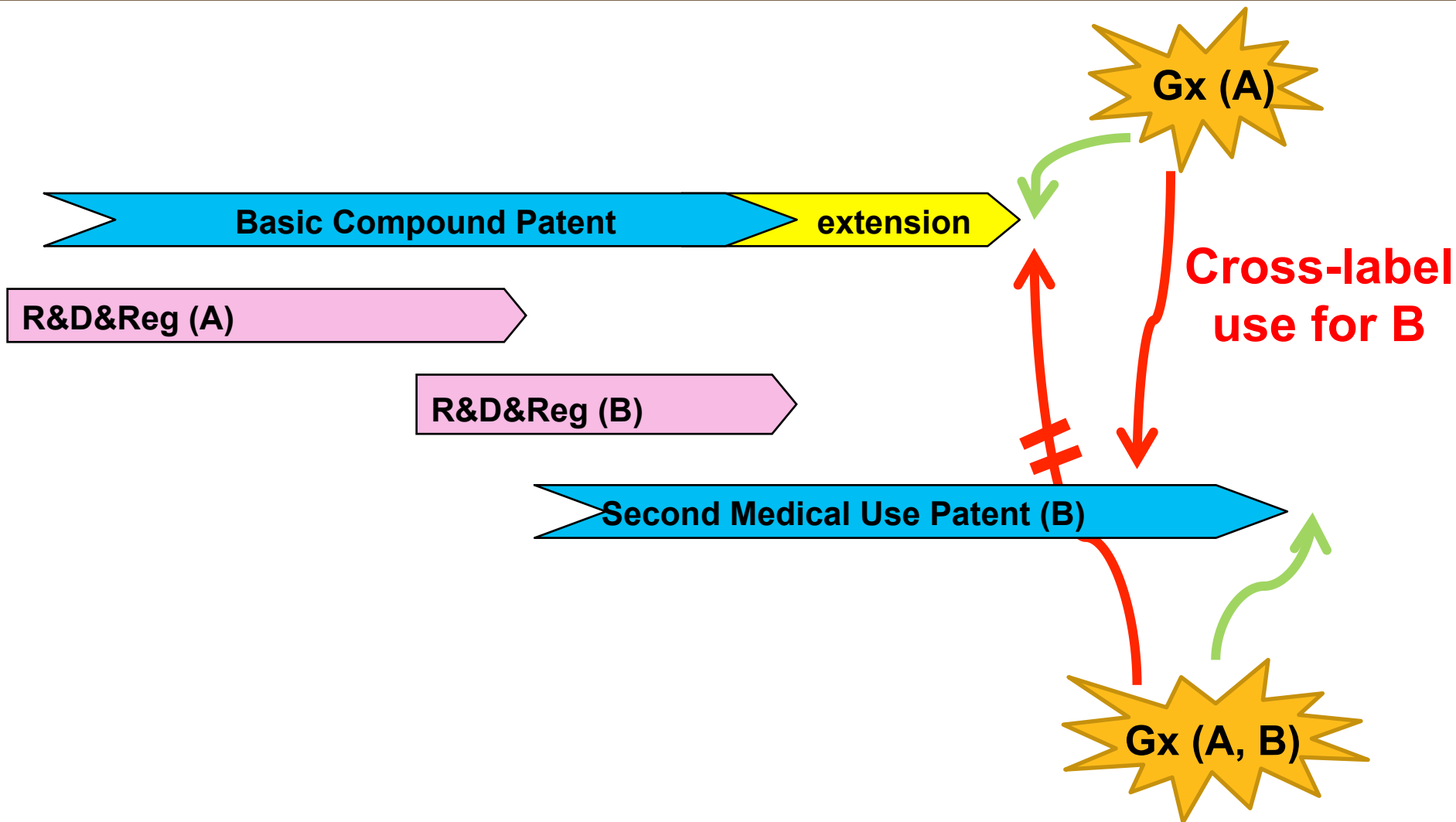
## **My personal views**

# New Second Medical Uses

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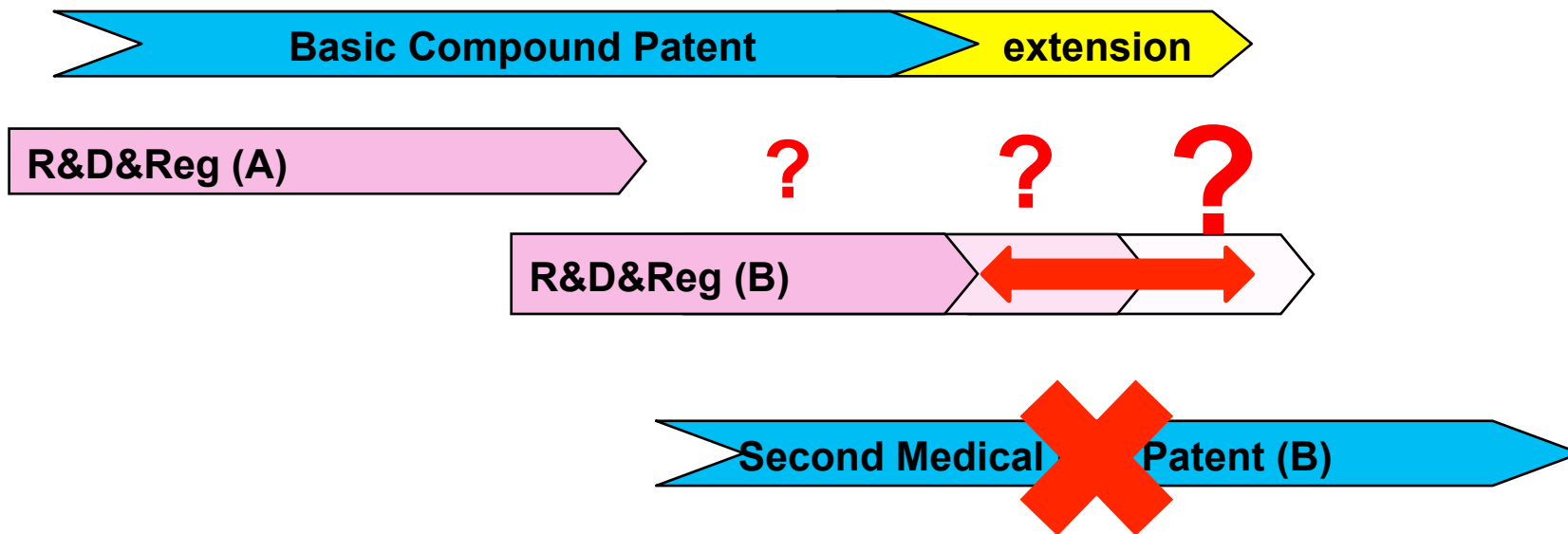
- Thalidomide: first commercialized for morning sickness, later for leprosy and multiple myeloma
- NCATS (NIH) & pharmaceutical industry in 2012: Discovering New Therapeutic Uses for Existing Molecules
  - Saracatinib shelved after Phase II for solid tumors
  - 2015: active in animal model for Alzheimer's

# Carve-out and Cross-label Use



# Search for New Therapies Worthwhile?

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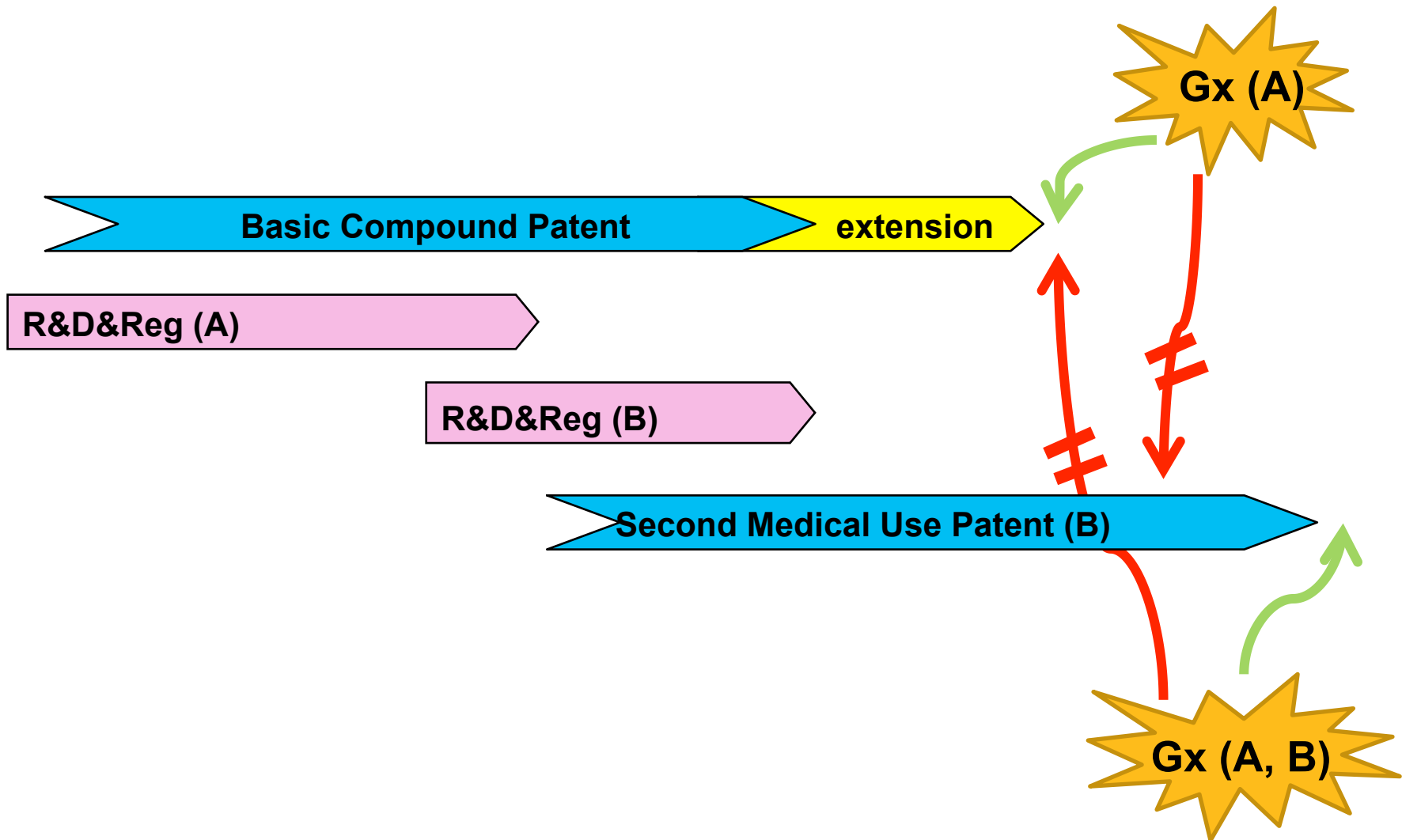


## Present Situation Bad for ...

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- **Patients & physicians:** less new therapies
- **Health care systems/payors:** less medium and long-term cost savings
- **Originators** (industry, academia): less incentive to provide innovative new therapies
- **Generics:** infringement liability, smaller markets

# Carve-out **YES** and Cross-label Use **NO**



## Awareness Increases

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- Second Medical Use Conference, London, 2013
- European Judges Conference, Venice, 2013
- AIPPI RS238, Toronto, 2014



## Aclasta – PI Novartis v Sun (CA, Netherlands)

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- Dosing regimen patent covering >95% of patients (osteoporosis)
- Patent finally revoked in UK
- Tender not limited by indication
- PI denied in The Hague DCt
- Purposive construction of Swiss-type claim
- PI granted
- Appealed to Supreme Court, decision on merits in Apr 2015, EP-opposition in Oct 2015

# Solution for Cross-label Use Issue – Netherlands

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Physician prescribes INN



Pharmacist dispenses generic



Insurer reimburses  
independently of indication

**Insurer to make tender  
indication-specific**

## Lyrica – PI Pfizer v Actavis (High Court, UK)

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- Indication patent covering 50% of patients (pain)
- Constructive talks before hearing
- Literal construction of Swiss-type claims as process
- Subjective intent for indirect infringement
- NHS to issue guideline for prescription of Lyrica for pain
- Appeal hearing in Apr 2015, hearing in case on the merits in Jun 2015

# Solution for Cross-label Use Issue – UK

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Physician prescribes INN

**Brand for patented use**



Pharmacist dispenses generic

**Mandatory dispensation  
of brand**



NHS reimburses drug

## Lyrica – PI Pfizer v Gx (Regional Court Hamburg)

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- Tender not limited to patent-free indications
- Indirect infringement of Swiss-type claims acknowledged
- Gx can participate in such tenders
- Gx to inform tender offerer that their product must not be used for patented indications

# Solution for Cross-label Use Issue – Germany

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Physician prescribes INN



Pharmacist dispenses generic



Insurer reimburses  
independently of indication

**Generic not to be used  
for patented indication**

# Reward fit for purpose?

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**... getting closer**