



Established Drugs for New Medical Uses

Reward by IP-exclusivity fit for purpose?

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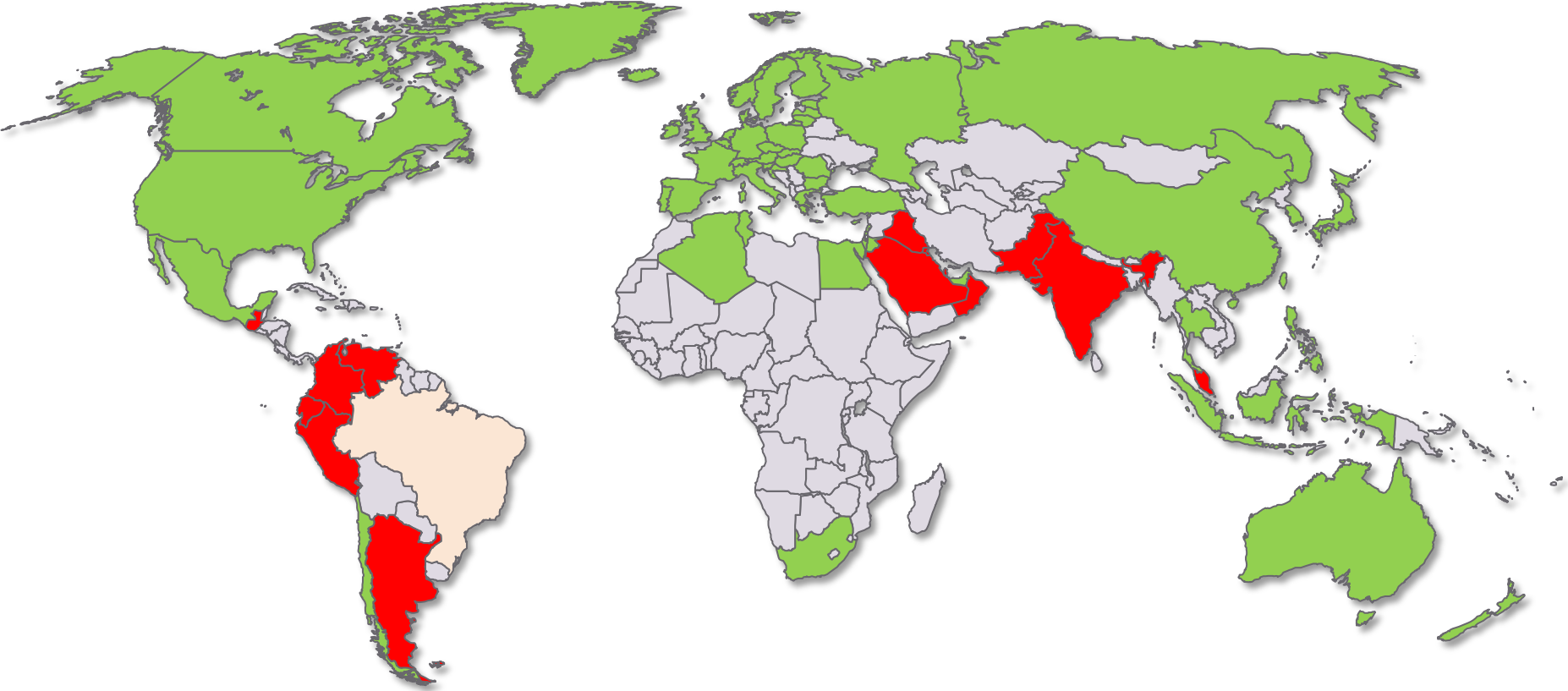
Head of Patents Litigation ex US, Novartis Pharma

Fordham IP-Conference, New York, 4 April 2013

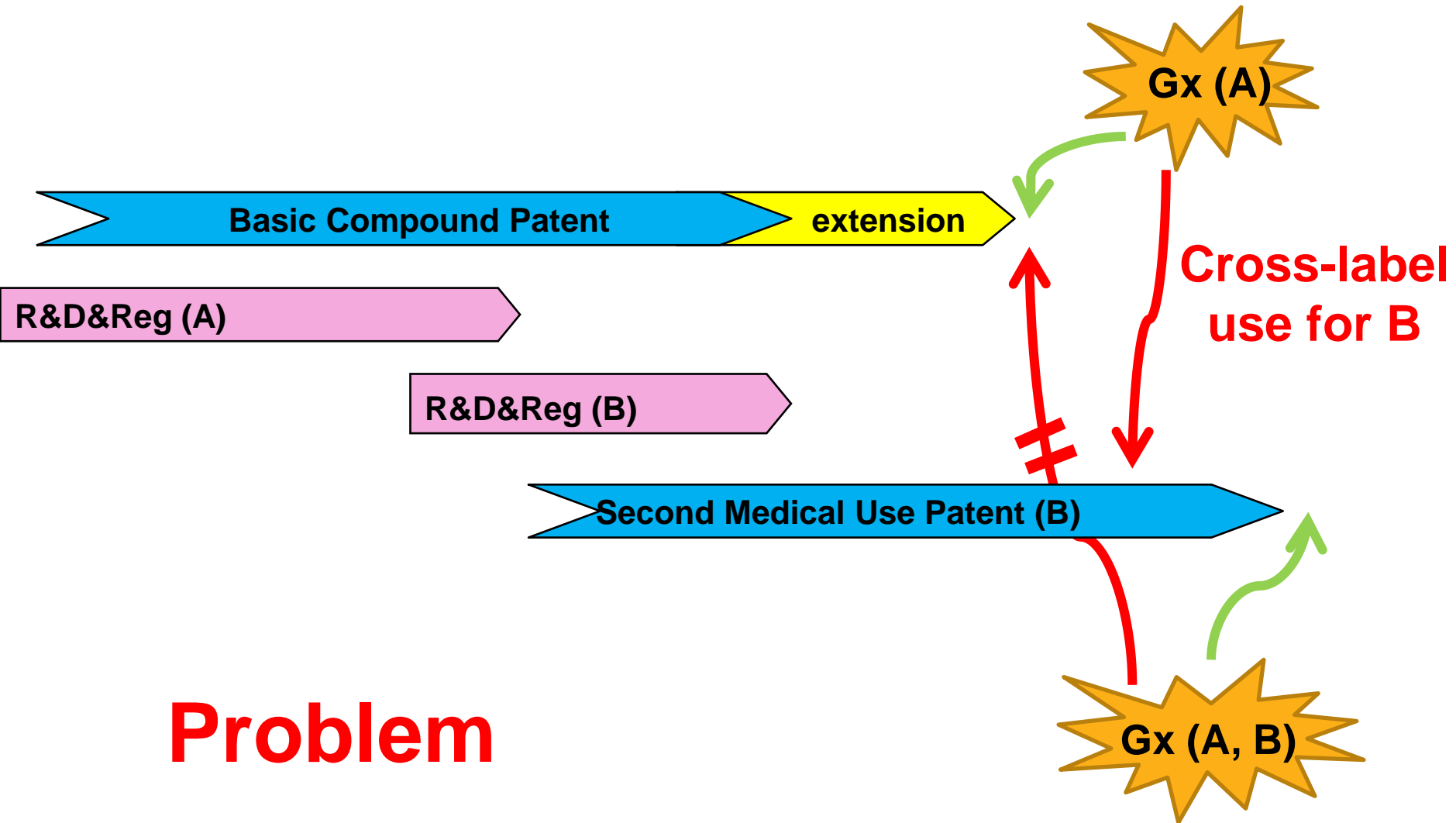


My personal views

Patentability of Second Medical Uses



Carve-out and Cross-label Use



Problem

Carve-out Issue – Example Germany

Physician prescribes drug



No indication on prescription

Pharmacist dispenses drug



Incentivized and/or mandatory substitution by cheaper Gx

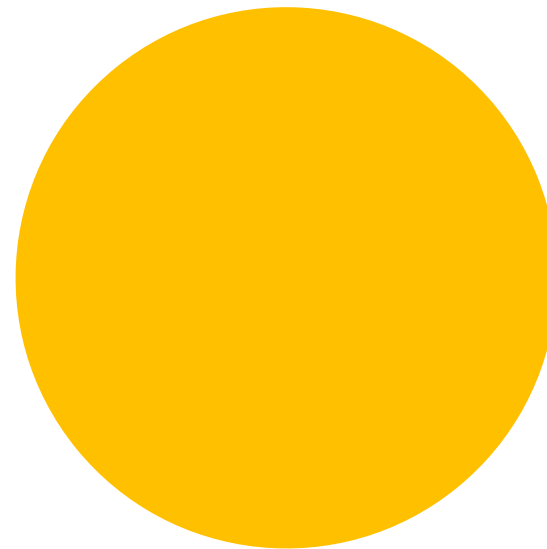
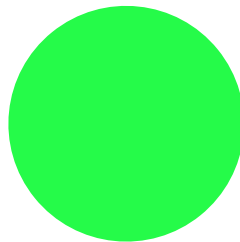
Insurer reimburses drug

Reimbursement irrespective of label

US – *Warner-Lambert v Apotex* (CAFC, 2003)

Approved v non-approved indications

Originator's label
= Generic's label



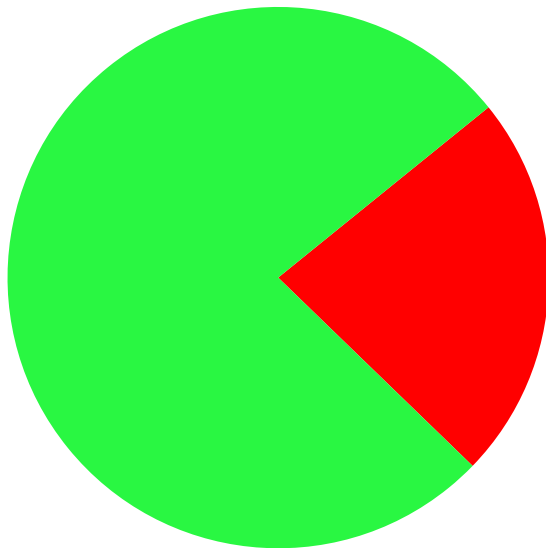
Off-label
use
patented

Knowledge of off-label use insufficient for intent for inducement to infringe

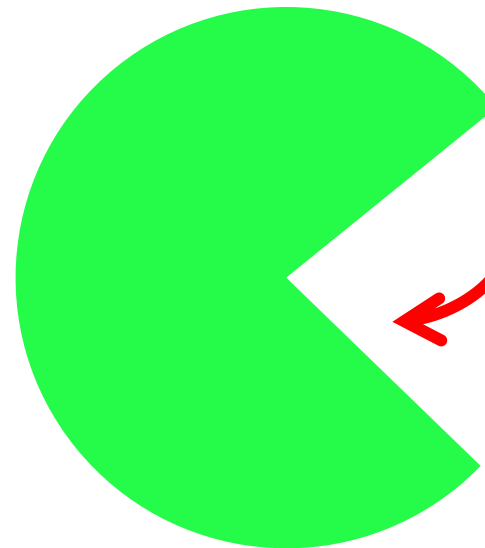
US – *AstraZeneca v Apotex* (CAFC, 2012)

Off-patent v patented indications

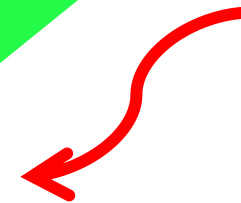
Originator's label



Generic's label



**Cross-label
use**



Legislator intended to allow carve-out and thus avoid infringement

Infringement in spite of carve-out would lead to evergreening

Search for New Therapies Worthwhile?



R&D&Reg (A)

?

?

?

R&D&Reg (B)



~~Second Medical Patent (B)~~

Conclusion

- Legislators have demonstrated appreciation of importance of innovation by second medical uses
- Complex interplay of patent law, regulatory law, pricing, reimbursement etc.
- Enforcement vs cross-label use difficult
- Legal uncertainty for Gx
- Problem of price reduction after Gx' launch
- **Patients' problem: insufficient incentive for originators to develop established drugs for new and important indications**

Potential Solutions – Stratification of Markets

Physician prescribes drug

Indication on prescription



Pharmacist dispenses drug

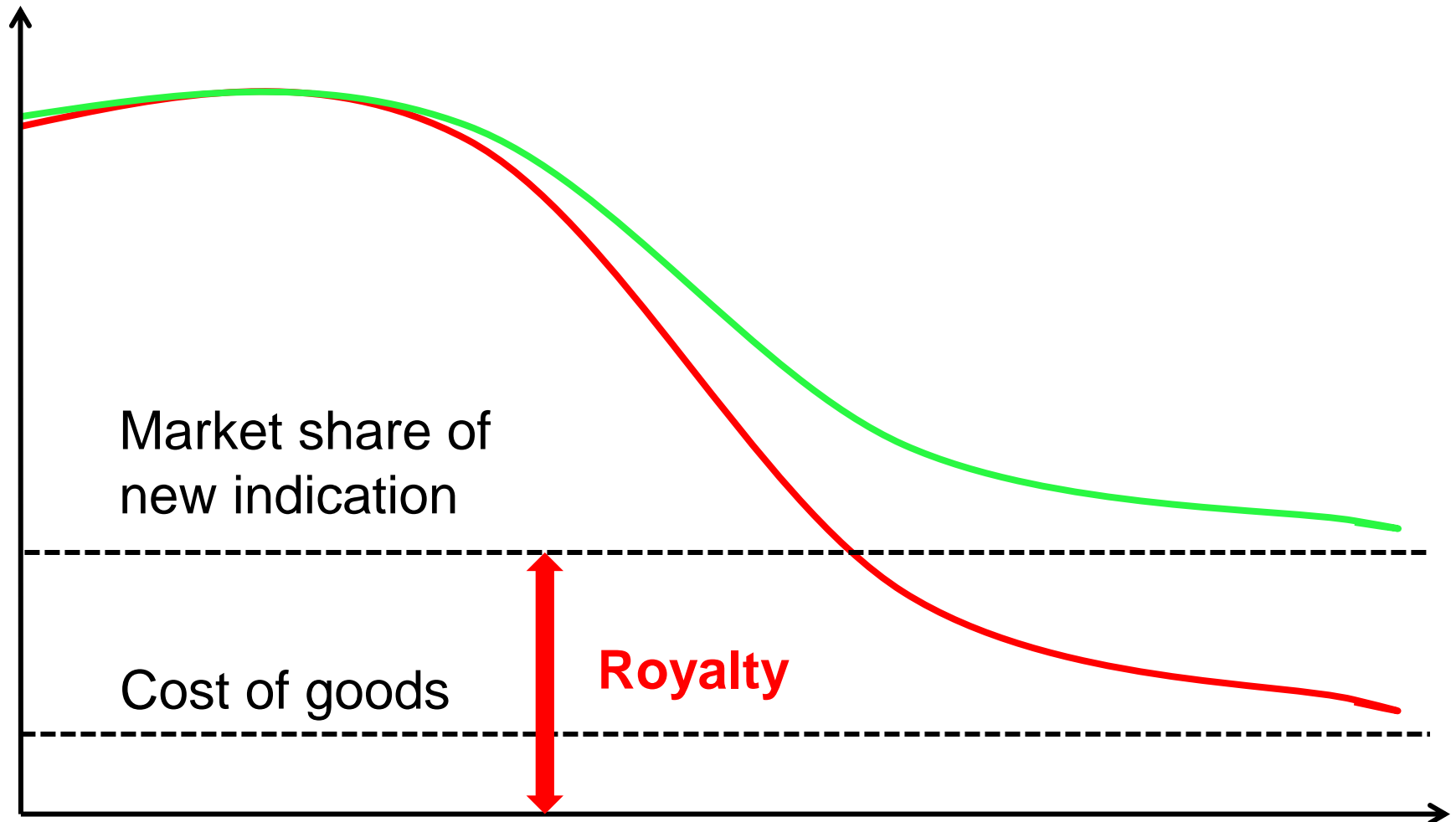
**Substitution only for
indication on Gx' label**



Insurer reimburses drug

**Reimbursement only for
indication on Gx' label**

Potential Solutions – Royalty for Protected Indication



Patentability Issues around Second Medical Use Patents

- Clinicaltrial.gov
- Patient confidentiality
- Public prior use in clinical trials
- ‘Sound prediction’ – Canada
- Sufficiency – China, Japan, ...
- Dosing regimen as therapeutic application – France
- Indications mentioned in basic patent
- **Alternative exclusivity for new indications?**

Thank you for your attention