



Pharmaceutical Patents and Evergreening

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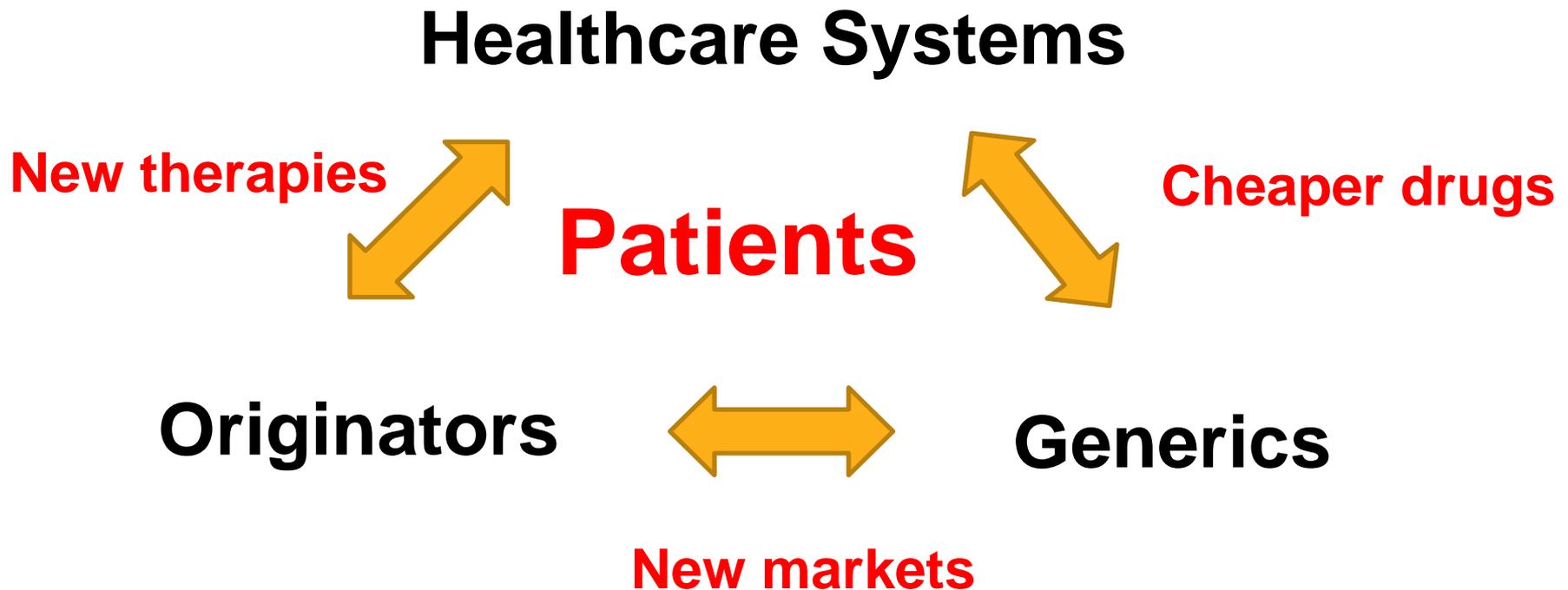
FICPI 2015, Cape Town, 14 Apr 2015



Originator

My personal views

Strong Interdependence



Loaded Terms

Me-too

Follow-up

NCE

20y-patent exclusivity

Basic patent

Patent thicket

Evergreening

Secondary patent

Extension of monopoly

Incremental innovation

Patents Covering Pharmaceuticals

Technical innovation continues after invention of the active



Compound

Salts

Solid forms (solvates, polymorphs, particle size)

Formulation, Release Profile

Manufacturing process, intermediates

Additional indications (second medical use)

Dosing regimen

Patient sub-populations

Biomarkers

Combinations

Improved Formulations

US: Divisionals – Evergreening?

- Practice of PTO leads to multiple divisional patents from single patent application:
 - Compound
 - Pharmaceutical composition
 - Method of treatment

COMBINED WITH

- 17y-patent term from grant

- **NOW: 20y-patent term from filing**

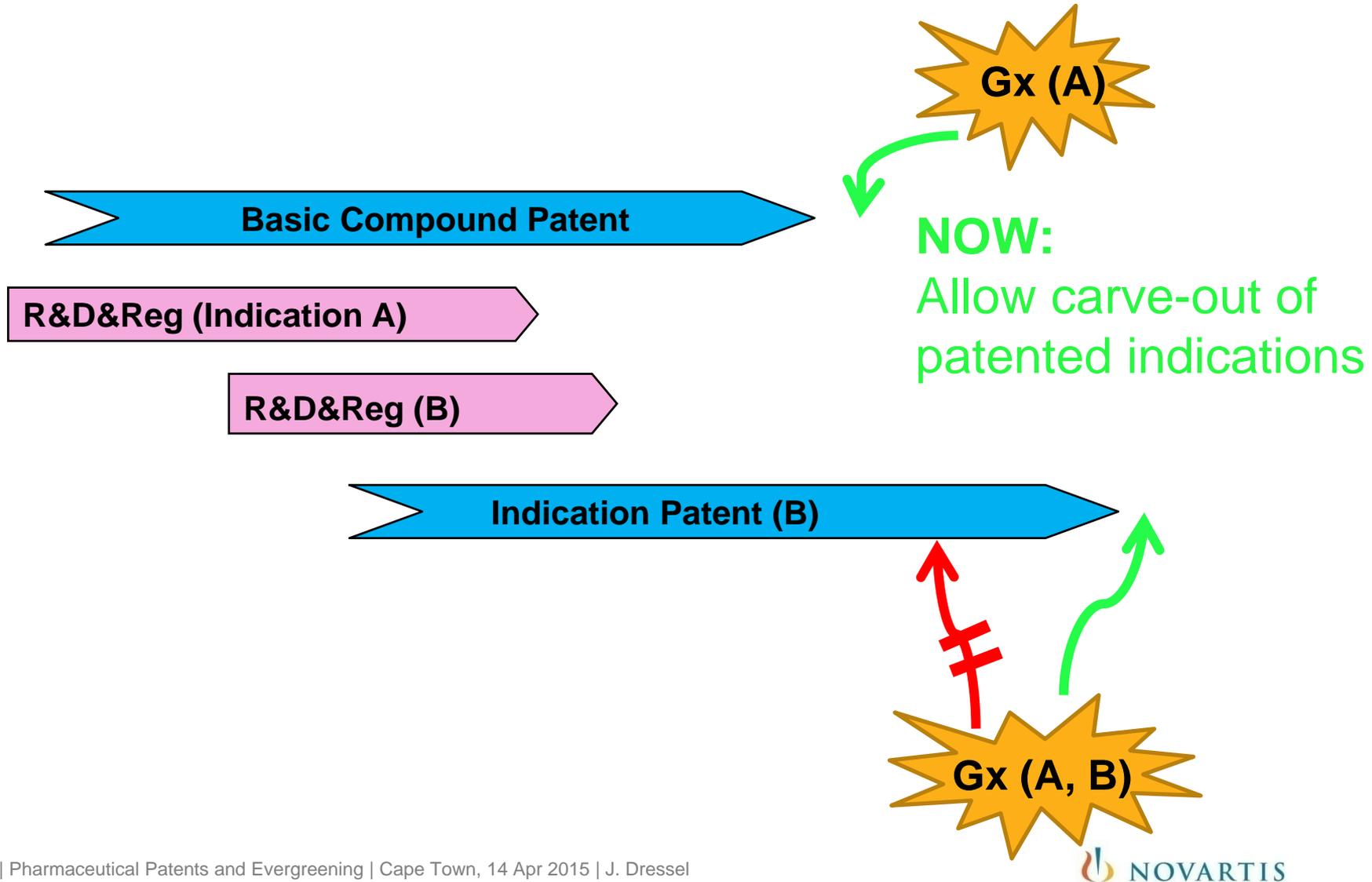
US: Multiple 30m-Stays – Evergreening?

- Hatch-Waxman patent linkage
 - Originator lists relevant patents (Orange Book)
 - Generic can refer to originator's approval after 4y
 - 30m-stay of generic approval to resolve dispute

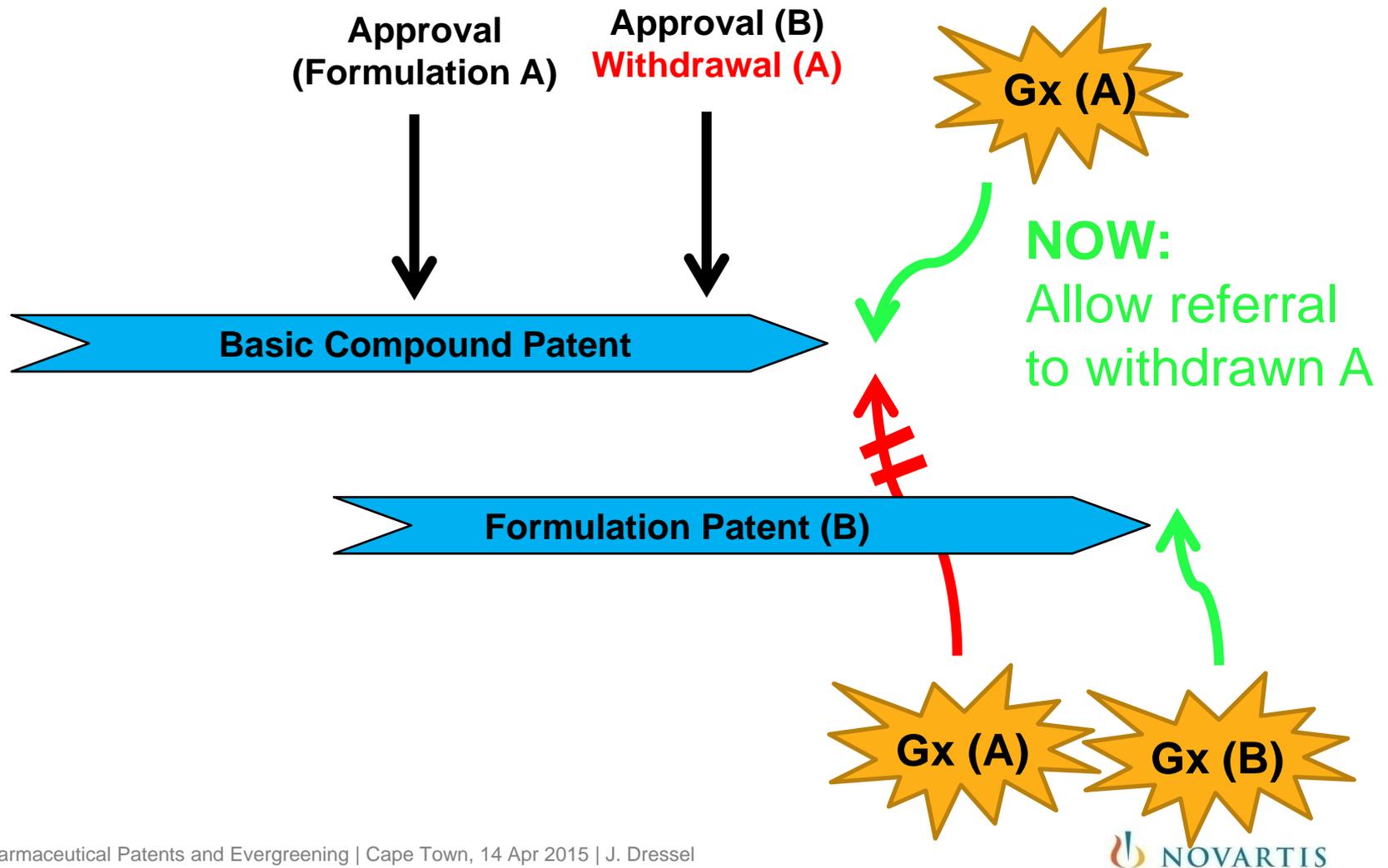
COMBINED WITH

- Grant of new patents (e.g. divisionals) – new 30m-stays
- **NOW: Single 30m-stay**

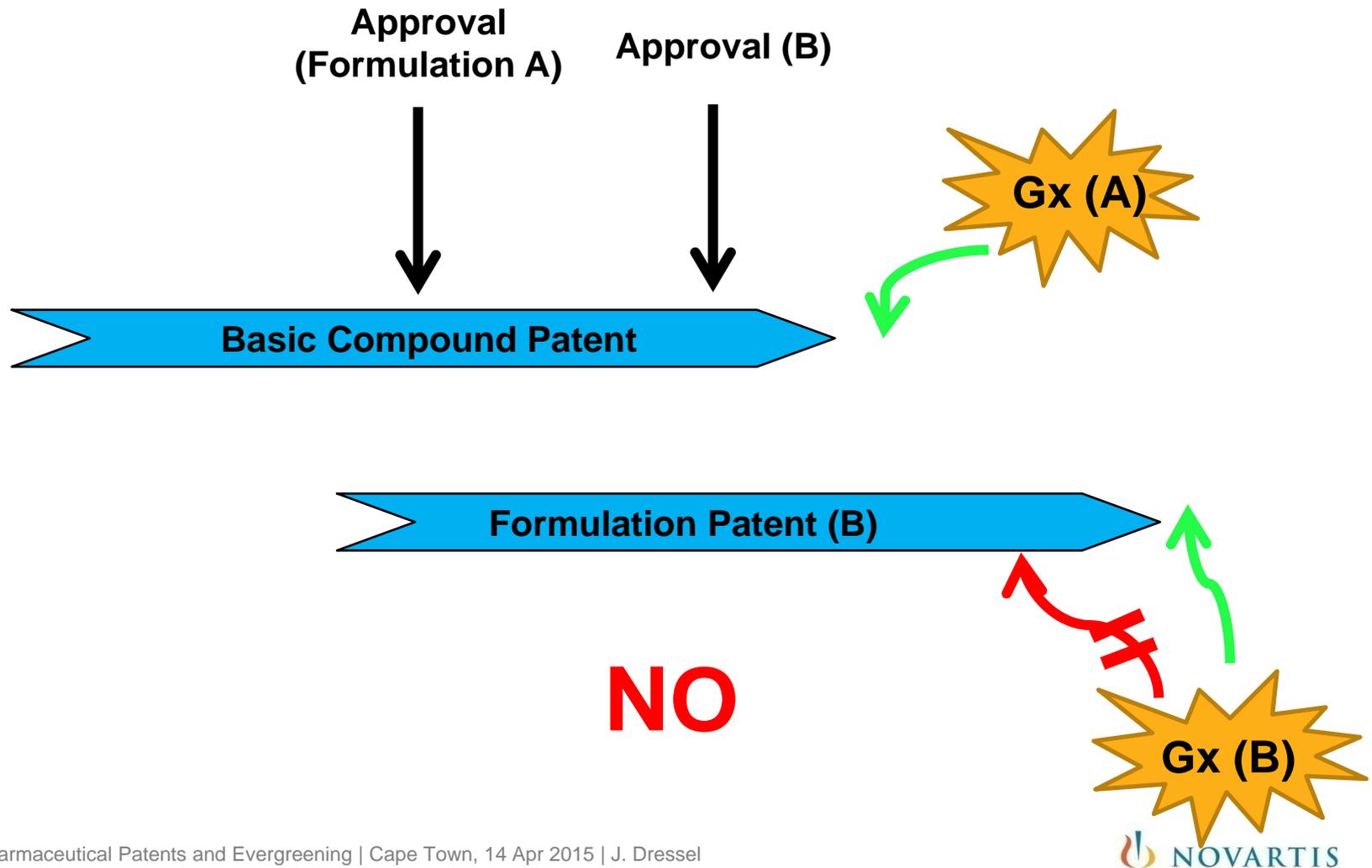
New Indications – Evergreening?



New Formulations – Evergreening?



Secondary Innovation – Evergreening?



Example Cyclosporin Formulations

- 1983 Sandimmune® (cyclosporin) launched – breakthrough in transplantation medicine
- Cyclosporin difficult to formulate (insoluble in water)
 - Sandimmune® oral emulsion preconcentrate
 - High *intra* and *inter* patient variability
 - Food effect

Technical Problem

Cyclosporin is Classified as a Critical Dose Drug

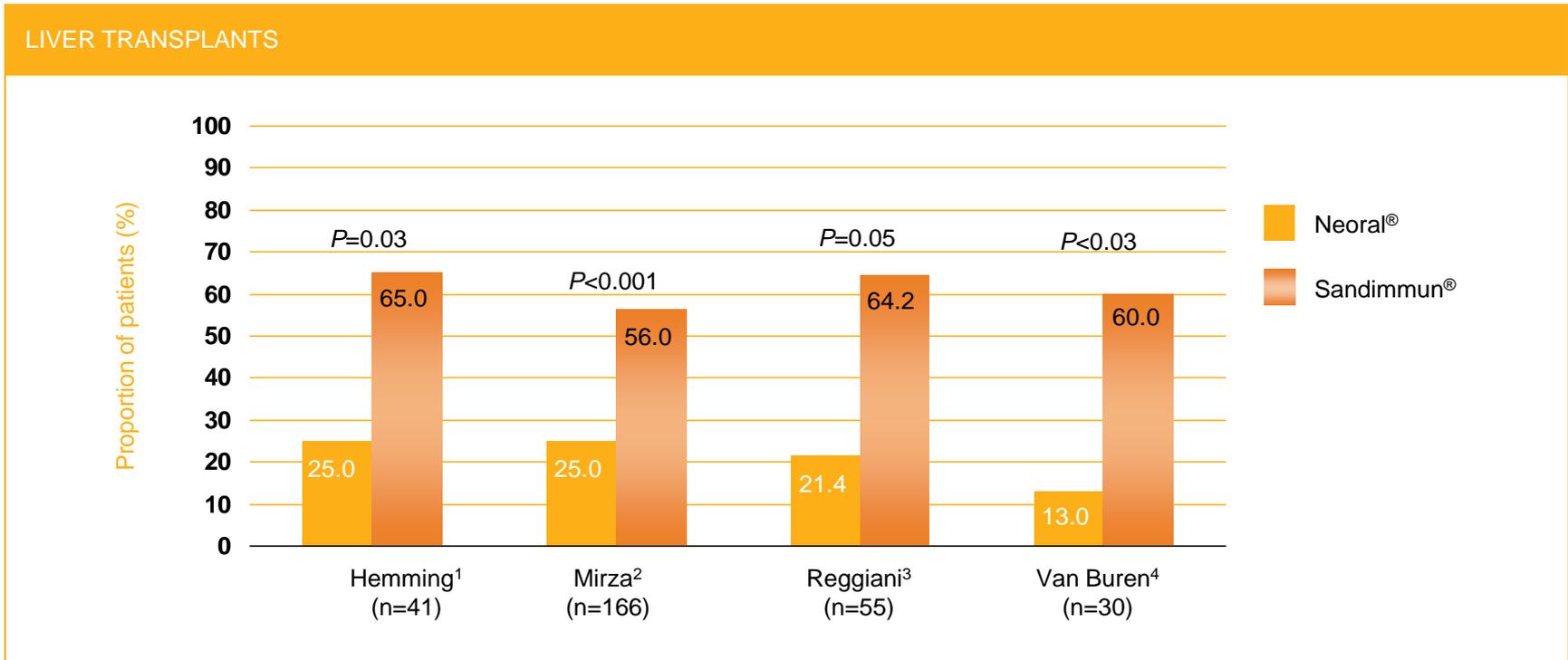


1. Vasquez EM et al. *Am J Health Syst Pharm* 1999; 56: 615-621

2. Bowers LD. *Clin Biochem* 1991; 24: 81-87

Solution – New Formulation

Acute Rejection: Neoral® versus Sandimmun®



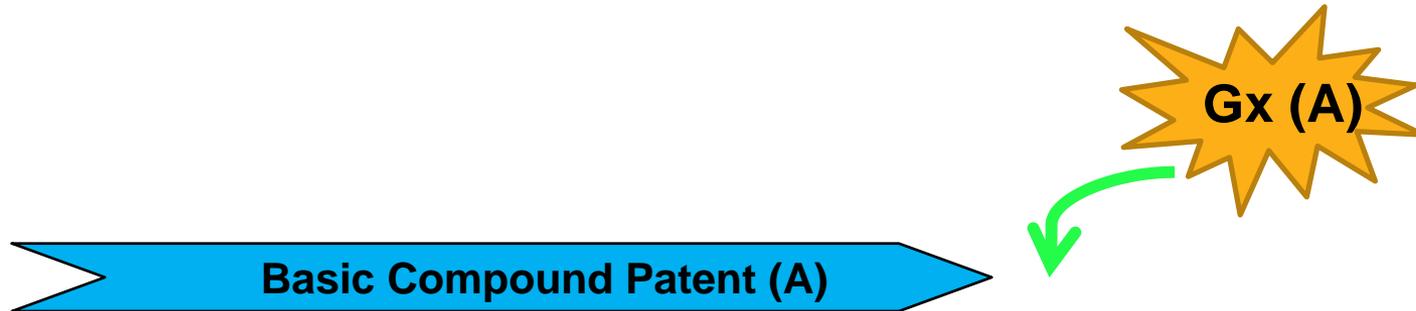
1. Hemming AW et al. *Transplantation* 1996; 62: 1798-1802

2. Mirza DF et al. *Lancet* 1997; 349: 701-702

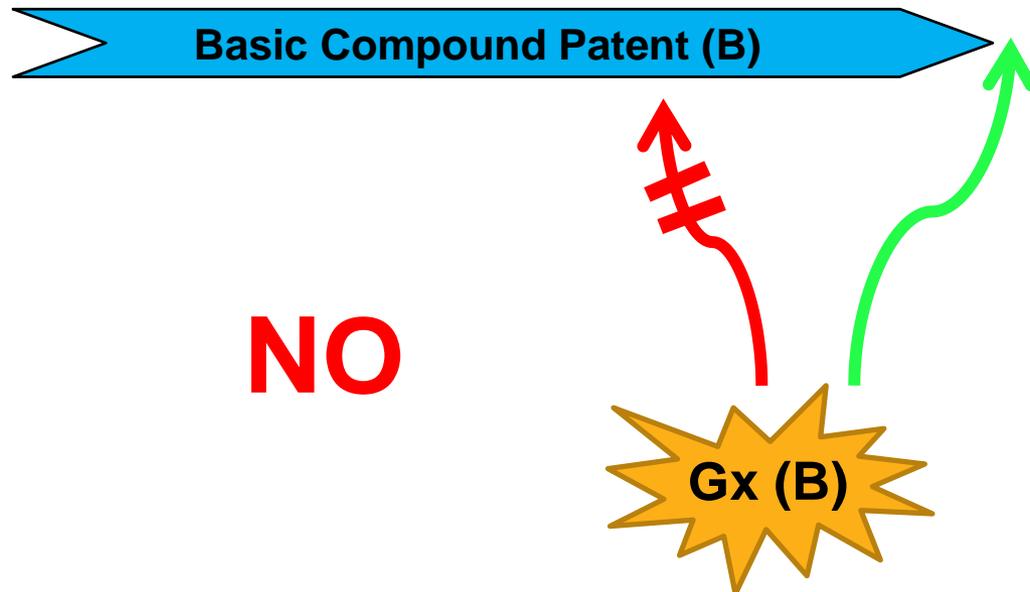
3. Reggiani P et al. *Transplant Proc* 1998; 30: 1855-1856

4. Van Buren D et al. *Transplant Proc* 1998; 30: 1830-1832

Me-toos, Follow-ups – Evergreening?

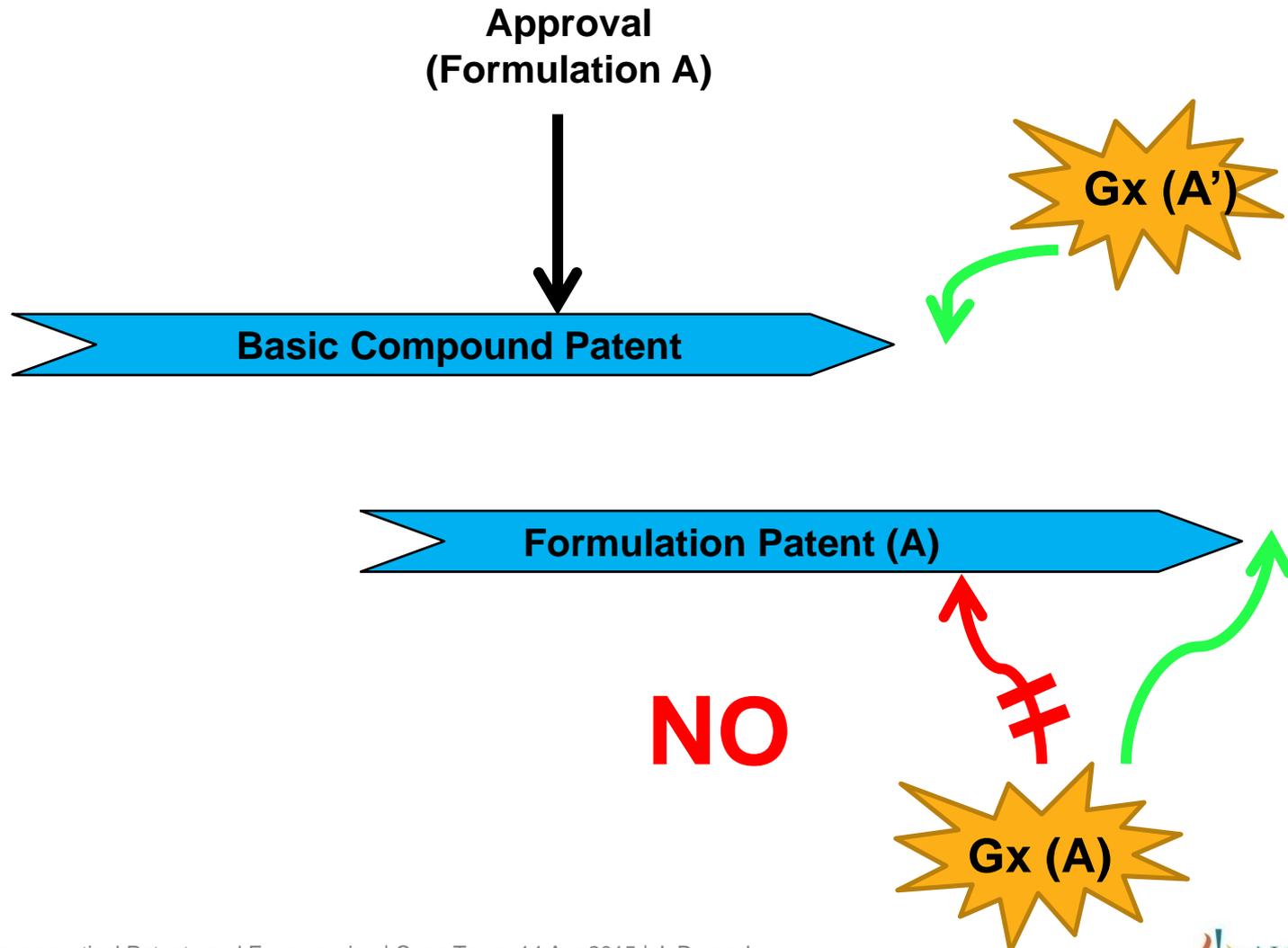


Me-too
Follow-up



NO

'More than one patent per drug' – Evergreening?



Proposed Definition of Evergreening

Evergreening

=

**squeeze between regulatory rule and patent leading to
unjustified or disproportionate prolongation of
exclusivity**

Avoid Evergreening ...

- By removing regulatory squeeze

NOT

- By changing patentability requirements

Search for Improved Therapies Worthwhile?

Basic Compound Patent

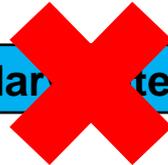
R&D&Reg (A)

? ? ?

R&D&Reg (B)



Secondary Patent (B)



Innovation beyond Active

	Generic	Generic Plus
■ Indications – new therapies		✓
■ Treatment regimes – higher efficacy, better compliance		✓
■ Formulations – higher efficacy, better compliance, cheaper	✓	✓
■ Manufacturing processes – cheaper or purer drugs, more environment-friendly production	✓	✓
■ Solid forms – higher stability, less side effects	✓	✓

Expenses for Healthcare – Example Germany

Most important cost blocks for statutory insurers, 2009:

- Hospitals: € 56 bio
- Treatments by doctors: € 31 bio
- Drugs: € 32 bio
- thereof patent-protected: € 7 bio
- ...

Total expenses: €171 bio

Avoid Evergreening ...

- **NOT** by
- Prohibiting secondary patents
 - Stifles further innovation esp. in developing pharmaceutical industries
- Additional patentability requirements like s.3(d)
 - ‘enhanced therapeutic efficacy’
 - Unrealistic assumption that closest prior art is a marketed drug
 - Artificial burden

I have a dream ...

- Globally harmonized patentability standards
- Strong and efficient patent examination
- Fair balance of technical contribution and exclusivity
- Strong patents
- Strong presumption of validity
- Fair, predictable and efficient enforcement
- Business certainty
- **Investment in risky and costly R&D – innovation helping patients**

The Economic Times, 10 Jan 2014

“Glenmark's anti-diabetes drugs shake up Indian anti-diabetes market

MUMBAI -- Mumbai-based Glenmark Pharmaceuticals has shaken up India's Rs 3,000-crore lucrative anti-diabetes **market dominated by multinationals** with its **new drugs**, Zitamed and Zita. The drugmaker, which is locked in a bitter patent infringement battle with US drug firm Merck Sharp and Dohme's (MSD) over these drugs, has managed to rake in Rs 16 crore in just eight months since it launched them.

[...] Glenmark has priced these drugs **30 per cent cheaper** than its competitors, [...]”

Business Standard, 10 Jan 2014

“Indian pharma's challenges

A shift to research and higher quality is overdue.

[...]

The longer-term solution is that the **more innovative and enterprising Indian companies make a successful foray into drug discovery. Firms that are able to market patented products earn high margins on them, which enables such companies to plough back more resources into research and development as well as come up with more useful discoveries.** The government can help in this. Strong public funding for joint research in therapeutic areas important for the Indian population can go a long way.”

Thank you for your attention