

THE R&D PROCESS

(AND THE CURRENT STATE
OF PLAY VIS A VIS NEW
VACCINES)

Forces impacting the pharmaceutical industry

- Increased visibility of global health issues
- Pressure from pharmaceutical parents company to meet financial targets
- Emerging competitors
- Changes in regulation
- Emergence of many combination products
- Increased range of new and complex technologies
- Bio tech “revolution”
 - More products
 - New technologies

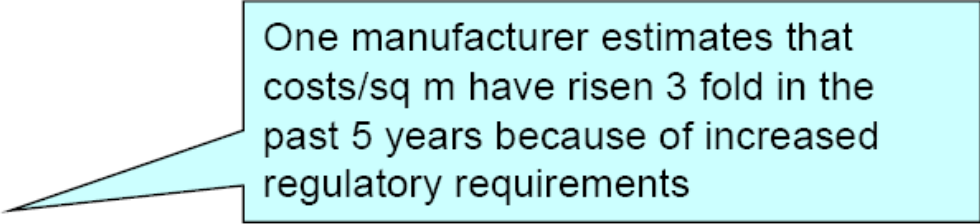
Emerging competitors

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- **India:** Serum Institute of India, Bharat Biotech
- **Indonesia:** Bio Farma
- **Cuba:** CIGB, and the Finlay Institute
- **Brazil:** Biomanguinhos
- **Others:** ?

Regulation (safety, biological, increasingly complex science)

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One manufacturer estimates that costs/sq m have risen 3 fold in the past 5 years because of increased regulatory requirements

Regulatory Issues

Regulatory requirements are increasing for all products:

One manufacturer estimates cost/sq m has risen 3 fold in past 5 years because of this

NRAs (National Regulatory Authorities) in developing countries have been weak historically:

NRAs in 32/51 producing countries are achieving required six regulatory functions

Only 73% of DTwP vaccine supply is of assured quality

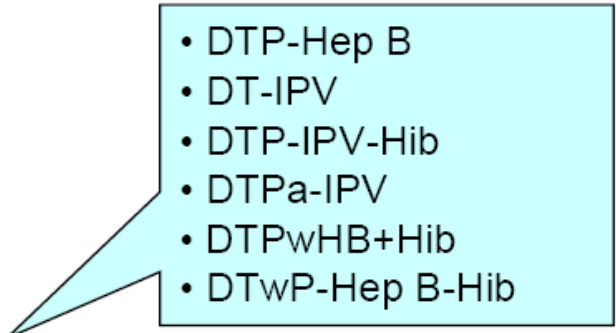
Regulation requirements in industrialized countries are changing:

EU only licensing products used within EU

(DTwP = DIPHTHERIA TOXOID, TETANUS TOXOID, and whole-cell PERTUSSIS VACCINE. The vaccine protects against diphtheria, tetanus, and whooping cough).

Combination products

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- 
- DTP-Hep B
 - DT-IPV
 - DTP-IPV-Hib
 - DTPa-IPV
 - DTPwHB+Hib
 - DTwP-Hep B-Hib

Costs of new products



- Clinical trials
- Factory production costs
- Licensing fees
- Production costs
- Quality Control

- All baseline costs
- Incremental opportunity costs/risk

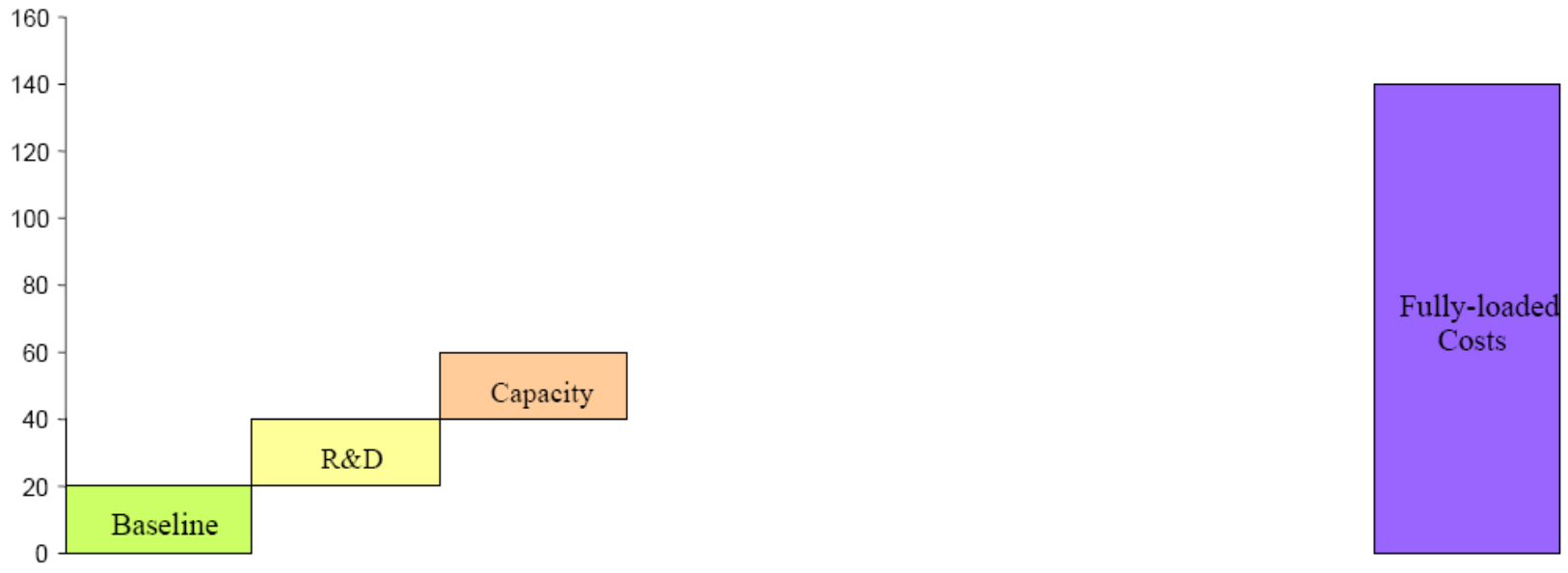
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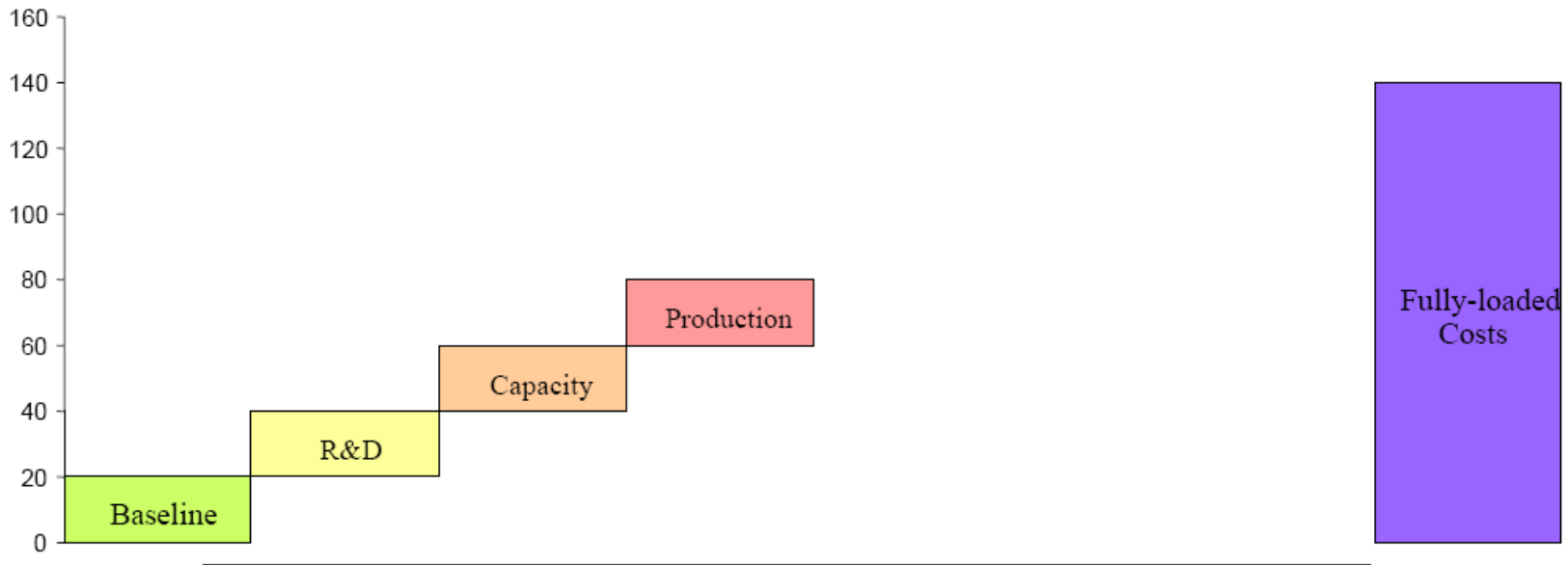
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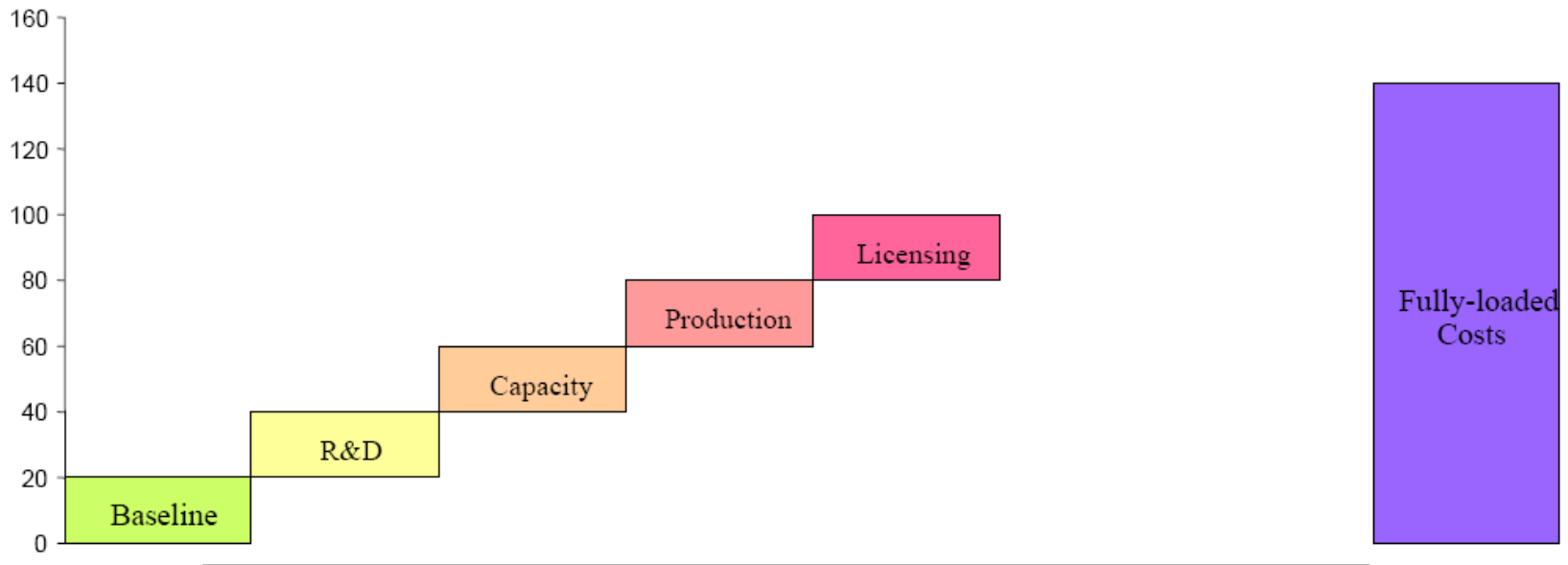
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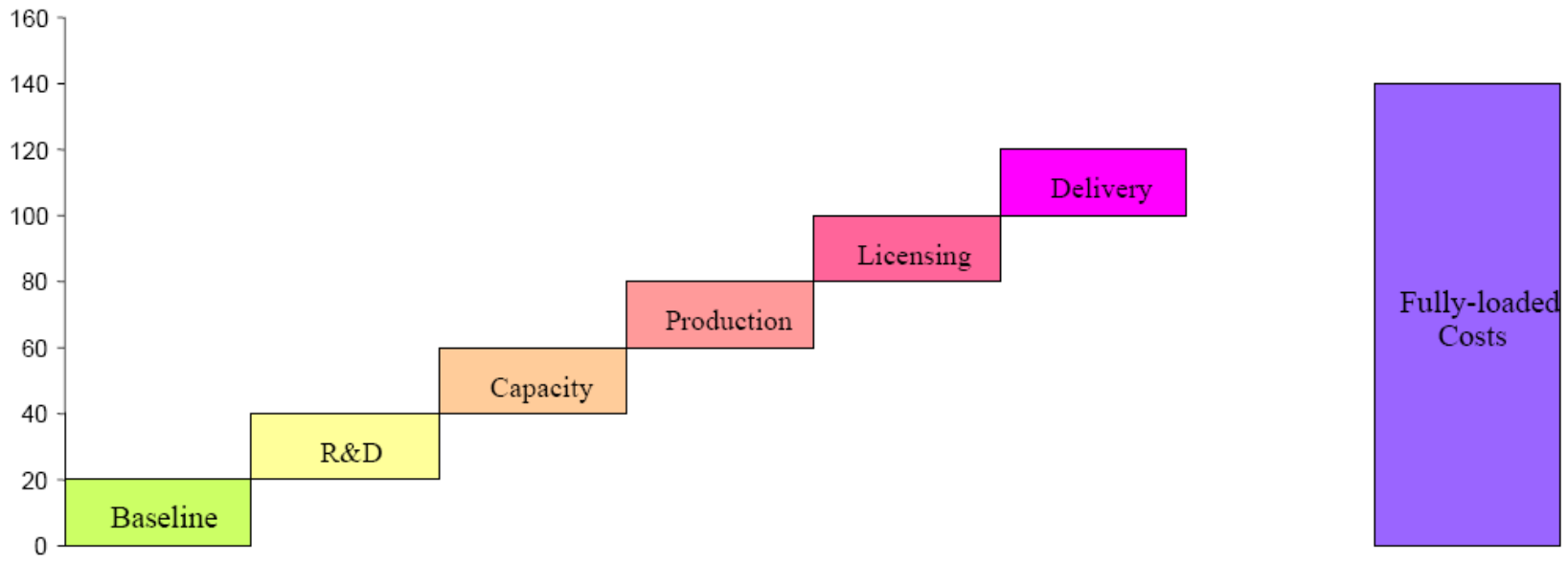
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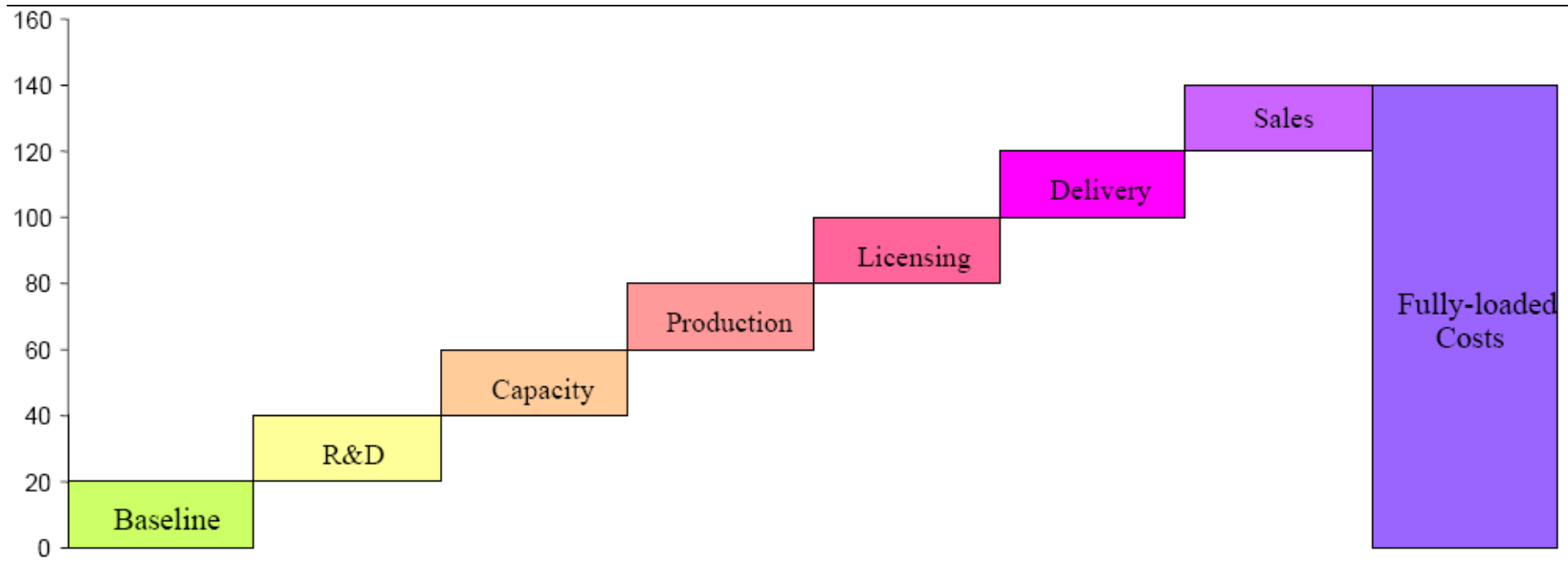
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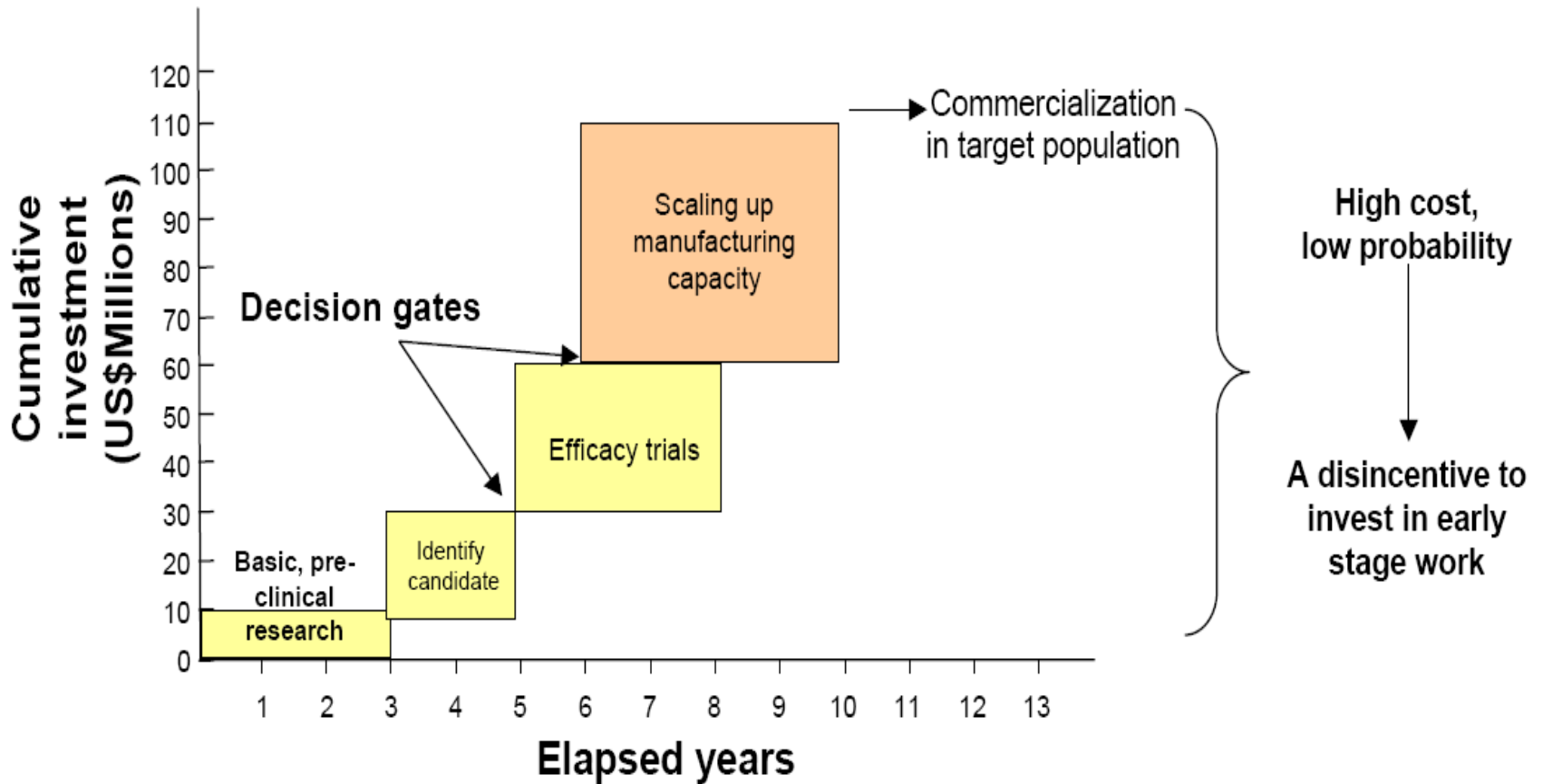
Risk shifts from public to private sector. How are the rewards shared?



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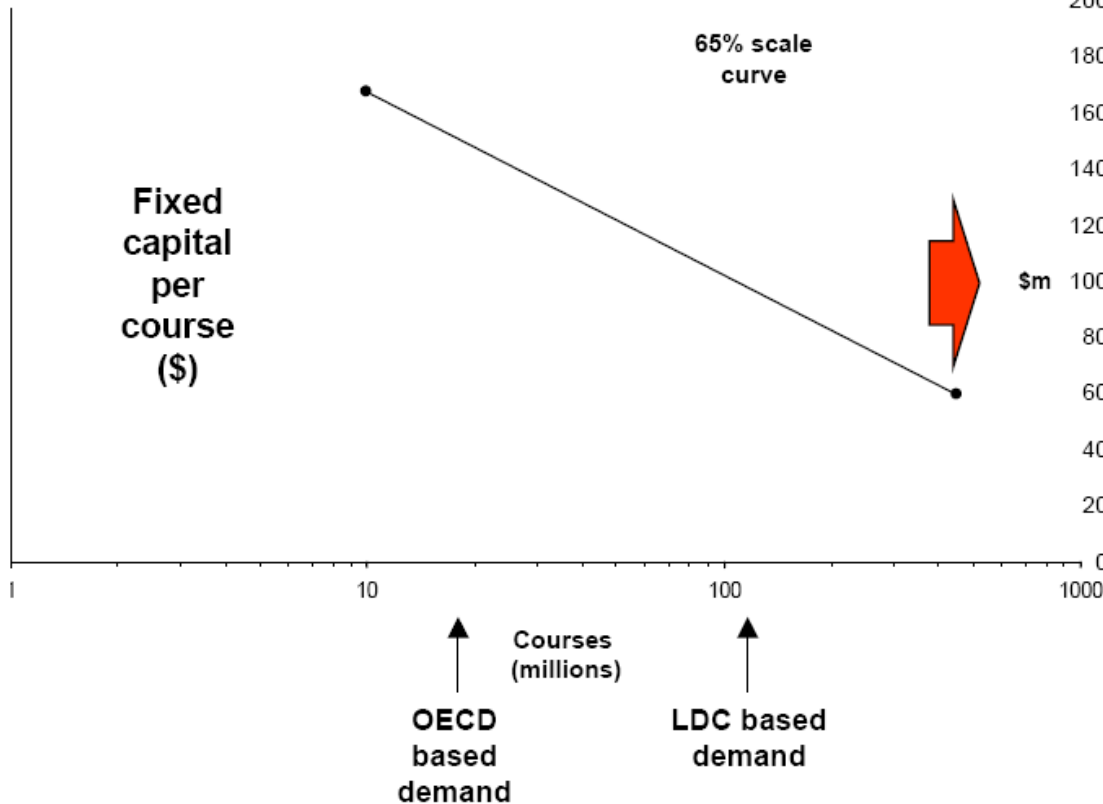
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Decision gates

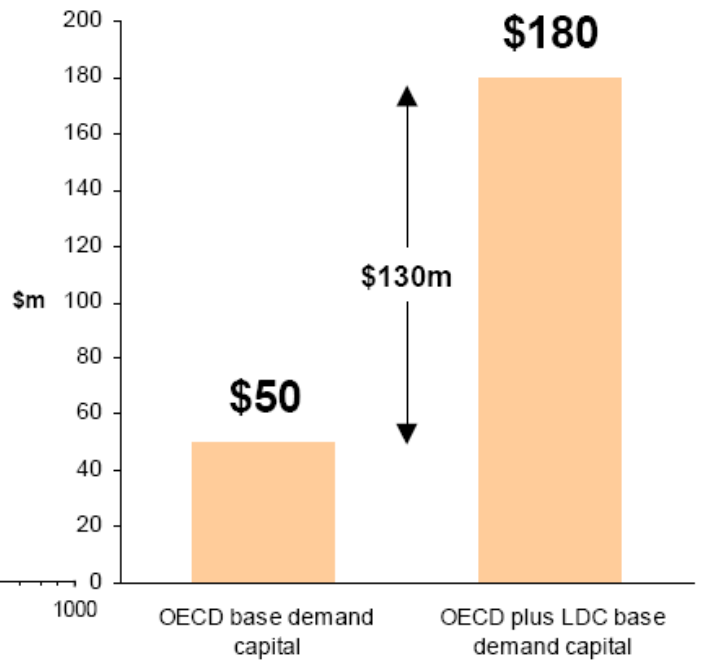


Large scale economies (illustrative)

Capital costs are highly scale sensitive

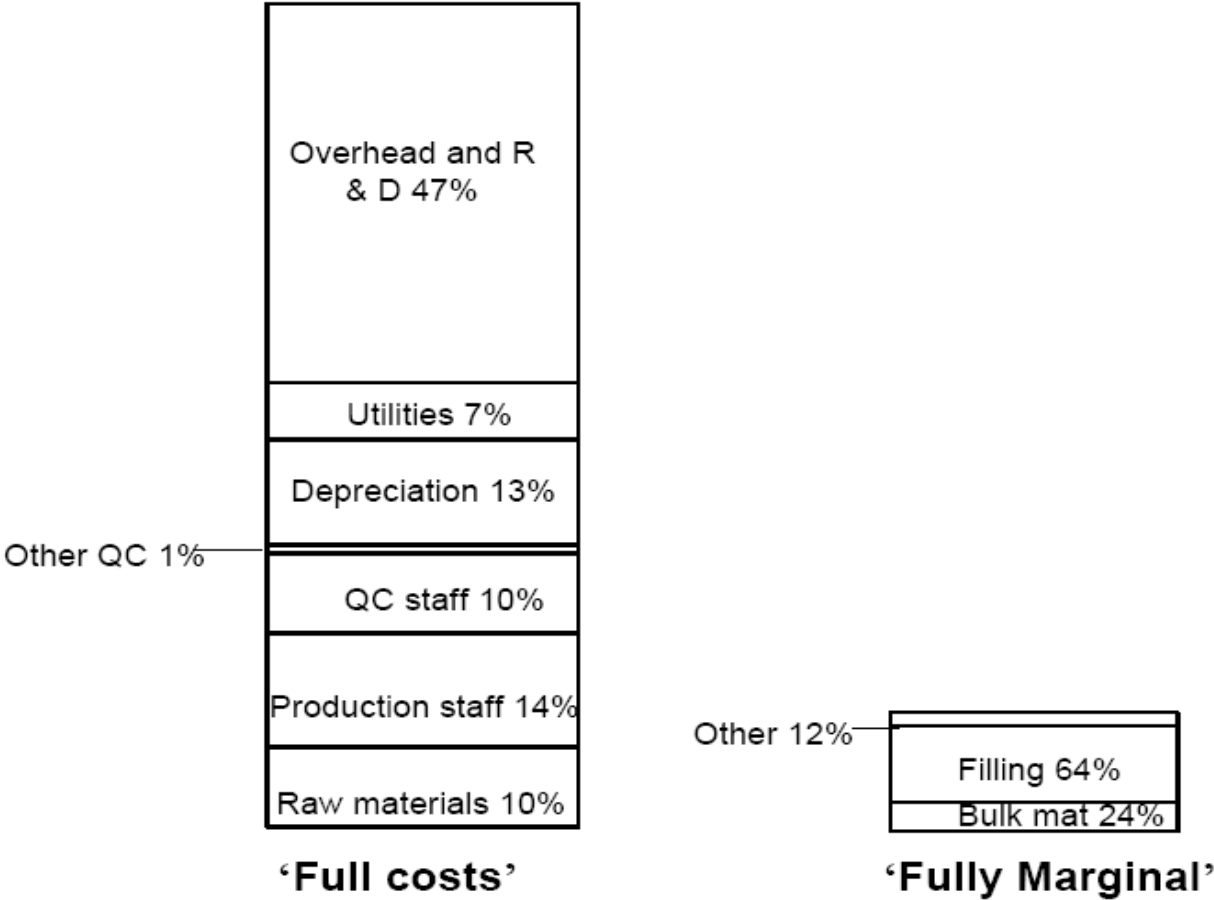


Incremental cost of global production capacity

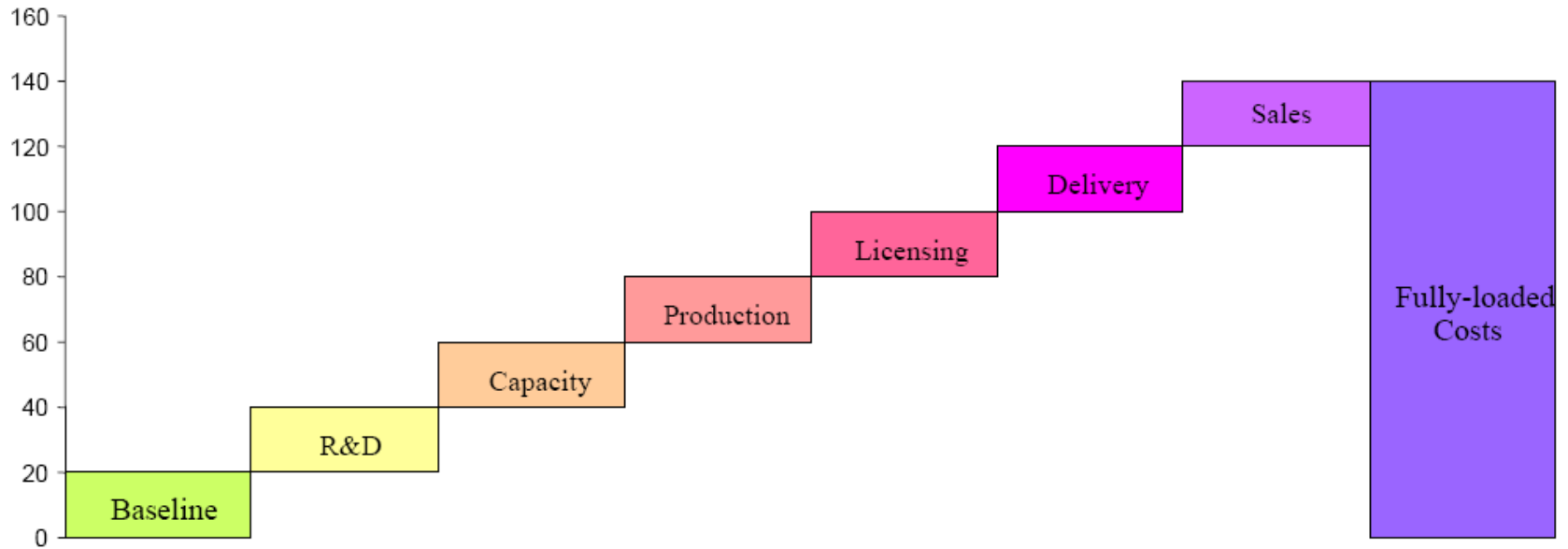


Marginal cost pricing for poorer markets

Average price



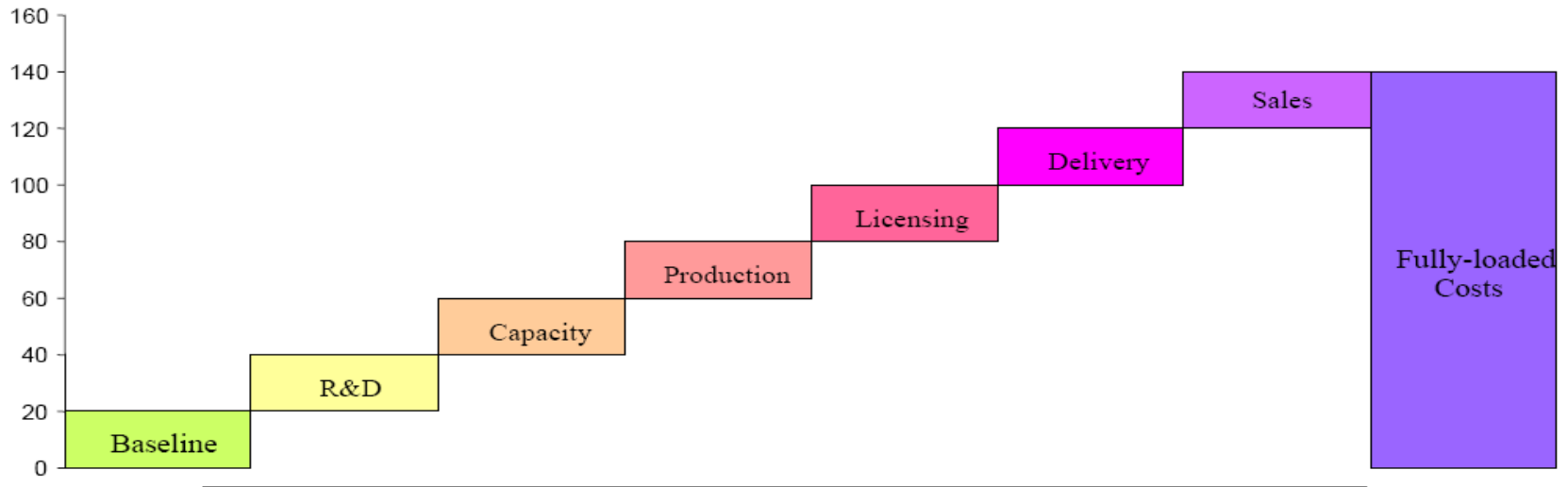
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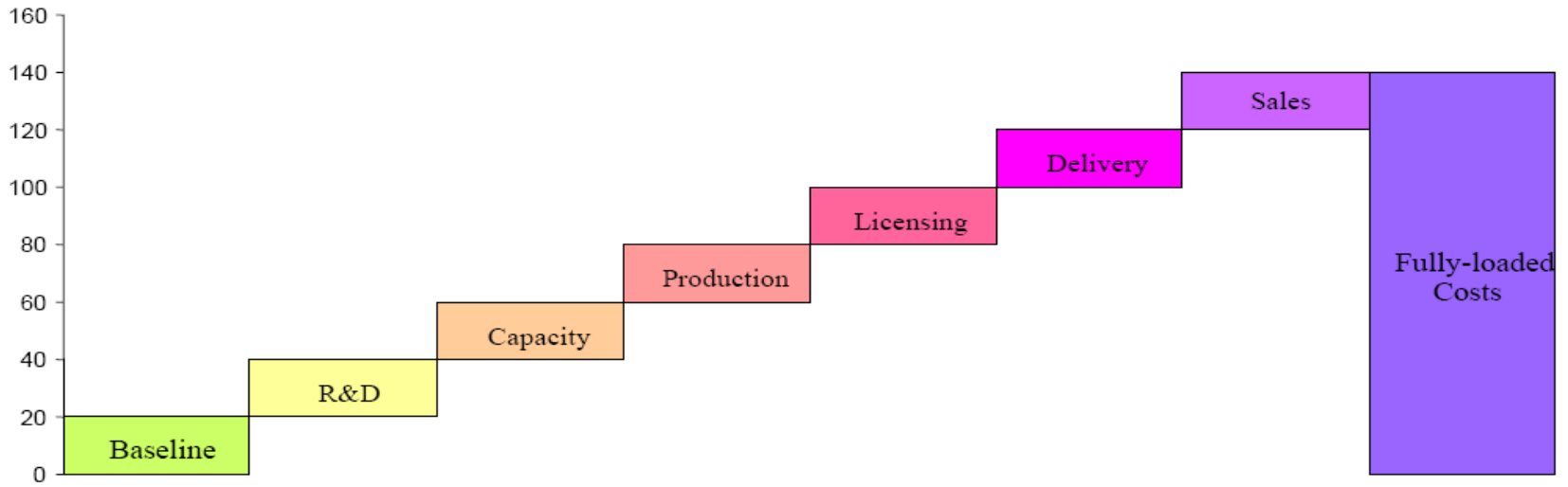


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- Failure
- Site problems
 - mgmt time
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- Promised product after trial over
- Parallel trials
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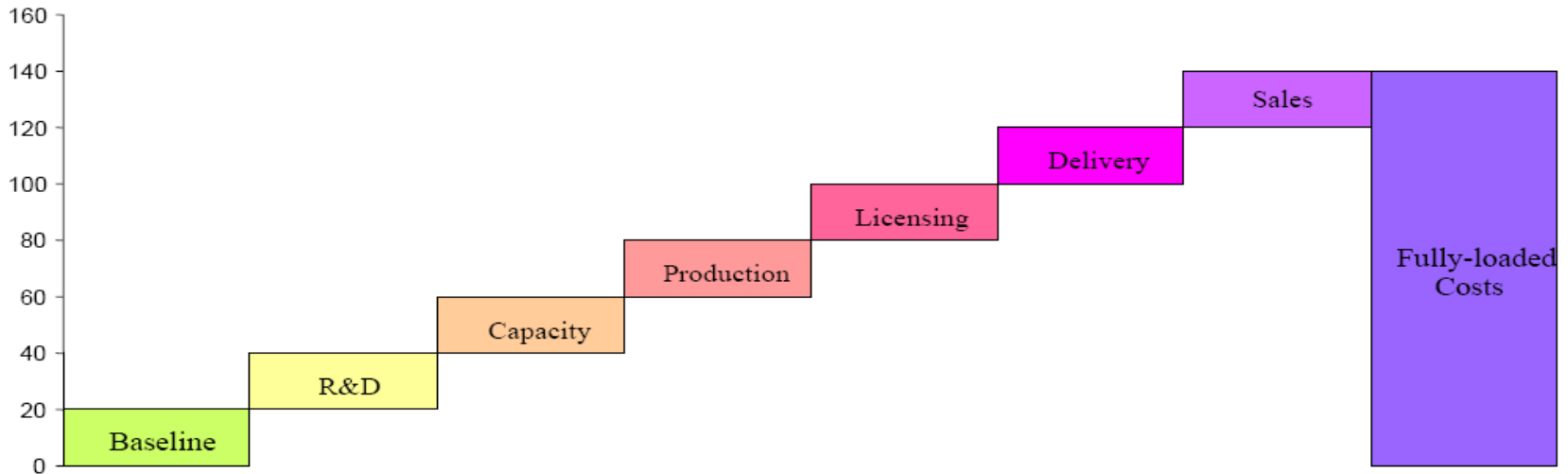


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- Degree of dedication
- Management over-runs

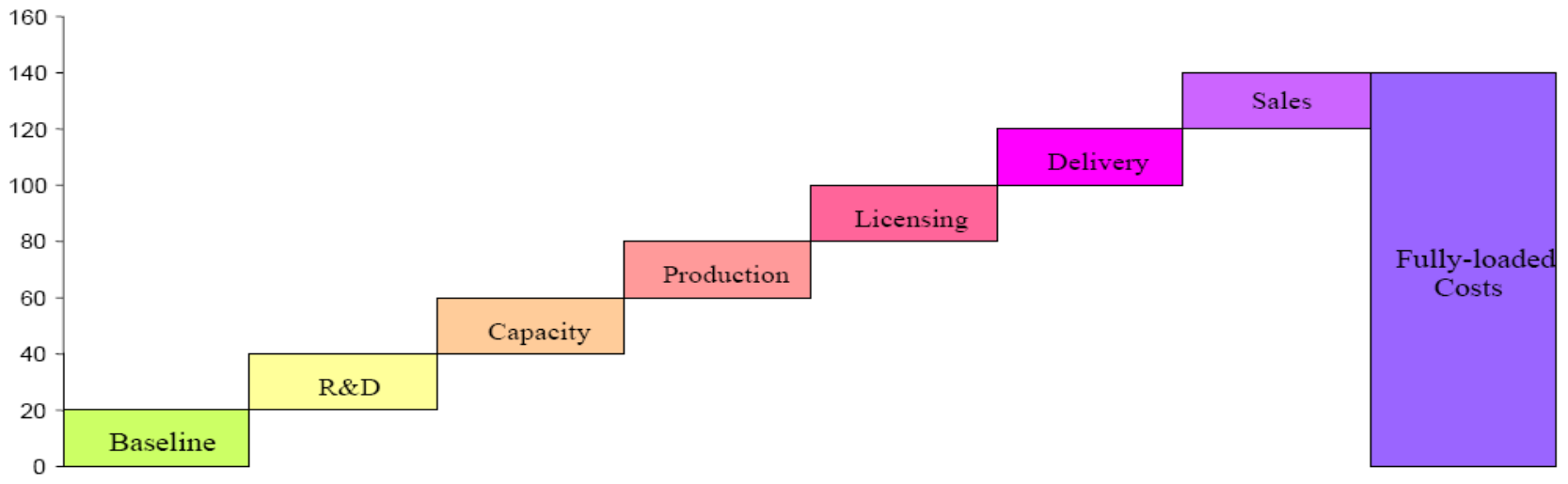
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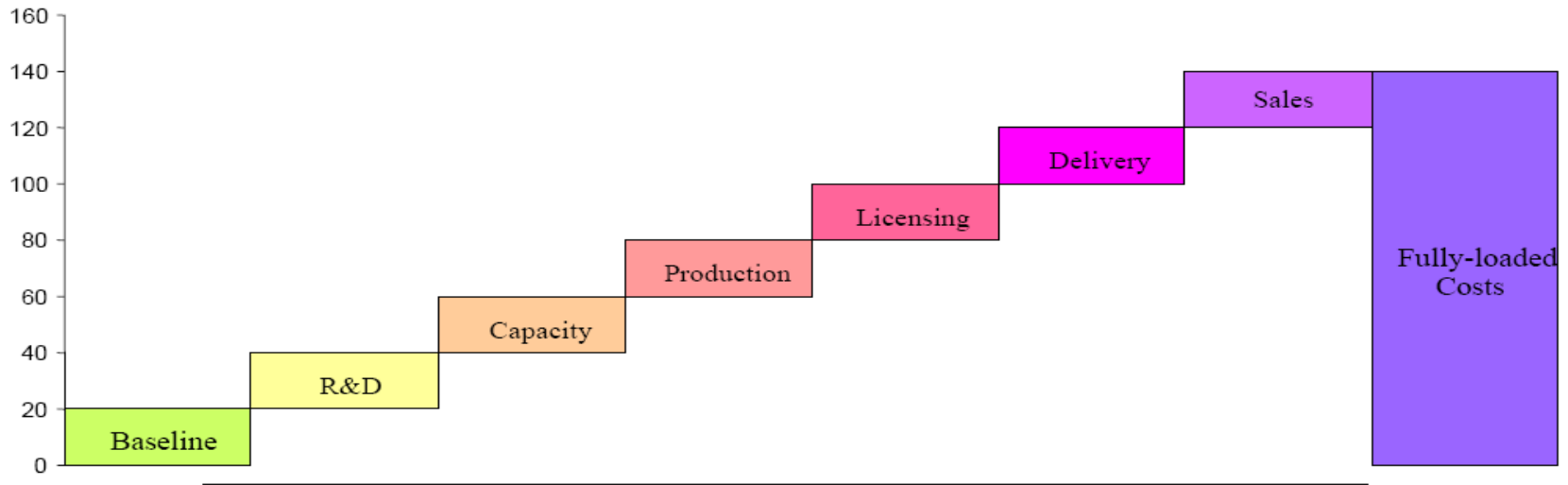
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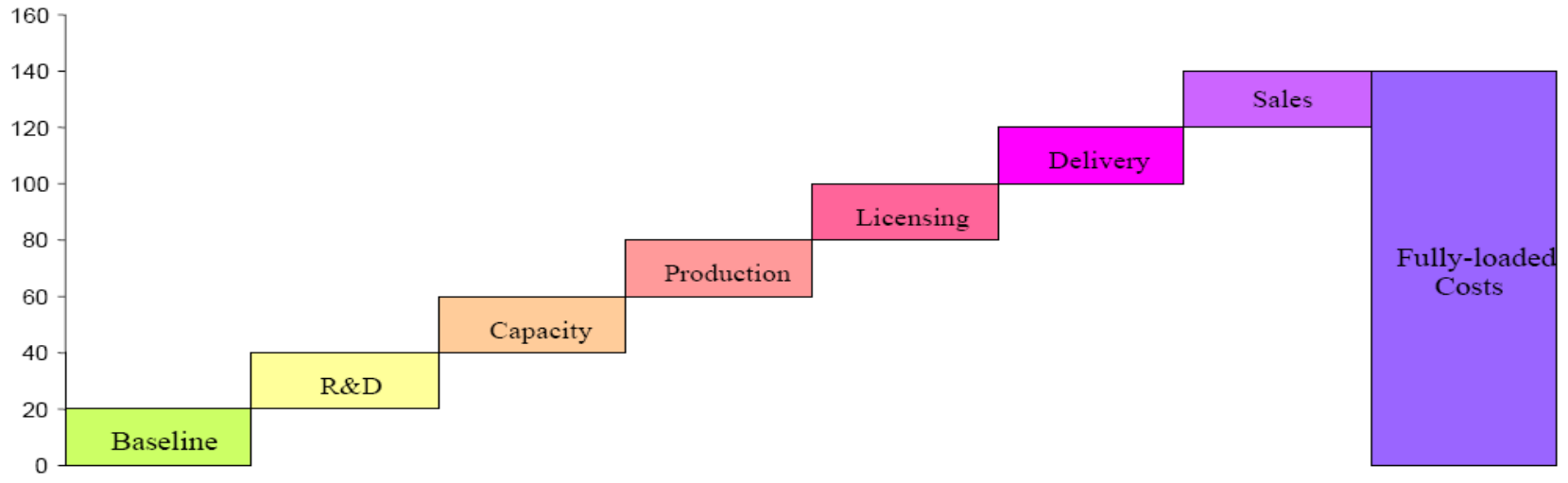
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- Absorbs management time
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- License denied
- Complaints/ adverse event
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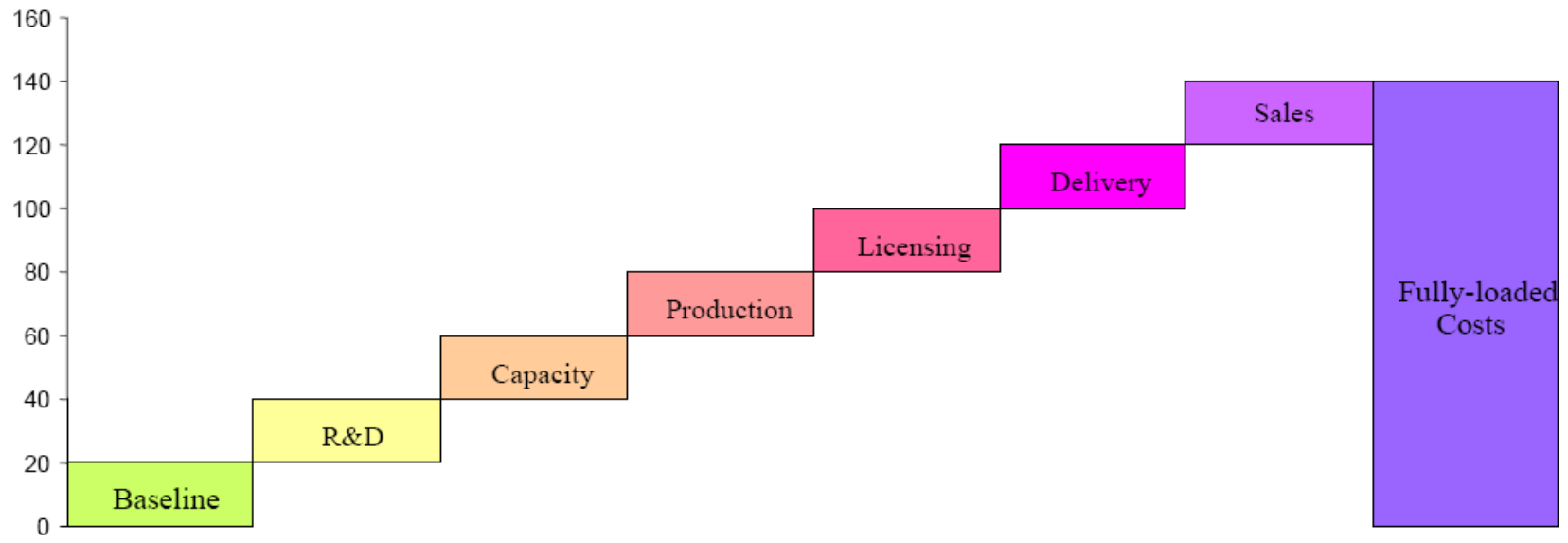
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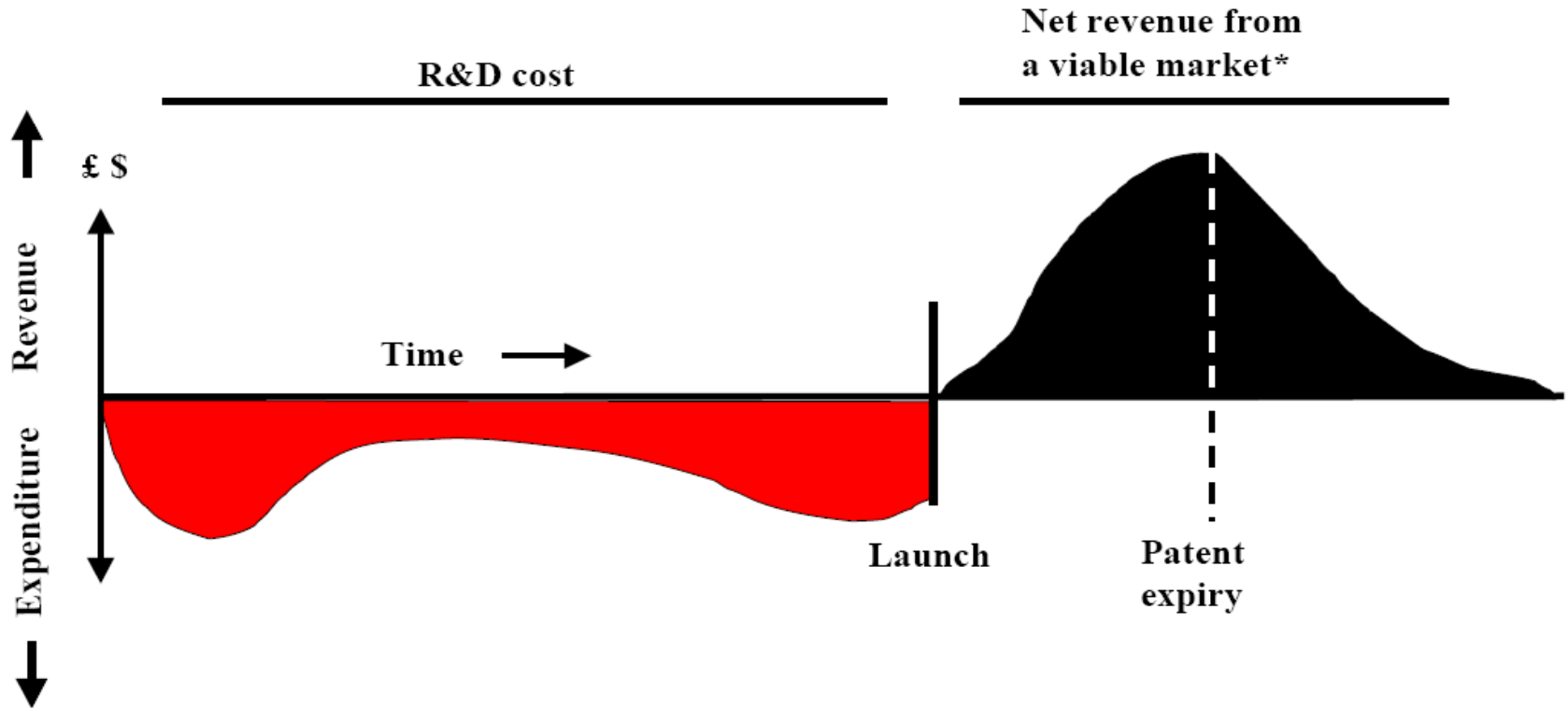
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- Unwillingness to pay
- Expected decline in price (due to public sector renegeing, etc.)
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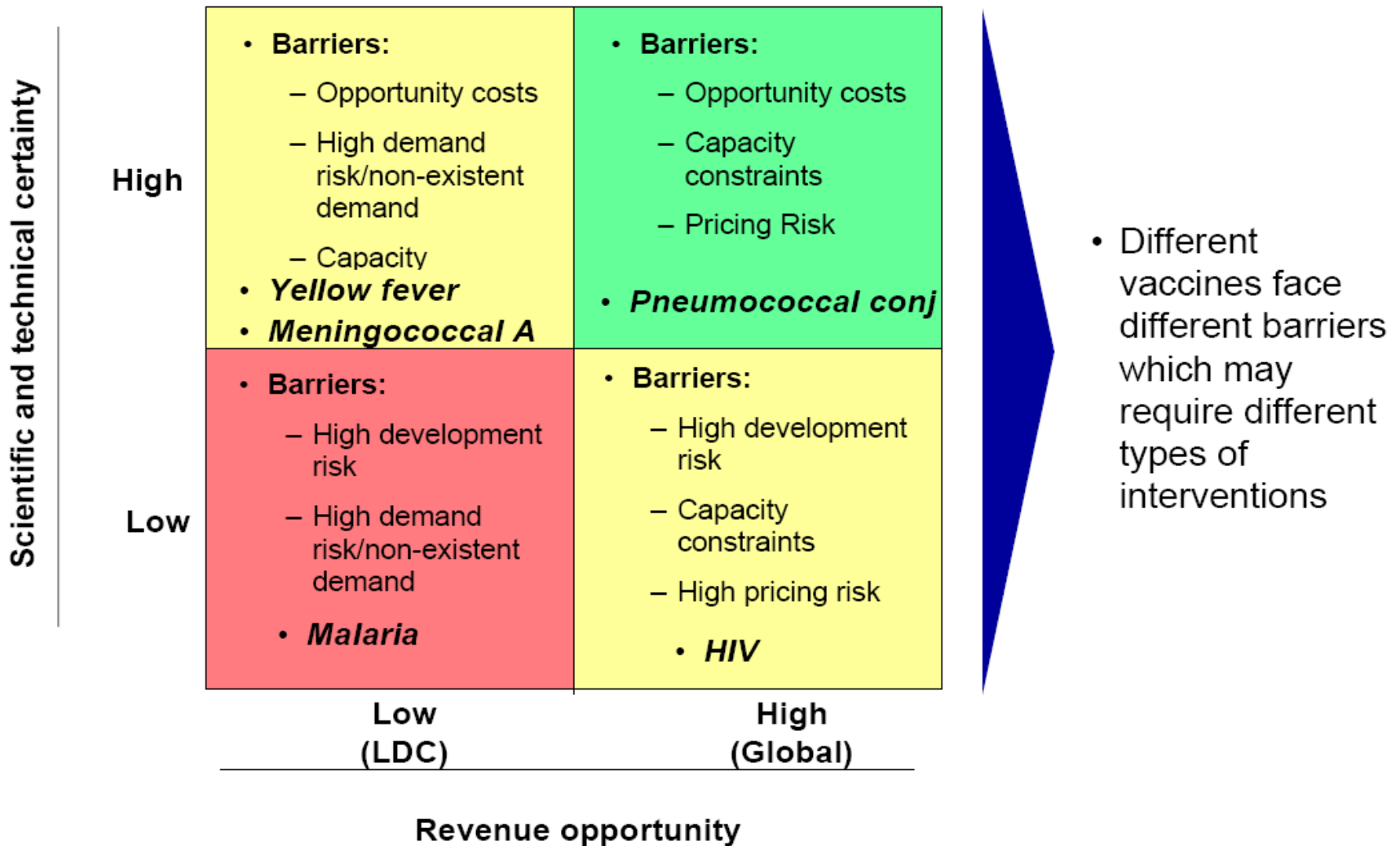
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Typical cash-flow for a product



*NB expenditure on clinical studies, manufacturing, marketing etc continues after launch but for simplicity has been netted out.

Science v Revenue



INCENTIVES?

A range of ‘push’ and ‘pull’

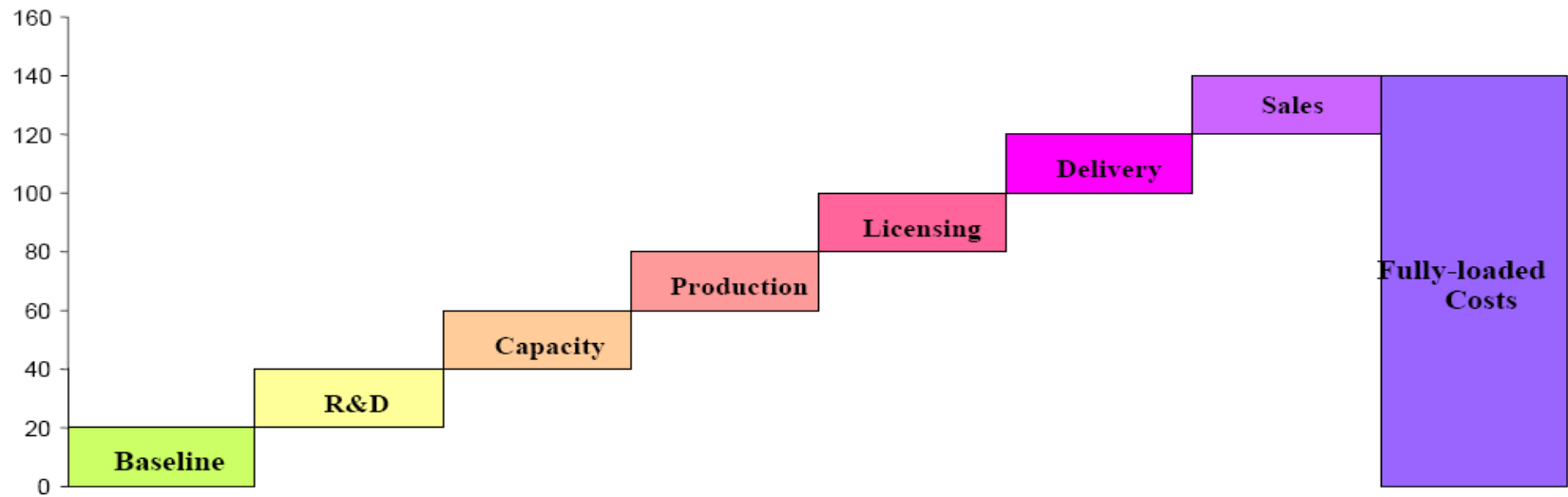
PUSH

- Direct investment in specific product trials
- Investment in trial infrastructure
- R&D tax credits
- Investment in production capacity
- Harmonize regulatory requirements

PULL

- Increasing the uptake of existing vaccines
- Strengthen/ensure delivery system
- Prizes and tournaments
- Tax credits on vaccine sales
- Tiered pricing to increase total revenues
- Transferable Patents
- Co-payments
- Market guarantees

Where to put 'push' and 'pull' ?





- Direct investment in clinical trials for specific products
- Strengthen trial infrastructure
- Tax credits for R&D
- Investment in capacity
- Improve forecasting
- Guarantee offtake
- Harmonize regulatory requirements
- Strengthen delivery systems
- Create demand earlier
- Assure today's market's
- Tax credits on sales
- Transferable patents
- Co-payments
- Guaranteed purchase fund

Investments needed

- Investment to ensure a delivery system capable of reaching infants and other target groups with priority vaccines
- Investment to rapidly develop priority vaccines targeting the diseases of the developing world
- Investment in production capacity to ensure the supply of global vaccines to the developing world
- Pricing which is affordable to the developing world
- Funding to purchase vaccines as soon as they are technically available

Conundrum

	<u>Current model</u>	<u>Required HIV vaccine model</u>
Introduction:	<ul style="list-style-type: none">• LDCs 10 years plus after OECD	<ul style="list-style-type: none">• At earliest scientific opportunity
Target population:	<ul style="list-style-type: none">• OECD	<ul style="list-style-type: none">• OECD + global
LDC-specific development spend:	<ul style="list-style-type: none">• Limited/zero	<ul style="list-style-type: none">• Significant spend probably necessary
LDC testing:	<ul style="list-style-type: none">• Limited/late	<ul style="list-style-type: none">• Significant/required early
Capacity availability:	<ul style="list-style-type: none">• Limited to OECD until maturity	<ul style="list-style-type: none">• Global early
		
	<p>Very low (marginal) prices available to LDCs only available at cost of delayed introduction</p>	<p>Prices or other incentives must justify full costs of accelerated LDC introduction</p>