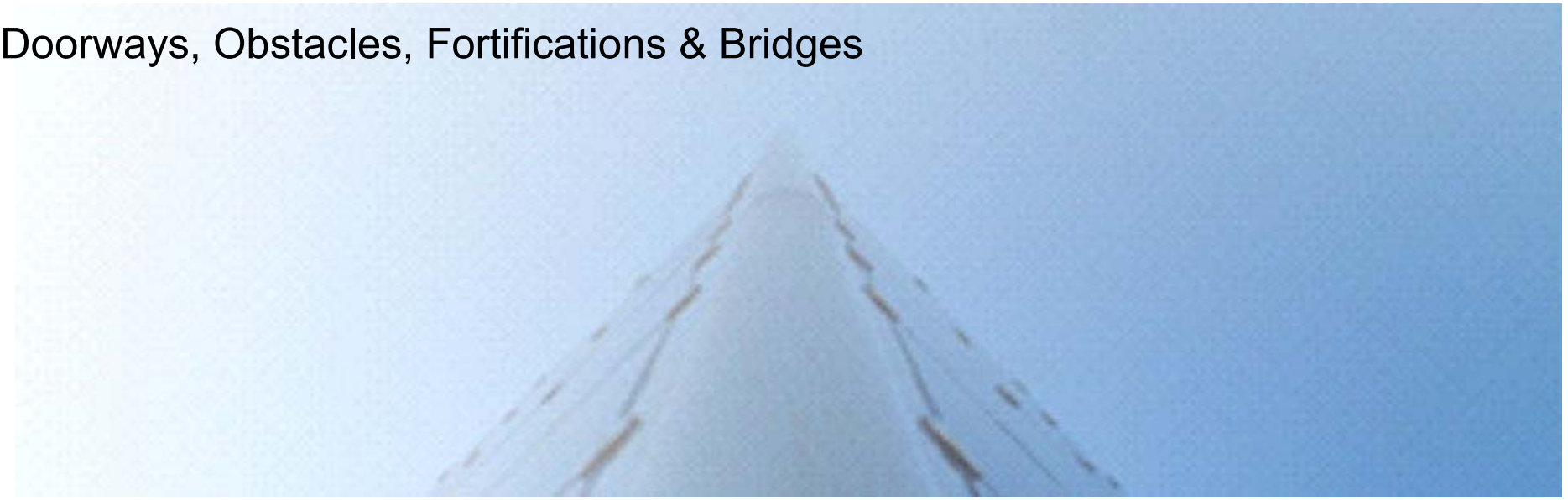
Research Patents in Biotech SMEs

Doorways, Obstacles, Fortifications & Bridges



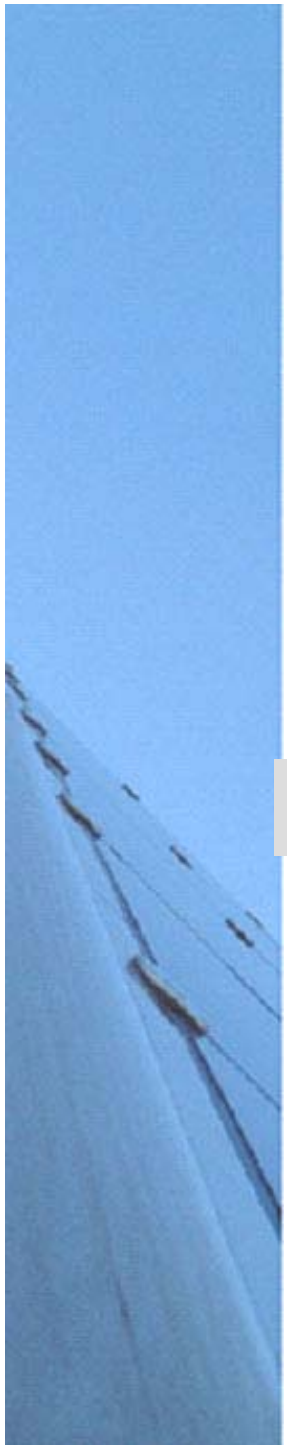
Neil Thomas PhD
Director of Intellectual Property, Genetrix Group, Madrid, Spain.

genetrix

Agenda

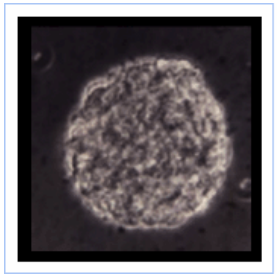
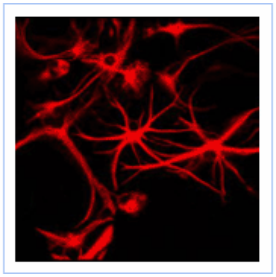
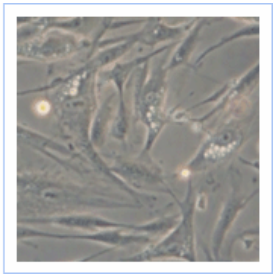
1. Introduction to Genetrix
   - Definition
   - History
   - The Group
   - IP at Genetrix
2. Research patents in Biotech SMEs: positive and negative effects
   - Doorways
   - Obstacles
   - Fortifications
   - Bridges
3. Alternative strategies, IP Resources for SMEs
4. Summary: Pros & Cons of Research Patents

enetrix

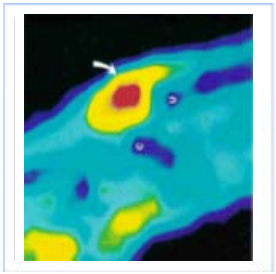
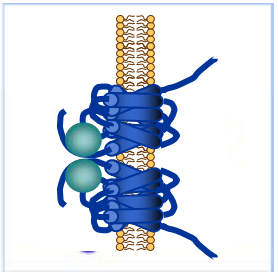


Introduction to Genetrix

Definition

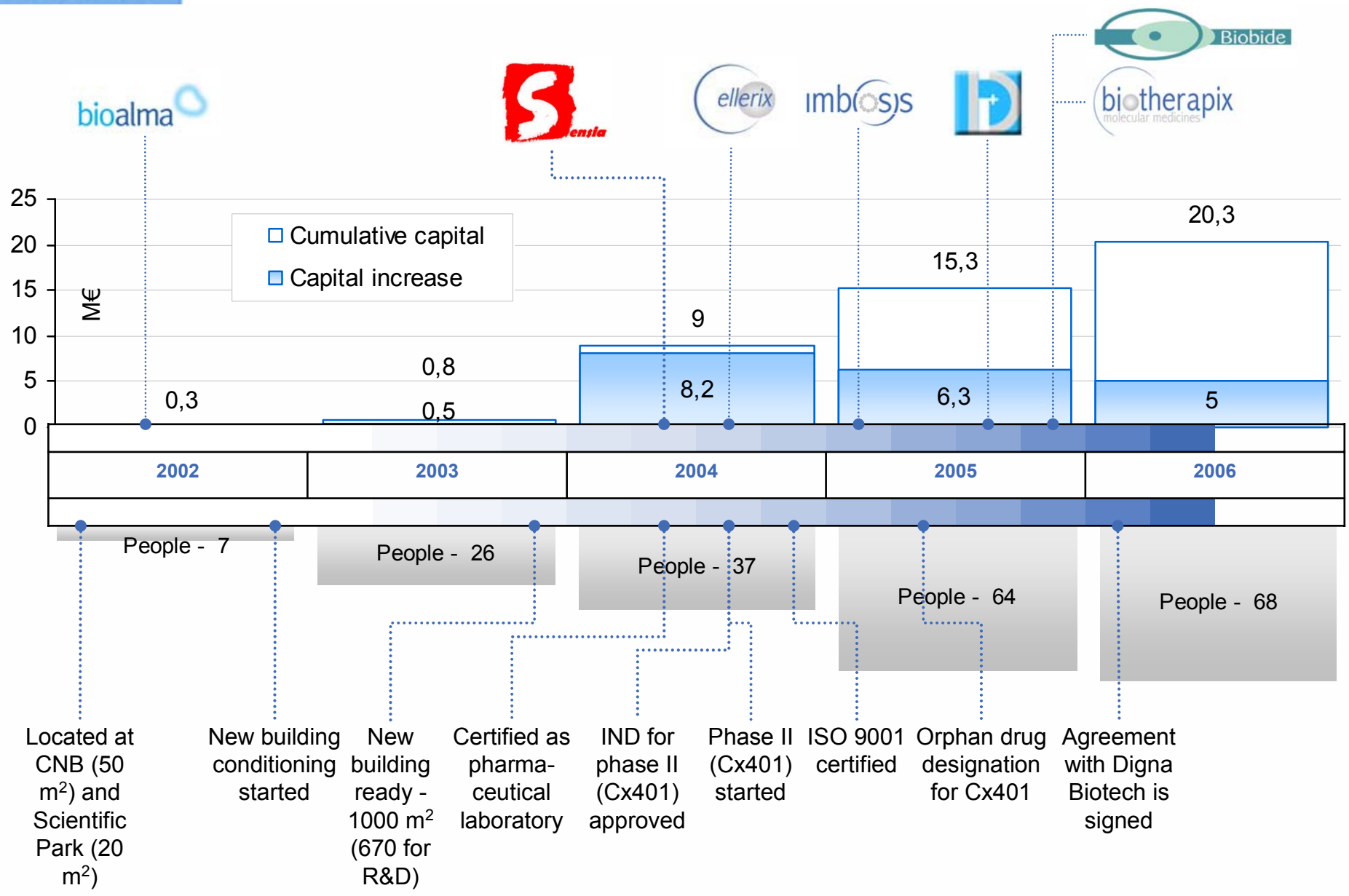




Genetrix is a group of biotechnology companies specialising in biomedicine and engaged in the promotion of leading biopharmaceutical business initiatives. Genetrix's main goal is the translation of basic and clinical research results into Medicine.

genetrix

History

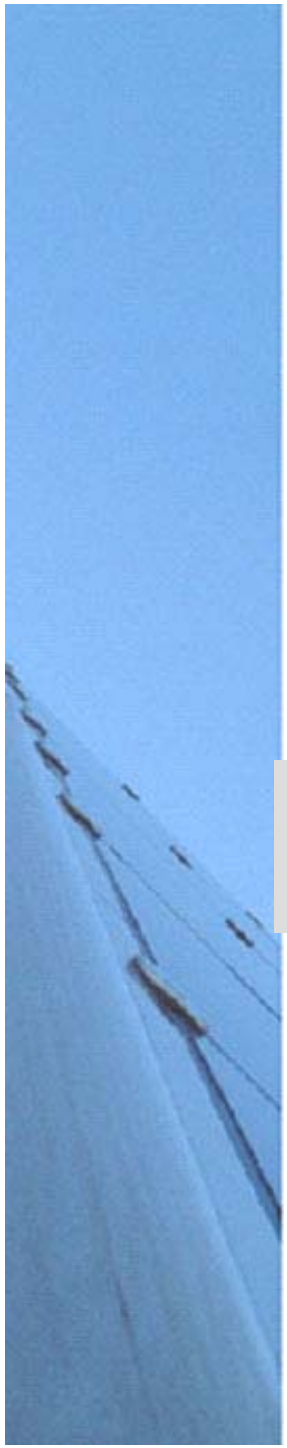

bioalma
Sentia
ellerix
imbiosis
Biobide
biotherapix
molecular medicines
25
20
15
10
5
0
M€
Cumulative capital
Capital increase
0,3
0,8
0,5
9
8,2
15,3
6,3
20,3
5
2002
2003
2004
2005
2006
People - 7
People - 26
People - 37
People - 64
People - 68
Located at CNB (50 m2) and Scientific Park (20 m2)
New building conditioning started
New building ready - 1000 m2 (670 for R&D)
Certified as pharma-ceutical laboratory
IND for phase II (Cx401) approved
Phase II (Cx401) started
ISO 9001 certified
Orphan drug designation for Cx401
Agreement with Digna Biotech is signed

IP at Genetrix

- Genetrix collaborates in the creation of a knowledge-based society, attracting and developing IP to promote wealth and social benefits.
- Genetrix's objective is the generation of mid-term economic and financial wealth to its shareholders, through the promotion of new companies in the Life Sciences sector.

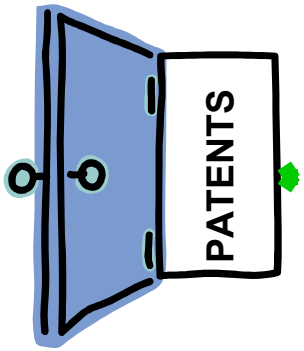
Spin-out company

- Genetrix has its basis on IP and aims to develop and exploit this IP commercially.
- The start-up of its activity was dependant on licensing or technology assignments.
- Genetrix's value is connected to its long-term growth potential, which is derived from knowledge, IP and management.



Research patents in Biotech SMEs: positive and negative effects

Doorways
to New Areas of Research



An available information resource

free, by subscription, outsourcing

May generate new research topics

or even kill existing projects

Exposes research aims of others

define the State of the Art

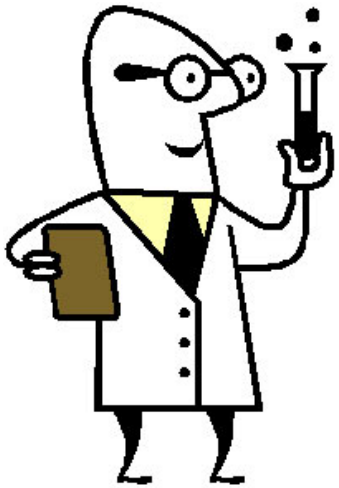
competitor monitoring

define unclaimed territory

enetrix

Doorways
to New Areas of Research

A reliable information resource?



Patents are published

but at 18 months

earlier inventor publications?

Sufficiency, Enablement, Written Description

must disclose claimed invention in repeatable way

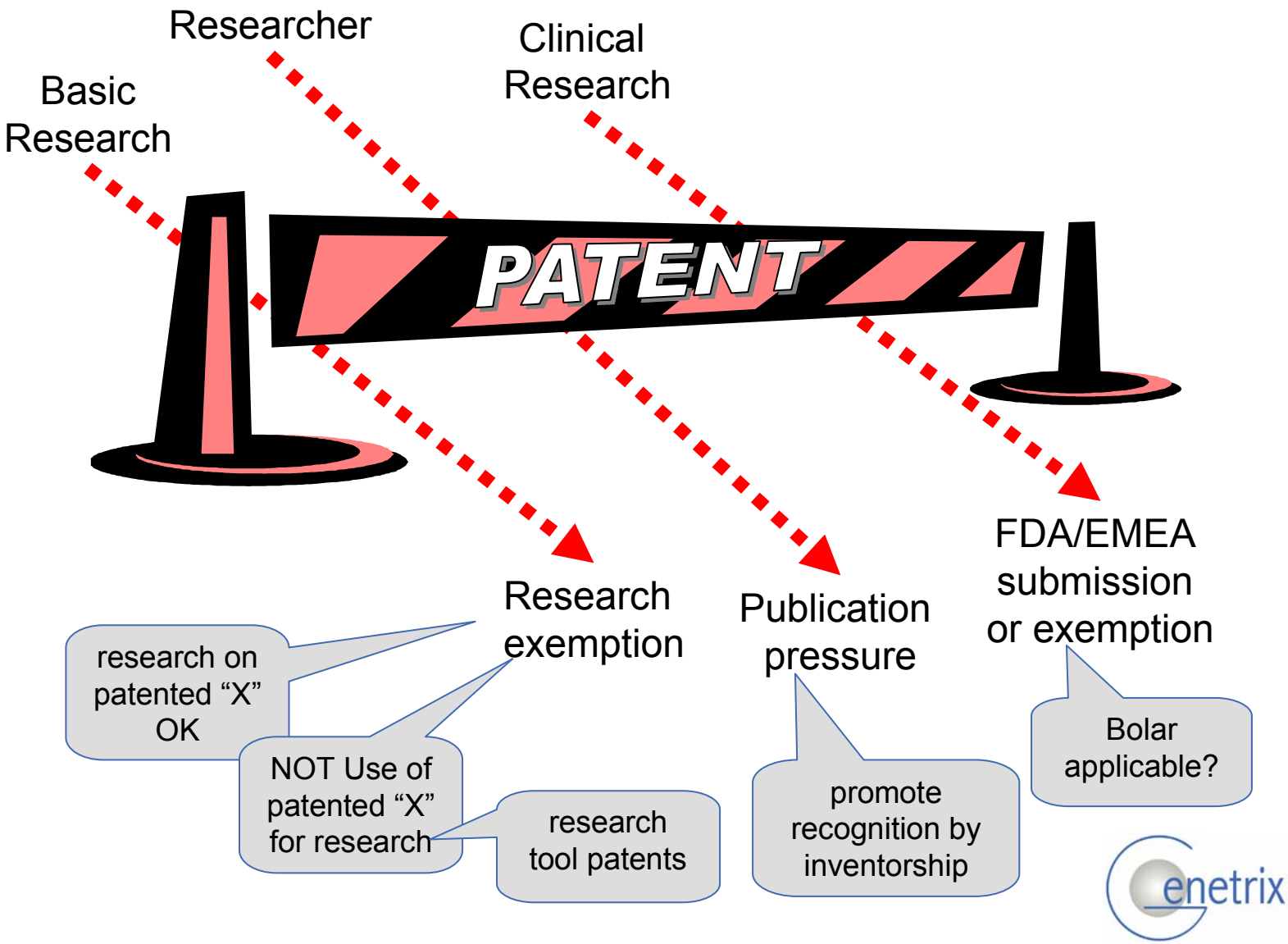
“Best Mode” (US)

“best way” known to inventor at time of filing

poor or inadequate disclosure = concealment = patent lost

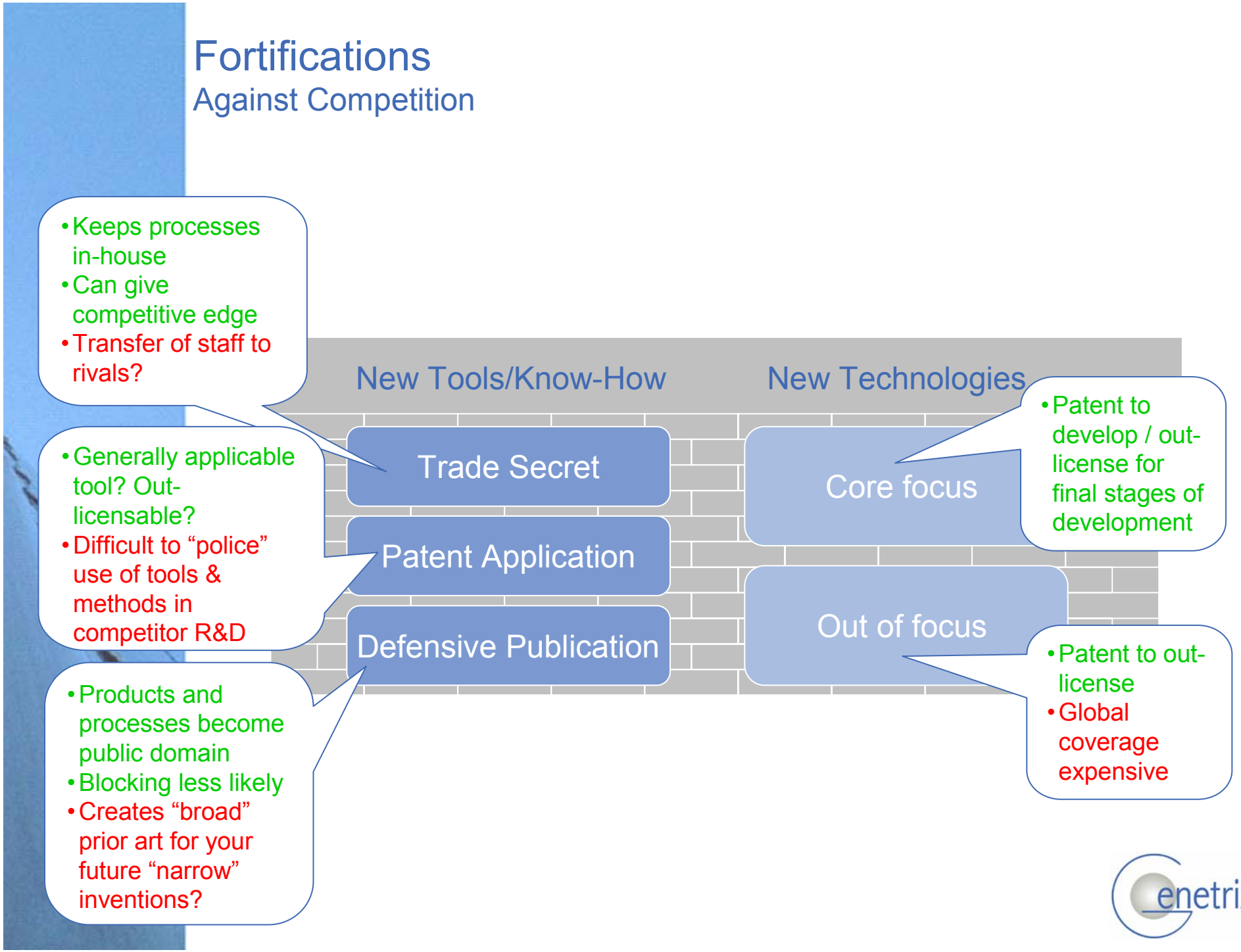
enetrix

Obstacles
to Research

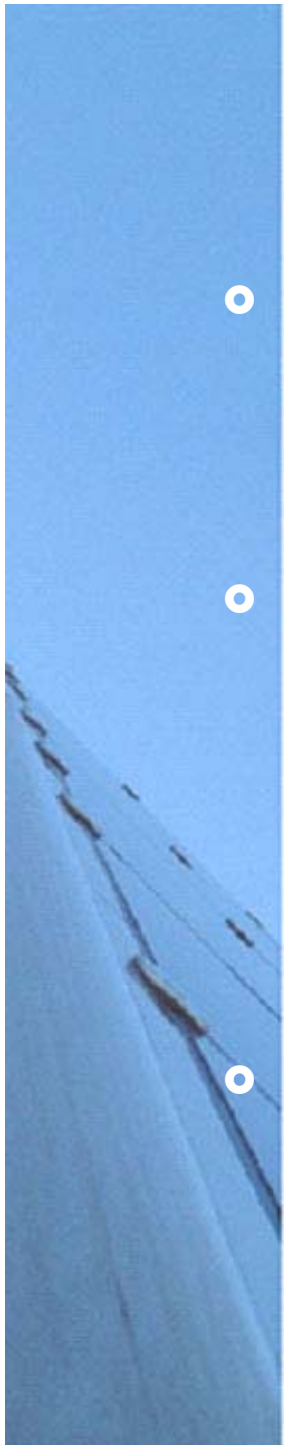


enetrix

Fortifications
Against Competition



enetrix



Bridges
to Finance and Partnering

- The business use of patents
  - to protect the intellectual capital of a company
  - to defend against competition
  - in raising finance
- Forming research and development partnerships
  - “Pre-agreement” discussions of patent applications safer – subject matter and ownership crystallised
  - In-licensed “Academic” patents can be packaged with out-sourced research for SMEs and royalties for the Institute
  - Out-licensed “SME” patents to other SME’s and “BigPharma” can share R&D costs and risks on route to market and royalties
- Securing “know-how” assets in recognisable and reassuring form
  - to attract investors – portfolios and IP awareness attractive
  - to demonstrate ownership and scope of protection of technology to potential partners

enetrix

Alternative Strategies to Patenting
for Biotech SME's

- Securing a monopoly position in the market without patents:
  - first to market approval - data exclusivity periods (10y EU; 7y US)
  - orphan drug status exclusivity (10y EU; 7y US)
  - specialised production capability - e.g. GMP facilities
  - database/library creation - access licences

- Other alternatives applicable/useful?
  - open source models from IT, Human Genome Project
  - can these give a return on huge investment to bring a drug to market?
  - unlikely: 20 year monopoly and patent extension system for drugs preferred
- Some IP Resources
- for SMEs:
- http://sme.european-patent-office.org/
- http://www.wipo.int/sme/
- http://cordis.europa.eu/lifescihealth/sme/rights.htm

enetrix

Summary: Research Patents

Pros and cons for biotech SMEs

- **Academic Patents**
  - Transform science into product possibilities
  - TTO's eager to license to SMEs for development on reasonable terms
- **SME Patents**
  - Secure intellectual assets
  - Attract funding
  - Allow exploitation or licensing
- **Big Pharma Patents**
  - Non-core patents often licensed to SMEs

- **Academic Patents**
  - Patenting mindset?
  - Expensive
  - Filed after publication if at all?
  - Ownership clear?
- **SME Patents**
  - Expensive to extend globally
  - Can disclose early stage information
- **Big Pharma Patents**
  - Can block SME R&D

enetrix

Research Patents in Biotech SMEs

Doorways, Obstacles, Fortifications & Bridges

Neil Thomas PhD
Director of Intellectual Property, Genetrix Group, Madrid, Spain.

Genetrix