Constructive Assessment of Emerging Technologies: bridging the gap between innovation and regulation

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nano TA

TA/Societal Aspects of Nanotechnology

Bridging the Gap Between Innovation and ELSA

nano TA

One of the Flagship programs in NanoNed consortium, 2005-2009

7 PhD students and 2 postdocs, in four universities.
first PhD in December 2007 (Rutger van Merkerk, *Expectations and Constructive TA of nanotechnology*)

nano TA

Has a dual position: must do high quality social science and humanities research,

<u>and</u> help embed nanoscience and technology in society (lubricant function?)

Part of a larger dynamic:
reflexive co-evolution of nano-ST and society

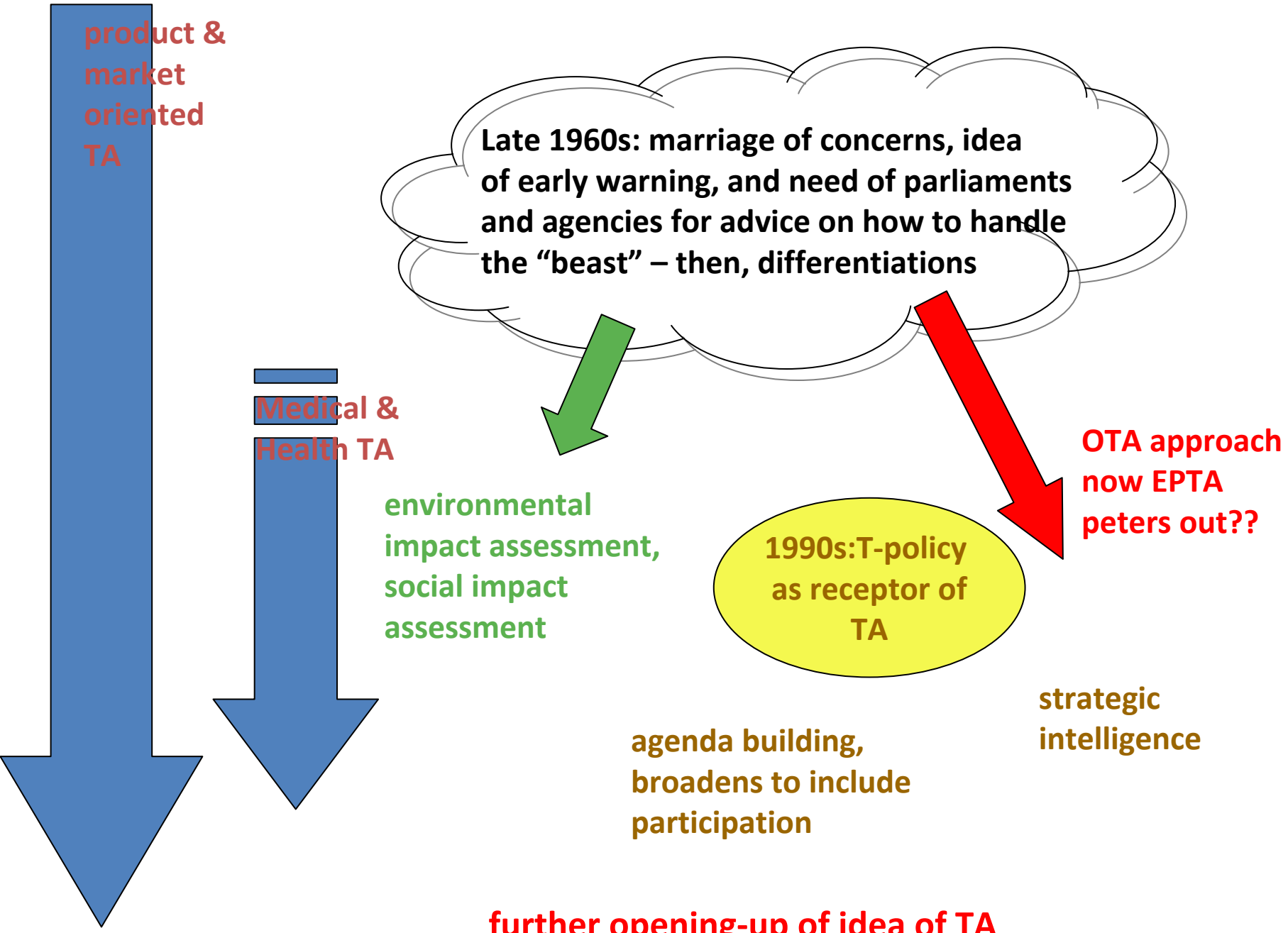
Add to traditional M&HTA

- Constructive: assessment at an early stage of technological/product development, when eventual performance is not yet clear
- Broadening: more aspects are taken into account – to bridge the gap between innovation and ELSA/regulation
- Cf. recent reference to ‘responsible innovation’
- ‘Regulation’ refers to more than cost-benefit analysis; has to address contestation of emerging technologies (e.g. stem cells, drug delivery)

Overall developments in/of TA (a patchwork of approaches)

- "Public" TA since late 1960s; now also:
- TA as a form of strategic intelligence (next to TF, R&D evaluation, cf. ASTPP)
- Informal, *de facto* TA (e.g. through controversies)
- Plus: the philosophy of TA: anticipate on impacts and feedback such anticipations in ongoing processes, including decision making, in order to reduce human and social costs of learning how to handle technology in society by trial and error

and work towards better technology in a better society


product & market oriented TA
Late 1960s: marriage of concerns, idea of early warning, and need of parliaments and agencies for advice on how to handle the "beast" – then, differentiations
Medical & Health TA
environmental impact assessment, social impact assessment
OTA approach now EPTA peters out??
1990s:T-policy as receptor of TA
strategic intelligence
agenda building, broadens to include participation
further opening-up of idea of TA

public engagement
with new ST

ELSA studies

broadening
of product TA,
medical TA

Constructive TA

assessment of
emerging technologies

sub-politics,
neo-corporatism

responsible development
of new technosciences

globalisation of TA?

Broadening of medical/health TA?

- More stakeholder involvement?
- Public engagement?

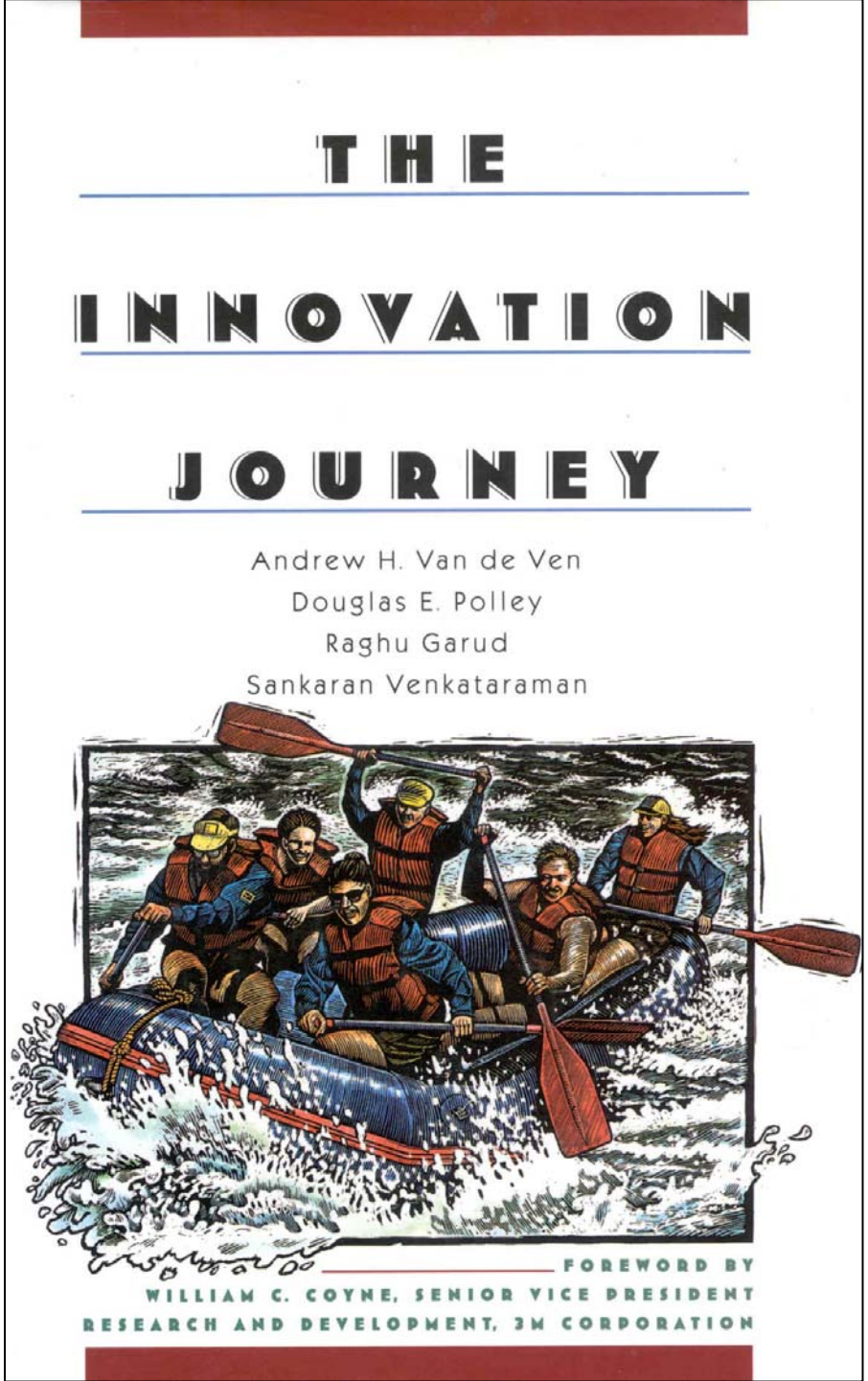
- Assessment at earlier stages of product development, where regular cost-benefit analysis is premature (so add scenarios? Cf. also Bayesian approaches)
- Focus of present M&HTA approaches is on selection, rather than variation
- So it neglects generation, assumes generation will somehow occur, and become a real option

Broaden the scope of M&HTA and its background thinking

- My two topics for today:
- Dynamics of generation (of technology, products), and role of assessment at an early stage (including feedback into ongoing developments)
- Role of expectations and promises (and concerns), and need to understand their role in ongoing developments

Generation

- New options (“hopeful monstrosities”), co-evolve with context
- Pattern of ‘innovation journey’, with shifts and setbacks (Van de Ven et al.)
- Some ‘stretches’ with own dynamics (e.g. in a ‘protected space’)
- Early assessments occur, but choices will be primarily about promises
- Thus about how to continue: more exploration, or go for exploitation

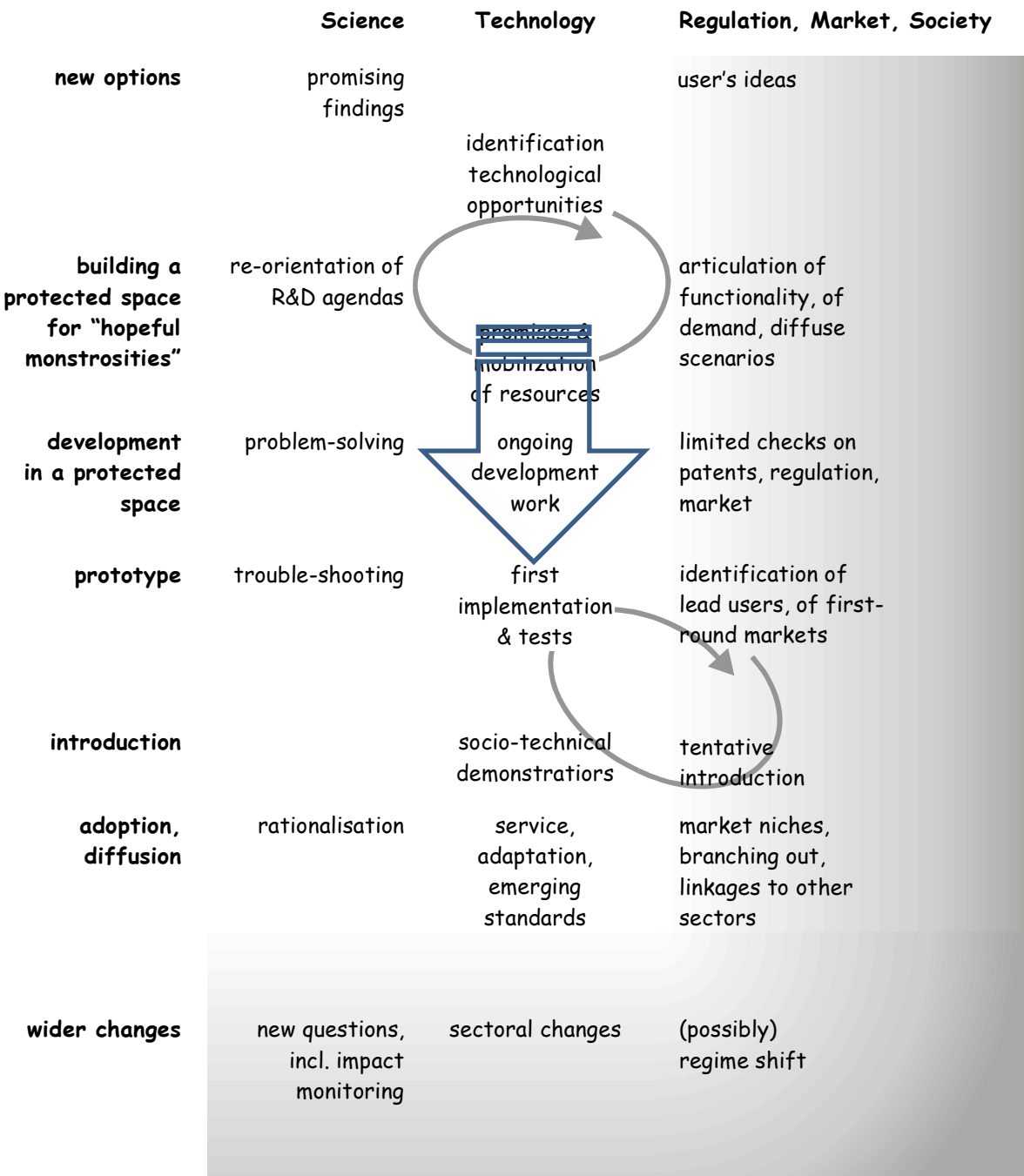


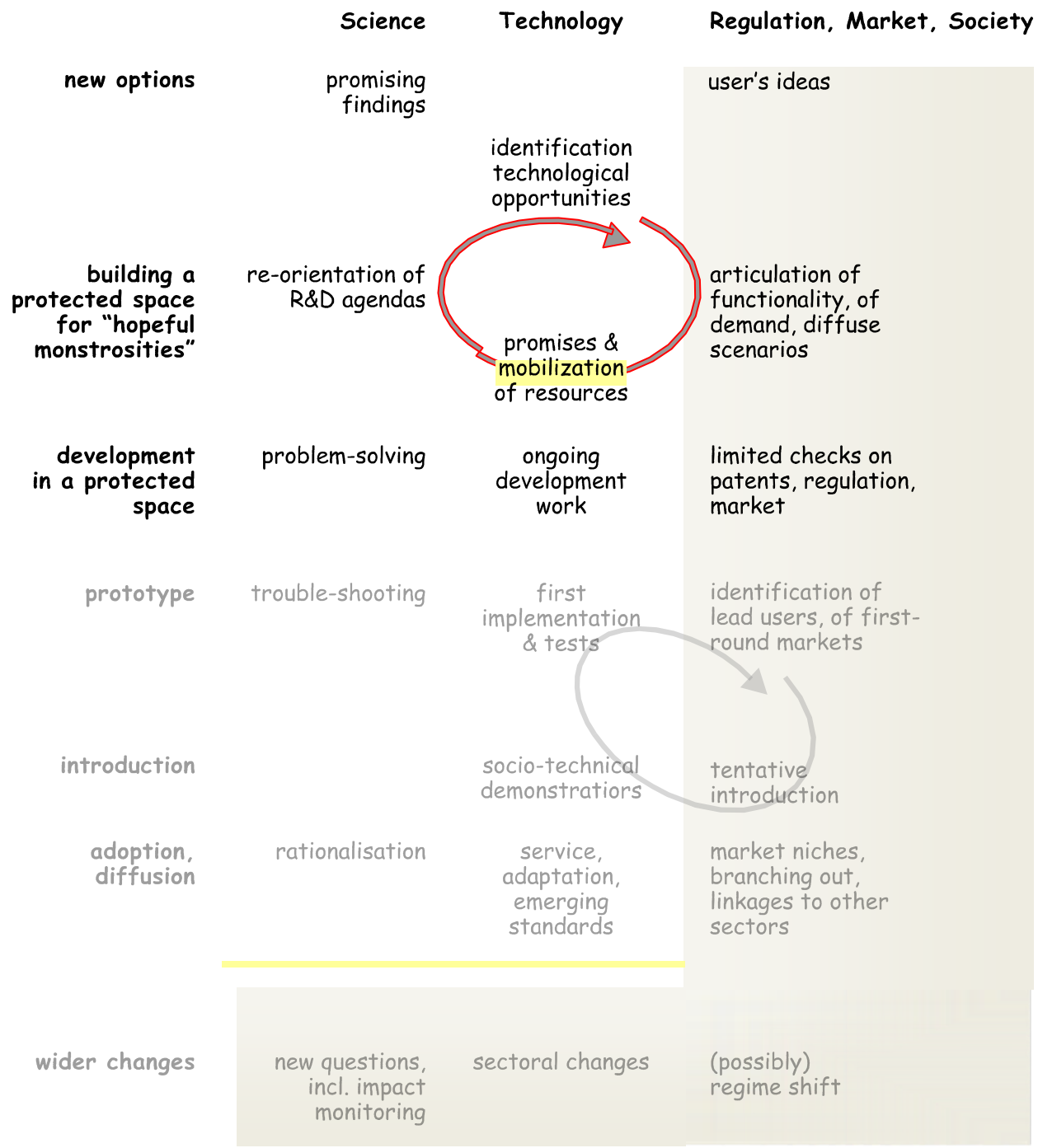
Based on a variety of in-depth case studies,
Van de Ven, Andrew H. et al.: *Research on the Management of Innovation: The Minnesota Studies*, Harper & Row, New York, 1989, paperback edition with Oxford University Press, 2000

Rip (and Schot) extended the idea of 'innovation journey' by

(1) continuing the journey to technological and market niches, sectoral change and sometimes regime change

(2) identifying closures leading to stretches of development with "own" dynamics

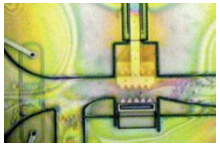


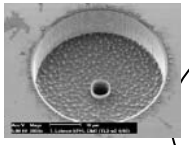


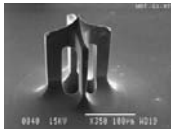
At an early stage, future developments are uncertain, a matter of projections (positive and negative)

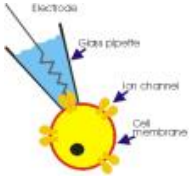
But there are recurring patterns which allow some anticipation

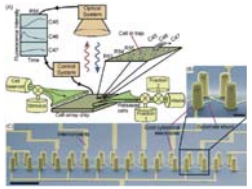
Boundary between exploration and exploitation of technology developments

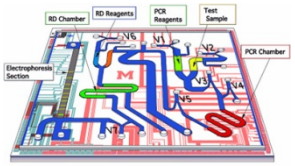


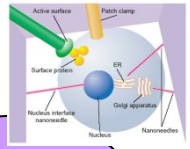












Proof of principle

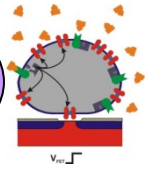
Experimental platform

Integrated platform

Product application

Product application

Product application



System integration

Transition from lab to company

Paths to application

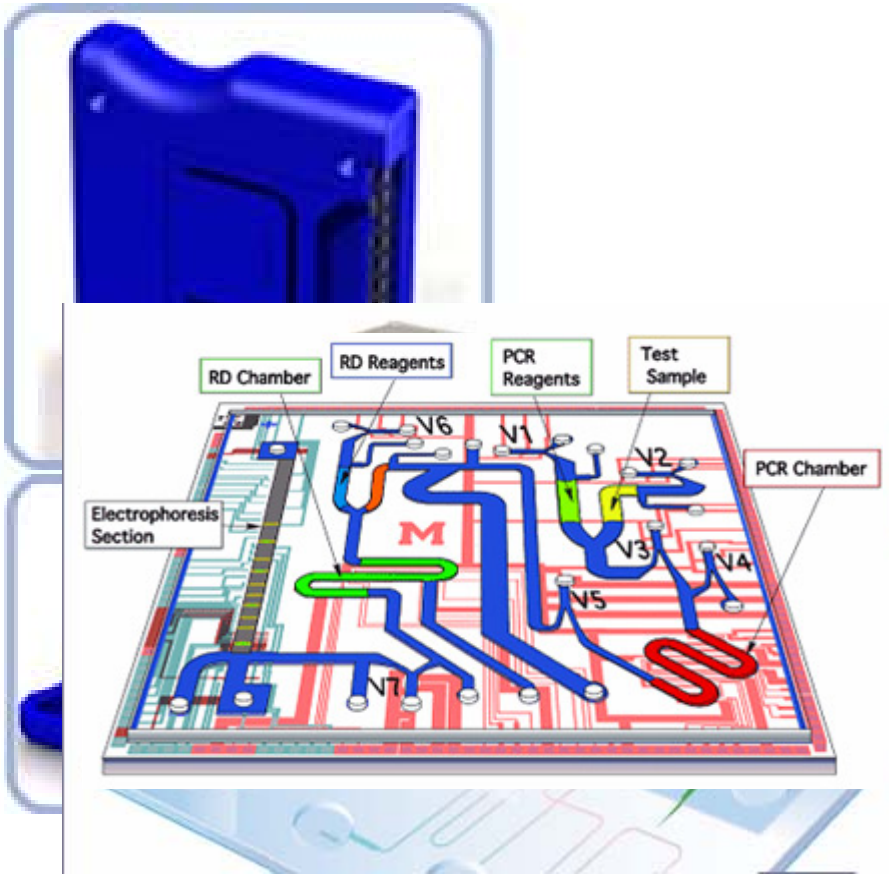
The innovation chain from fundamental research to product

Multi-path mapping

- Innovation chain on the vertical axis, time on the horizontal axis
- Future developmental paths can be mapped on such a two-dimensional diagram
- More dimensions necessary to capture full complexity? Definitely so at later stages
- Example of start-up company Medimate (which sketched possible futures for itself after participating in our workshop on scenarios and multi-path mapping)

Medimate MultiReader

Lab-on-a-Chip



Builds on earlier work in the lab (MESA+, UT), has developed this application for three years, is now ready for a test (with psychiatric patients)

societal embedding

concurrent engineering, anticipate new roles and responsibilities

Reliability? Liability?

Path-Map of Point of Care electrolyte analyser

Application area

Lithium analysis MD Patients

Application X for Patients A

Application Y for Patients B

Z analysis Diagnosis of C

Point of Care electrolyte diagnostic products

Market size = XX M€

Integrated platform

Point of Care electrolyte analyzers prototypes

- Portable and with disposable chip
- Clinical trials
- Mass production
- Monitoring and diagnosing

Prototypes

Experimental platform

Demonstration model for electrolyte analysis in blood

- Multianalyte research tool
- Shows different analyte detection possibilities

Research- and demonstration-model

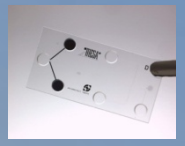
Research

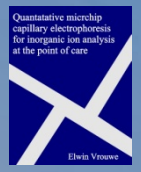
Conductivity Detection

Capillary Electrophoresis

Microchip fabrication

Miniaturization with Lab on a Chip technology





Proof of principle

TIME

Two developments:

- Lithium analyser will be tried out;
- Medimate gets support from health insurer Achmea;
- Broad promises are now confronted with real-world issues of reliability and liability

- Medimate considers other paths enabled by its technology platform, and has to make choices in which to invest.
- Gets support from Inno-HTA (IJzerman c.s.)

Medimate and Inno-HTA

- **EARLY ASSESSMENT OF HIGHLY INNOVATIVE MEDICAL TECHNOLOGY: CLINICAL AND ECONOMICAL GAINS OF POINT OF CARE APPLICATIONS FOR MEASURING POTASSIUM CONCENTRATIONS**

- *Gijs van de Wetering, BSc (1), Marjan J. Hummel, PhD (1), Cees Doelman, MBA, PhD (3), Steven S. Staal, MSc (2) and Maarten J. IJzerman, PhD (1)*
- *1. Dept. Health Technology & Services Research, BMTI, University of Twente, the Netherlands*
- *2. Medimate Point Of Care Technology B.V., Enschede, the Netherlands*
- *3. Medisch Spectrum Twente, dept. Clinical Chemisrty, Enschede, the Netherlands*

Methods and findings

- An **elimination method** was used to identify attractive PMCs based on seven different economical, clinical and technological factors. Analytic Hierarchy Process (AHP) was applied to prioritize the selected PMCs both on market potential as well as the ability of the PMC to satisfy key factors that determine its adoption into the market.
- For all investigated PMCs, a chip for the detection of potassium in blood is estimated to be most attractive for Medimate to invest in.
- A **cost-effectiveness model** (based on a Markov health state transition model) for a potassium chip for Heart failure (HF) patients which suffer from edemas, was developed. Ten-year cohort simulations were carried out, followed by a 200,000 trial Monte Carlo simulation.
- Using a WTP value of €25,000 per QALY gained, incremental cost-effectiveness ratios (ICERs) were calculated. Sensitivity analysis was carried out on both costs per chip as well as number of measurements per year.
- A potassium chip is cost-effective for HF patients suffering from edemas (<14KEuro/QALY) and could provide a valuable asset to current treatment.

- Methods used to assess cost-effectiveness are very dependent on source reliability and focus should be on minimizing expert subjectivity and verifying literature sources

Lessons

- The Inno-HTA methods are used to make detailed (and action-oriented) assessments,
- But to have an overview of possible paths ("generation"), other methods are necessary
- Multi-path mapping, based on a technology platform, has a "linear" bias (increasing performance of a given device)
- Innovation journeys shift, branch out (e.g. other, unexpected uses) and can run into problems when the innovation is taken up more widely – scenario approaches are necessary.

Bridging the gap between innovation and ELSA (ethical, legal, societal aspects)

Workshops with a broad range of actors, supported by socio-technical scenarios about societal embedding of nanoST developments

have become accepted in the nano-world

CTA offers support to variety of actors to improve their strategies and interactions

so is a "distributed management" tool, enhancing reflexivity because other actors are encountered

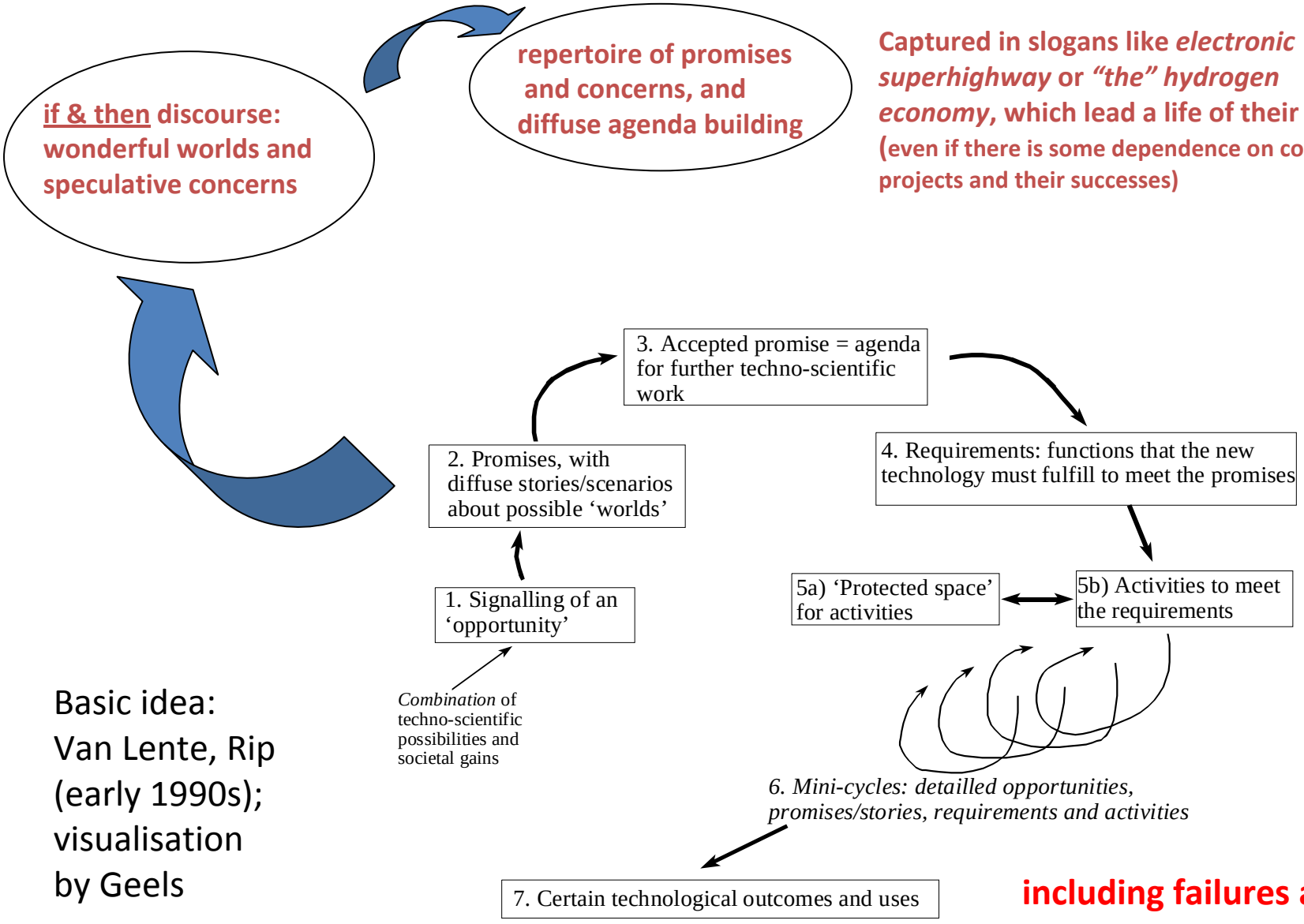
contributes to reflexive co-evolution of nano-technologies and society

TA of emerging technologies which live on promises

- Don Eigler (IBM): There's lots of nanoscience going on, but nanotechnology is mostly science fiction
- Consideration of effects/impacts of nanotechnology (up to third industrial revolution, human enhancement) is social science fiction
- Promises serve a purpose (they mobilise resources, support and legitimacy), but should not be taken at face value
- Consider dynamics (forcefulness, made true)

For emerging technologies, two dynamics of promises

- (1) Promise-requirement cycles, narrowing down to realizing specific technological options (or failing to do so)
- (2) Broad agenda-building (including the “if & then” discourse) largely independent of concrete developments
- Example of ‘electronic superhighway’, early 1990s: continued as a slogan in spite of project failures (analysis by Kornelia Konrad)



Basic idea:
Van Lente, Rip (early 1990s); visualisation by Geels

Early example: plastics

- "I just want to say one word to you: Plastics. There's a great future in plastics!" (from the movie *The Graduate*)
- A life lived in a world "**free from moth and rust and full of colour**" (1941)
- These are projections, but related to concrete products, and driven by big incumbents (chemical companies)
- Plus effect of World War 2: technology development to produce substitutes for natural products
- So real effects!

The materials of material culture: multiple narratives

Plastic: a waterproof vision of the future

image of 2000 in 1957, from Corn and Horrigan (1996)

slides borrowed from
Elizabeth Shove

A life lived in a world "**free from moth and rust and full of colour**".

Yarsley and Couzens (1941)

and as he gets old, he will be wearing **silent** plastic teeth; playing chess with moulded chessmen on a plastic board "until at last he sinks into his grave **hygienically** enclosed in a plastic coffin" (158).

This coffin is believed to be the largest phenolic moulding in the world. Designed by James Doleman and made by the Ultralite Casket Co Ltd, it was manufactured from imitation walnut phenolic resin with a wood flour filler devised by the Bakelite Company Ltd of London. 1938

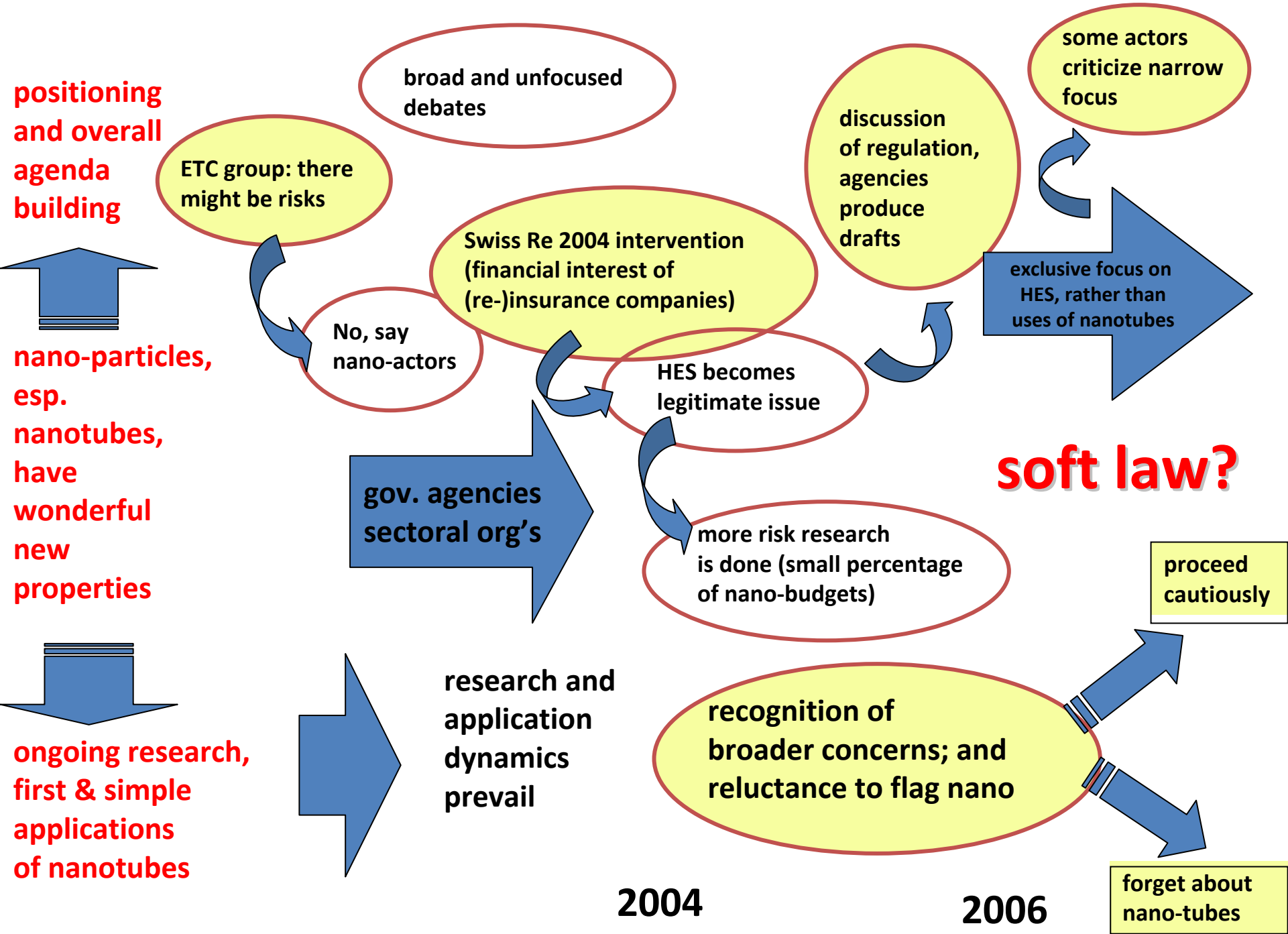
http://www.ingenious.org.uk/See/?s=S2&target=ctx&DCID=10276584

Present-day emerging technologies

- ‘Umbrella terms’ like nanotechnology carry the promise (and draw outside interests, esp. from policy makers, and also from critical civil-society groups), while actual developments have their own dynamics
- A two-level, and largely uncoupled, development (ex. human enhancement)
- Promises in medical/health domain, like ‘cure for cancer’, ‘individualized medicine’, ‘point-of-care diagnostics’ (and Medimate works toward this)
- How to include this in M&HTA? Such promises drive developments, but cannot be subjected to detailed “calculative” assessments

Actual promise dynamics entail de facto assessment

- Occurs all the time, because positions have to be taken taken and argued in a situation of uncertainty/ignorance
- One effect: societal agenda-building responding to promises and concerns that are voiced, and related actions/interactions
- Can be more important than dedicated TA exercises, which are one input into the process
- So understand such processes!


positioning and overall agenda building
nano-particles, esp. nanotubes, have wonderful new properties
ongoing research, first & simple applications of nanotubes
broad and unfocused debates
ETC group: there might be risks
No, say nano-actors
Swiss Re 2004 intervention (financial interest of (re-)insurance companies)
HES becomes legitimate issue
discussion of regulation, agencies produce drafts
some actors criticize narrow focus
exclusive focus on HES, rather than uses of nanotubes
soft law?
gov. agencies sectoral org's
more risk research is done (small percentage of nano-budgets)
research and application dynamics prevail
recognition of broader concerns; and reluctance to flag nano
proceed cautiously
forget about nano-tubes
2004
2006

Lessons for M&HTA

- Medical & health sector has to live with promises and concerns, of various actors (including firms, patients, NGOs, regulatory agencies), and come to terms with them
- Evidence-based approaches help?
- Often only patchwork of data, of uneven quality – what to do then?
- Include broader contexts and dynamics in the diagnosis; accept narrative evidence

In conclusion

- A renewed M&HTA is in order:
- M&HTA's tradition is "hard" (quantitative); important for comparative selection
- There are other situations to do M&HTA
- So add Constructive TA: "soft" (qualitative) – to capture & anticipate dynamics
- And pay attention to contexts and their dynamics in which the dedicated M&HTA exercises are embedded