

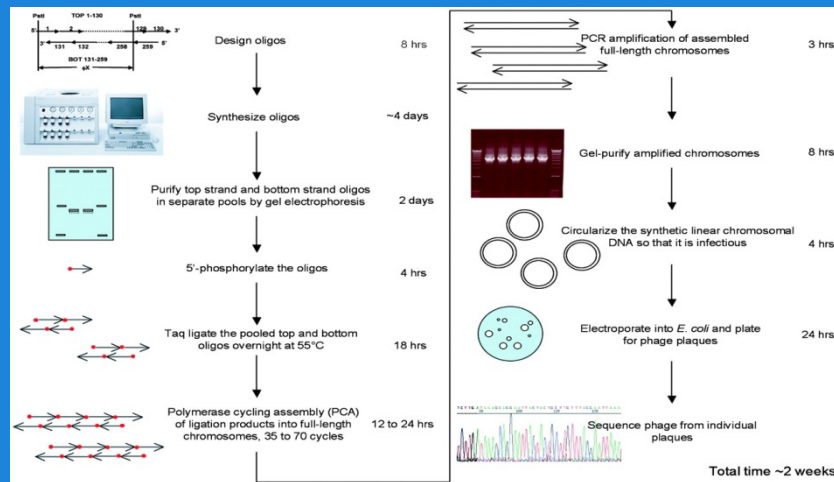
Synthetic Genomics

Options for Governance

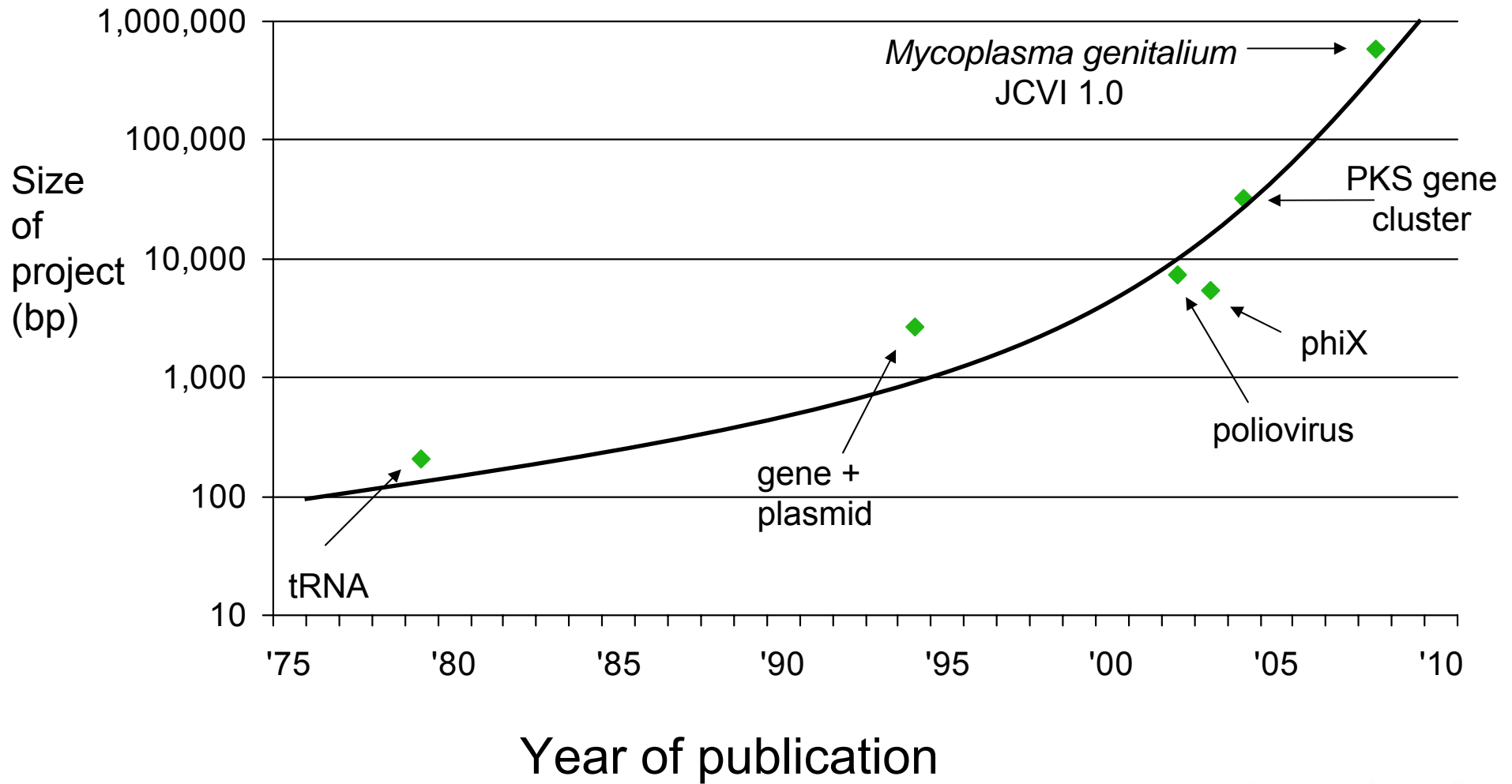
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Synthetic genomics at JCVI

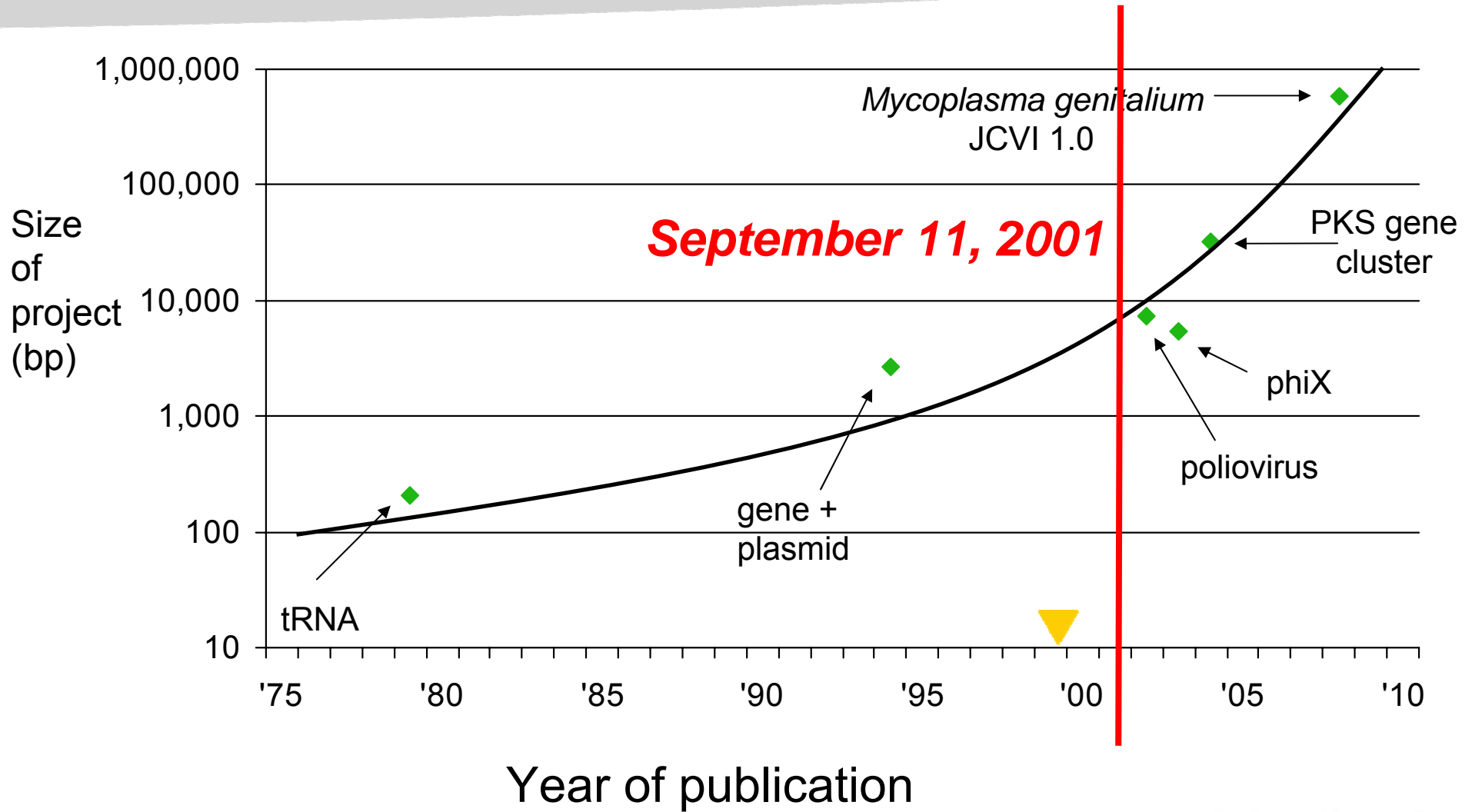
■ Φ X174 synthesis



External Events Influence How a Technology is Perceived



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Governance Concerns Related to Synthetic Genomics

- Along with the promise of benefits, *all* new technologies raise societal concerns
- Five key societal concerns:
 - Bioterrorism
 - Laboratory Safety
 - Harm to the Environment
 - Distribution of Benefits
 - Ethical and Religious Concerns

Bioterrorism

- Societal concerns
 - New way to obtain pathogens
 - Construction of a pathogen with increased resistance to known treatments or increased virulence
- What is different about synthetic genomics?
 - Can no longer limit access by physical means alone
 - Most pathogens easier to obtain by other means
 - *Except a few viruses: 1918 influenza, Smallpox, Ebola*

Laboratory Safety

- Societal concerns
 - Concern is for risks to users from specific microbes
 - No concern for harm to users from synthetic DNA itself
- What is different about synthetic genomics?
 - Speed and scale
 - Researchers new to the field

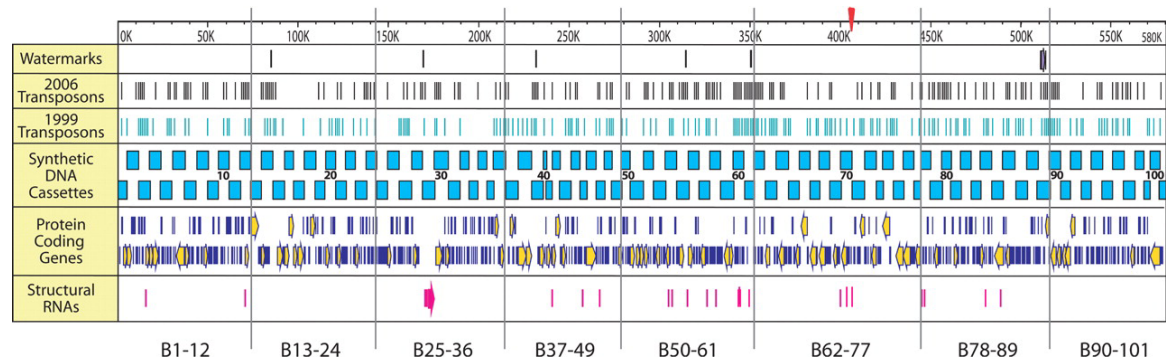
SYNTHETIC GENOMICS | Options for Governance

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A synthetic chromosome



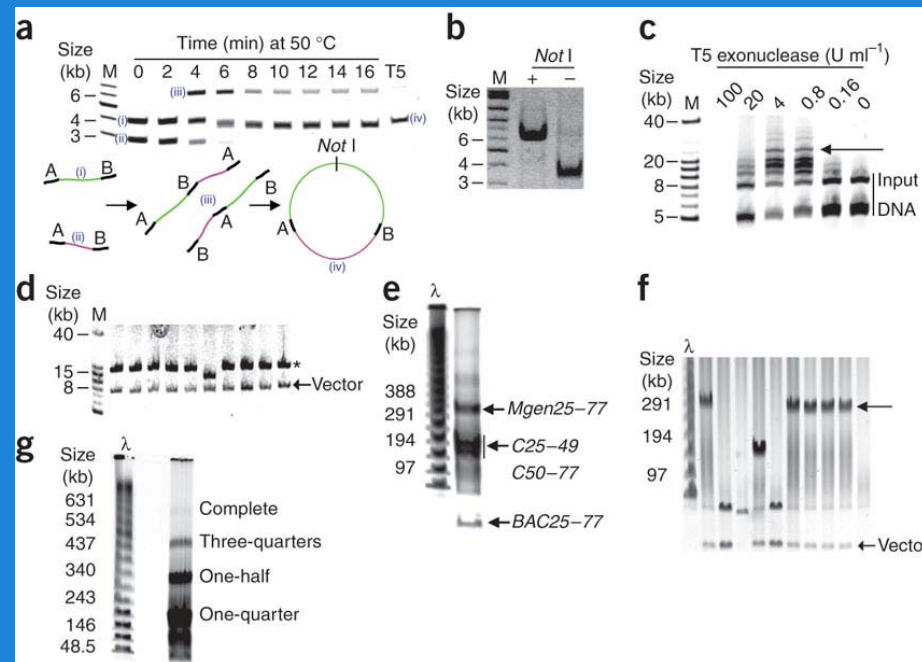
TIME



10 MICRONS

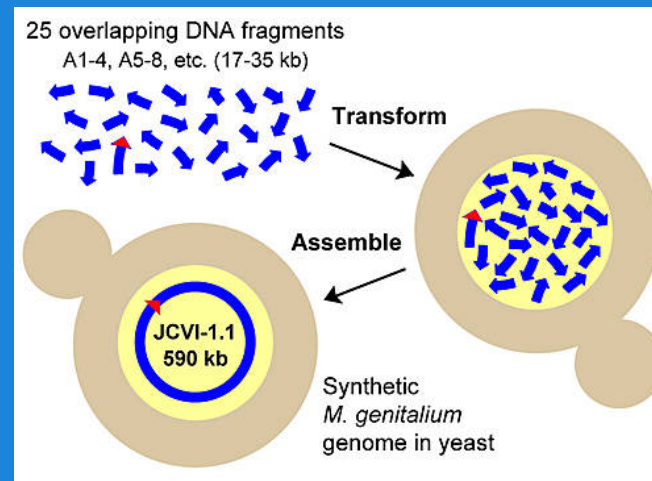
Synthetic genomics at JCVI

- Enzymatic assembly of multi-kilobase molecules

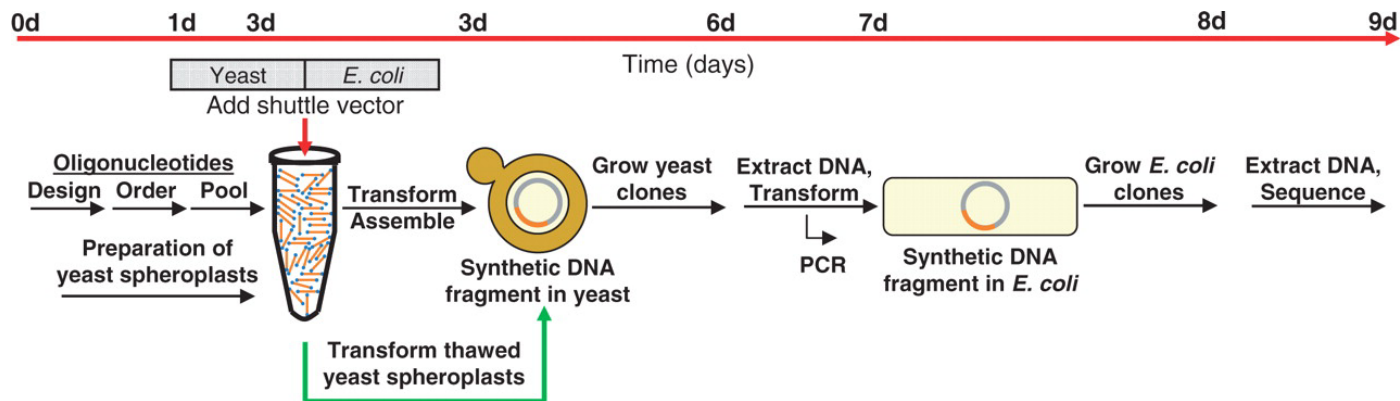


Synthetic genomics at JCVI

- One-step assembly of *M. genitalium* genome

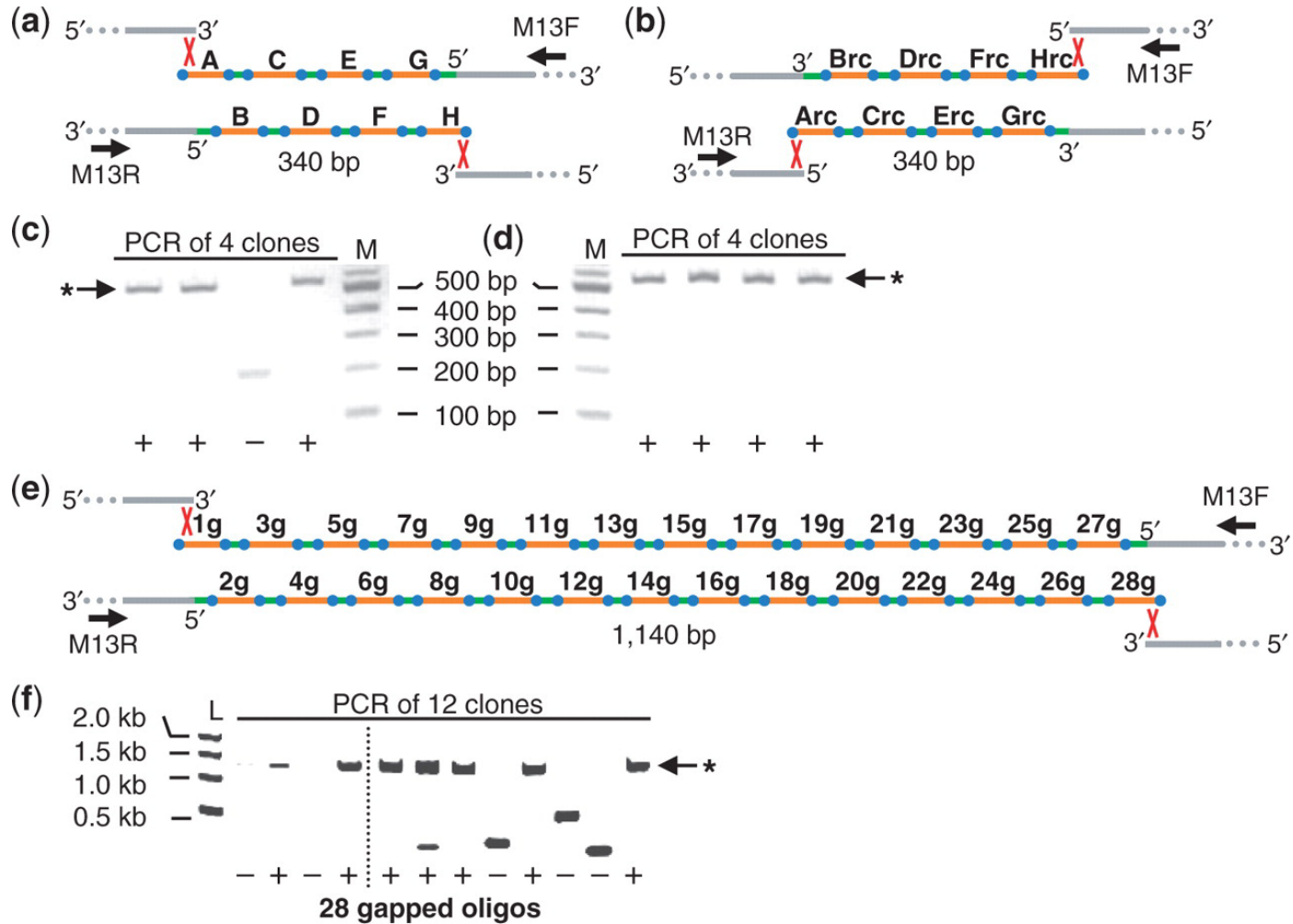


Schematic overview and timeline for the assembly of overlapping ssDNA oligonucleotides (orange lines with blue circles) into a linear dsDNA yeast/*E. coli* shuttle vector (pRS313; grey) within the nucleus of a yeast cell



Gibson, D. G. Nucl. Acids Res. 2009 37:6984-6990; doi:10.1093/nar/gkp687

Twenty base-pair overlaps are sufficient for oligonucleotide assembly in yeast



Gibson, D. G. *Nucl. Acids Res.* 2009 37:6984-6990; doi:10.1093/nar/gkp687

Societal Concerns Related to Synthetic Genomics

- Five key societal concerns:
 - Bioterrorism
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 - Harm to the Environment
 - Distribution of Benefits
 - Ethical and Religious Concerns

Harm to the Environment

- Societal concerns
 - No concern for harm from synthetic DNA itself
 - Only concern is whether specific engineered organisms pose risks to the environment
 - Part of larger societal debate about rDNA since the mid-1970s (starting with Asilomar)
- What is different about synthetic genomics?
 - Speed, scale, power of the technology

Distribution of Benefits

- Societal concerns
 - Intellectual property concerns
 - Patents, open source
 - “Concentration” within a small number of firms
- What is different about synthetic genomics?
 - Maybe little; raised for every emerging technology
 - However, the synthetic biology community itself is divided on this issue

Ethical and Religious Concerns

- Societal concerns
 - Hubris (“playing God”)
 - Concerns about changing the relationship of humans to nature
- What is different about synthetic genomics?
 - Construction of a free-living organism from chemicals adds a new concern to the list

Stakeholders

- Citizens
- Consumers
- Businesses
- Scientists
- Policymakers
- Governments
- Do-it-yourself community

And their representative groups

Regulation and governance of synthetic genomics

- Changes to NIH guidelines?
- Changes to Coordinated Framework?
- Changes to TSCA?
- Changes in patent review (domestic and international)?

Where we are today...

- The technology is improving and the user base is expanding
- Applications are beginning to appear and many new ones are being developed
- Societal impacts are being scrutinized
- Governance options are being seriously considered...
 - By the research community itself, the developing industry, and by governments

Disclaimer

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