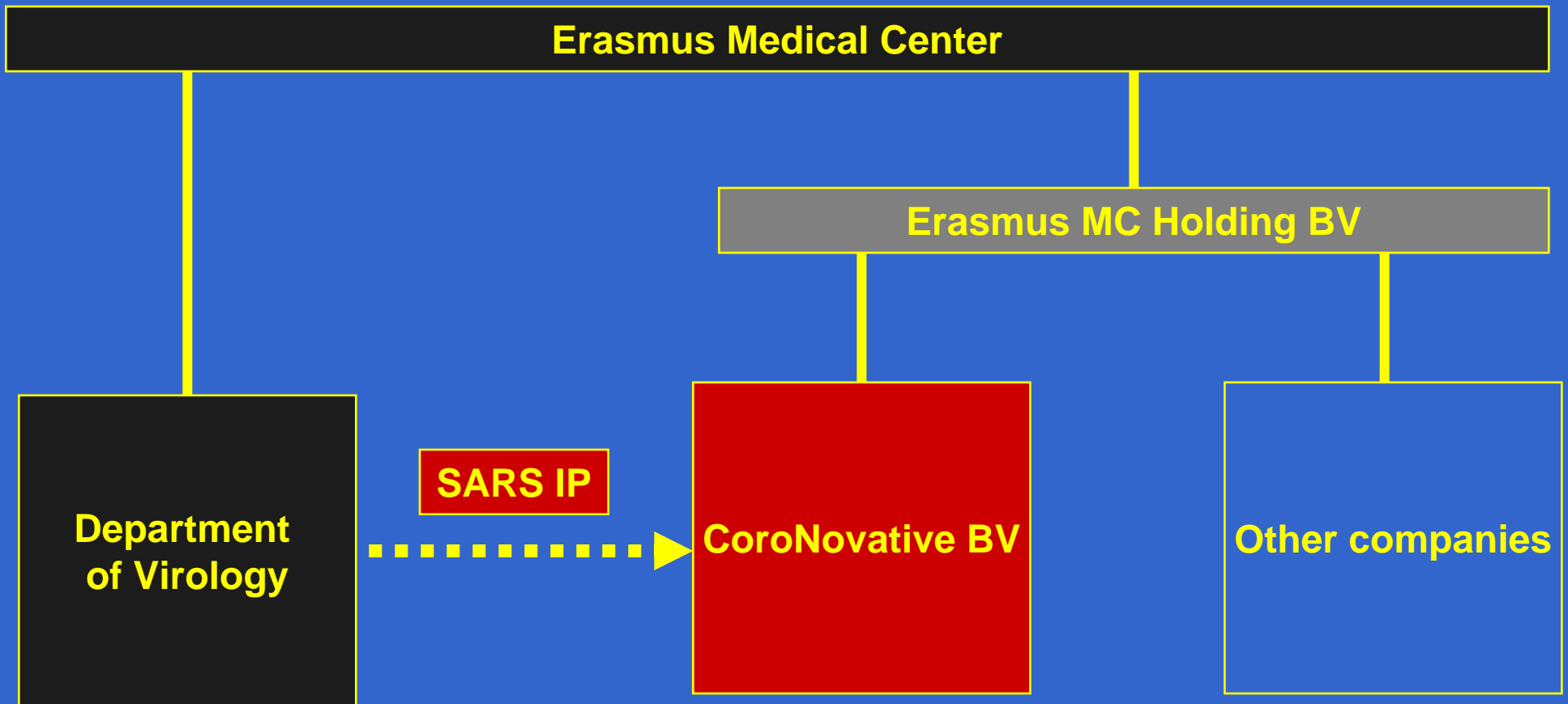


**HOW PATENTS MAY AFFECT THE DEVELOPMENT OF A SARS  
VACCINE: THE POSSIBLE ROLE OF PATENT POOLS**

**CIPIH Lunch Time Seminar**

**22 October 2004**

# WHO WE ARE



# OBJECTIVE

**This presentation aims to highlight:**

- **The current situation relating to patent applications on SARS**
- **The impact that this may have on development of vaccines and diagnostics**
- **A proposal to address the problem**

**This presentation will not address:**

- **Views on patent law and patenting philosophy**
- **A detailed solution to the problem**

## IP RIGHTS TO SARS CoV UNCERTAIN

### “Primary” patent applications incorporate SARS genetic sequences

Several entities have sequenced parts or the whole of SARS CoV

- Bernhardt-Nocht Institute
- British Columbia Cancer Agency
- Centres for Disease Control
- Erasmus Medical Centre
- Hong Kong University
- Other members of the WHO task force?
- Other entities?

### “Secondary” patent applications filed by numerous entities

Reverse genetics

Diagnostics

Vaccines

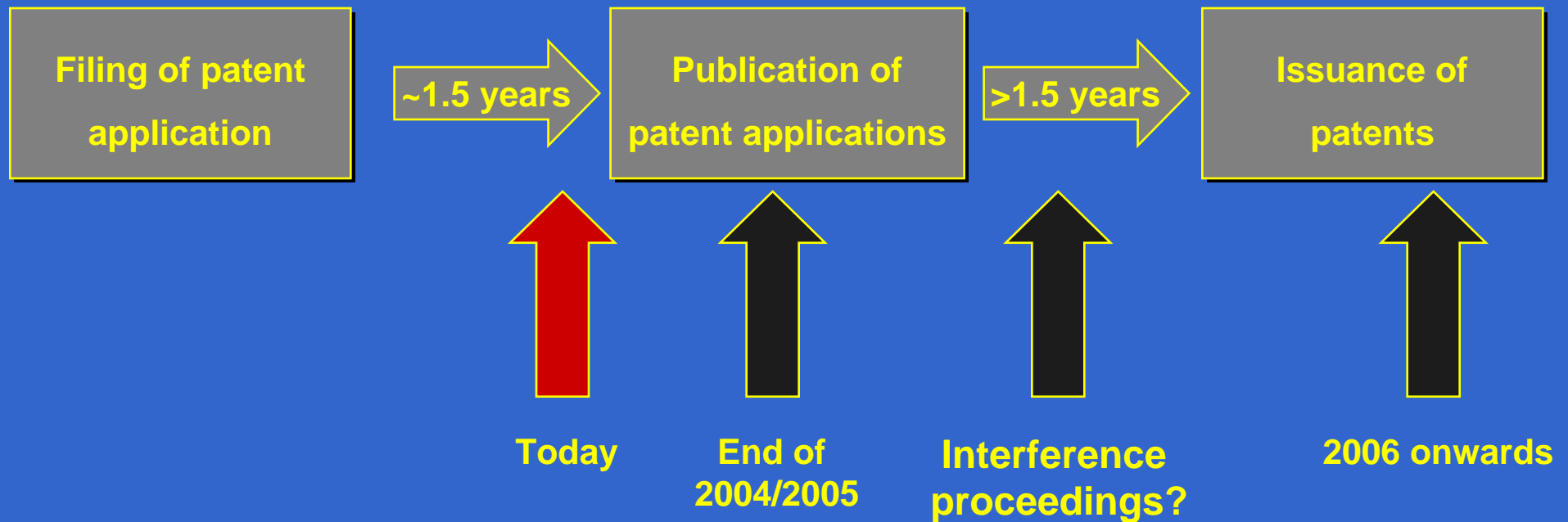
Antiviral

Protein (eg soluble Spike)

Antibodies (eg anti-NP)

etc

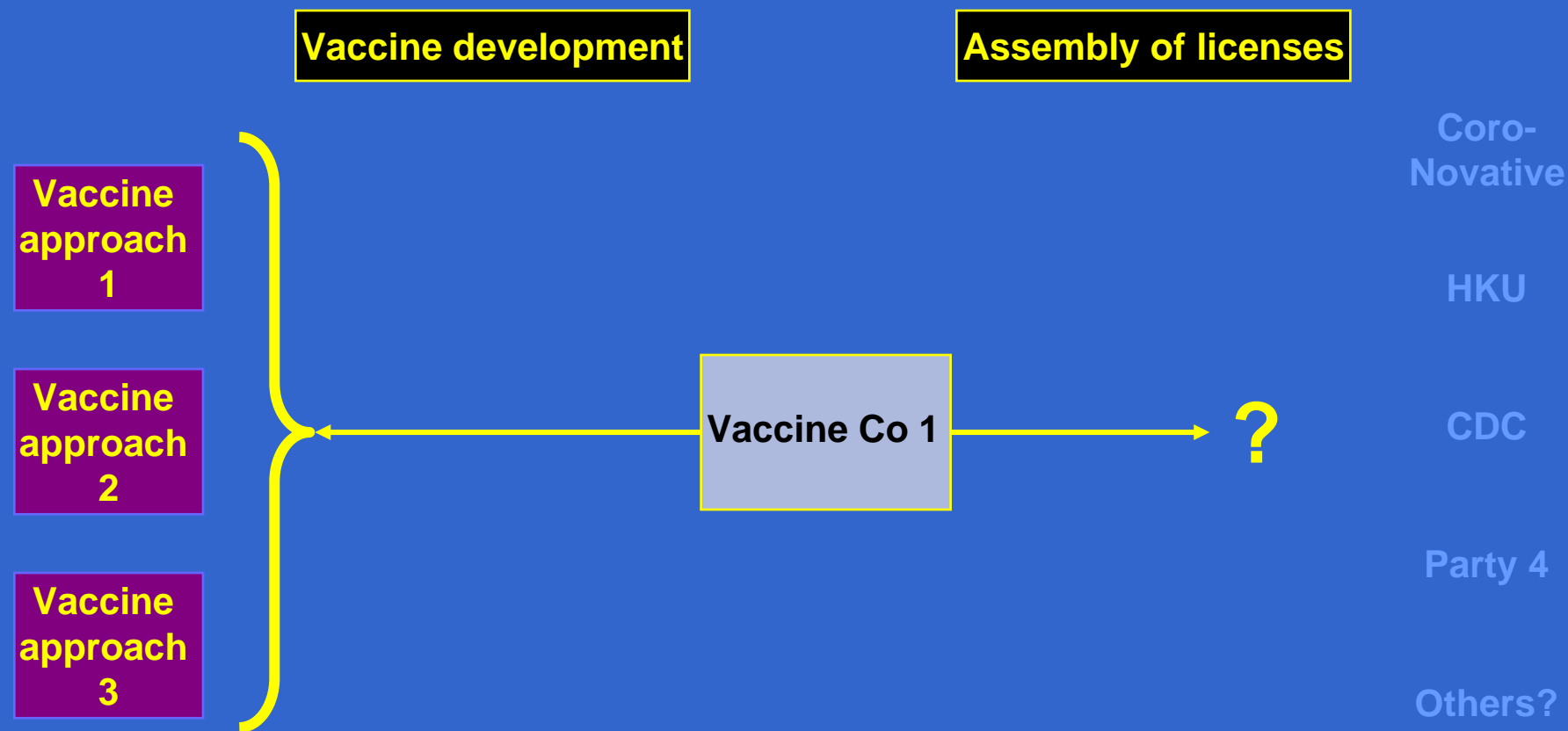
# IP SITUATION MAY TAKE SEVERAL YEARS AND THE LAW COURTS TO RESOLVE



**Uncertainty over patent rights increases risks to those that seek to use them and to owners of IP**

# RISK TO LICENSORS FROM UNCERTAINTY OVER PATENT RIGHTS

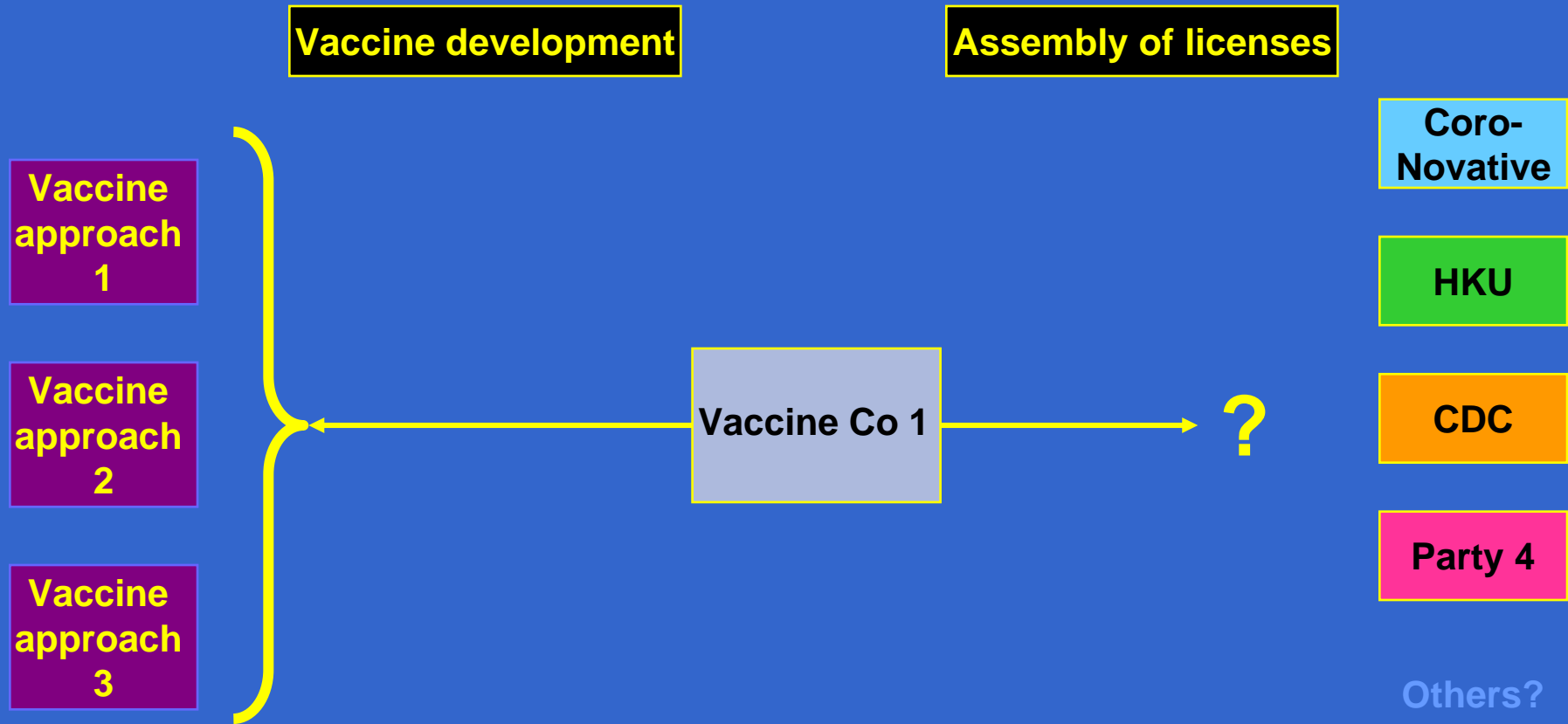
From Who Should IPR be Licensed? Is all necessary IPR Available for Licensing?



**“We have been simultaneously contacted by a number of parties, all claiming to have solid IP positions in the field” – Major diagnostics manufacturer, 2003**

# 2004: SITUATION WITH SARS IP CLARIFYING

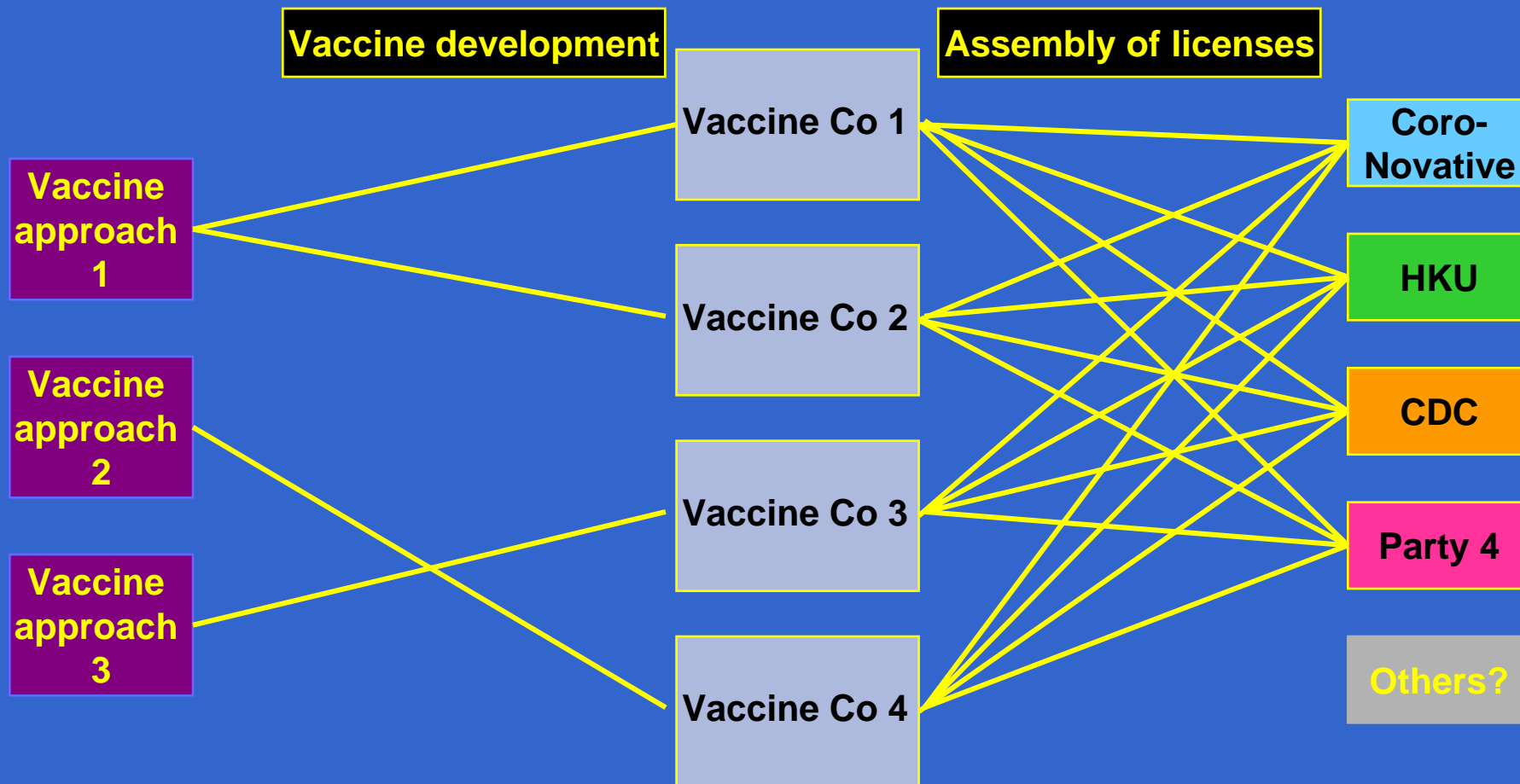
## SARS IP Fragmented and Likely to Lead to Interference Proceedings



**Uncertainty may remain for several years**

# RISK FROM IP FRAGMENTATION

Licensing Difficulties Increase Costs: Multiple Agreements, Stacked Royalties, Delays



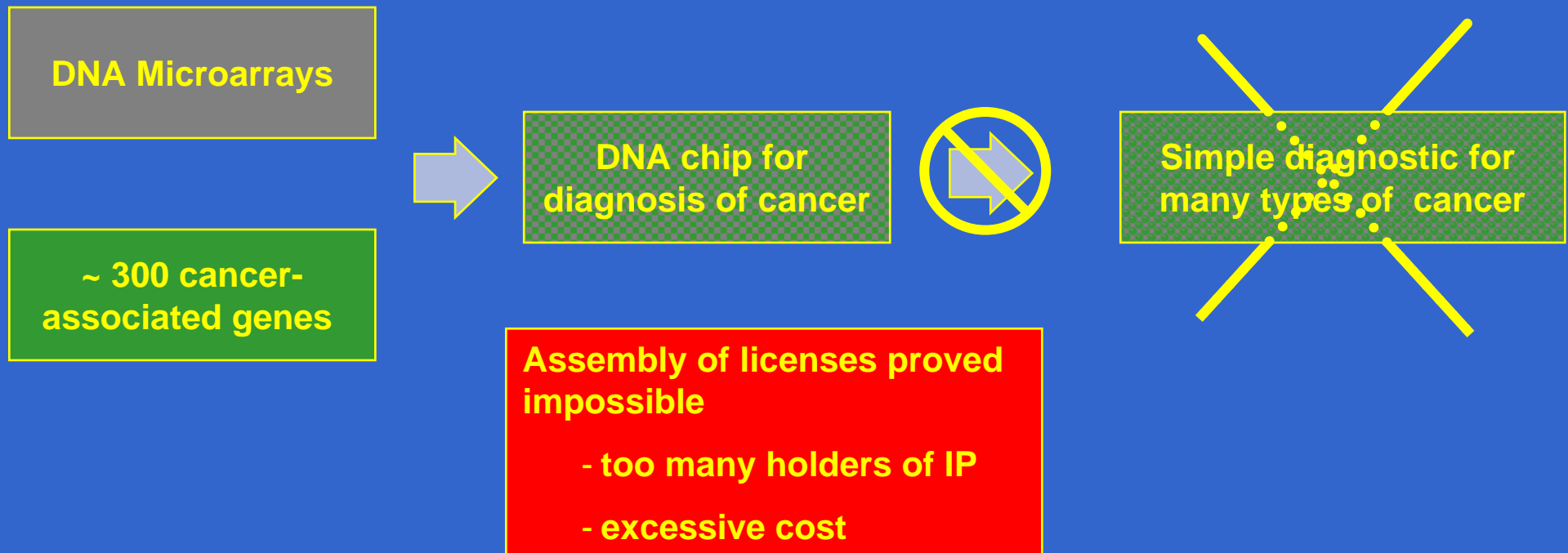
**A "lose-lose-lose" situation: licensing difficulties may delay or block development**

Example

# EXAMPLE OF IP FRAGMENTATION STIFLING DEVELOPMENT: THE MISSING CANCER DNA MICROARRAY

Product Concept

Product development



**IP difficulties can stifle commercially viable propositions**

## WHO SARS CONSULTATION GROUP RECOMMENDATION

***“The WHO SARS consultation group proposes that a strategy be developed, in consultation with stakeholders, to address potential SARS Coronavirus-related IP issues and thus enhance development of intervention approaches”***

**Extract from Recommendations, World Health Organization SARS consultation group – November, 2003**

# “COOPERATIVE POOLING” AS AN ANSWER TO THE PATENT THICKET

Several Types of Pooling Exist

	Cooperative Pooling	3 <sup>rd</sup> Party Aggregation	Forced Cooperation
Example:	DVD pool, MPEG-2 pool, FireWire pool		Radio Company of America (RCA)
Description:	Patent holders agree to combine their technologies via a separate entity	Company combines technologies from multiple external sources	Companies required by government to allow combinations of technology

## Example

# DVD COOPERATIVE POOLS ILLUSTRATE THE CONCEPT

Rights holders formed pools of essential patents for DVD-ROM and DVD-Video...

**1998 Pool:**  
Three companies pool patents into a division of Philips

Sony  
Pioneer  
Philips



**1999 Pool:**  
Six companies pool patents into a division of Toshiba

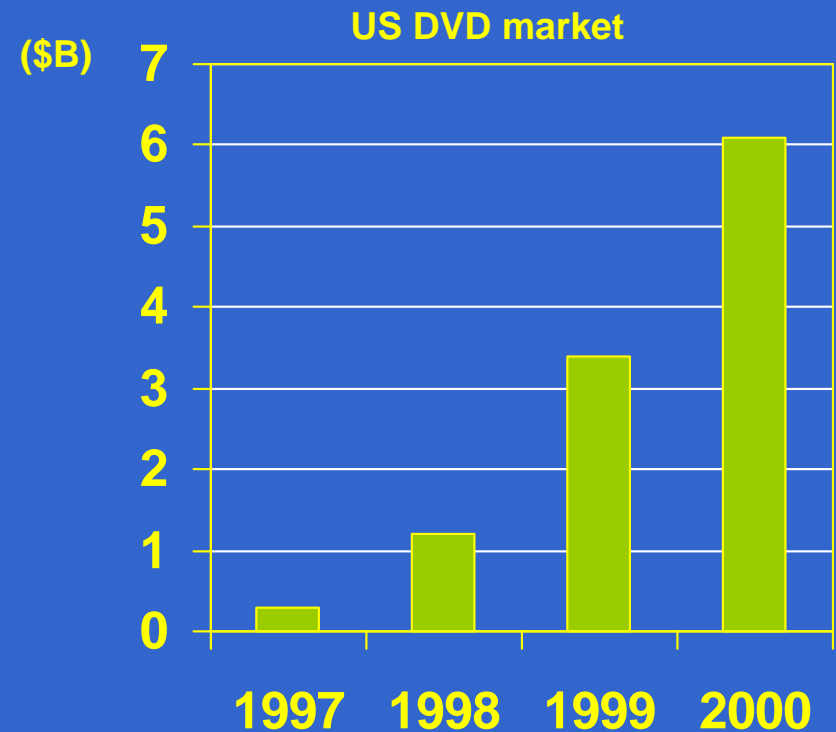
Hitachi  
Matsushita  
Mitsubishi  
Time Warner  
Victor  
Toshiba



**Benefits from pools:**

- Reduced licensing transaction costs
- Elimination of potential royalty stacking and hold-up

...enabling wide-spread adoption of DVD technology



# FORMATION OF A PATENT POOL IS A MULTI-STEP PROCESS

May Take up to One Year

Identify relevant parties

Gain agreement between parties

Letter of Intent

Independent  
evaluation of patents

Regulatory authority  
approval

Develop operating model

Sign Full  
agreement

Go  
live

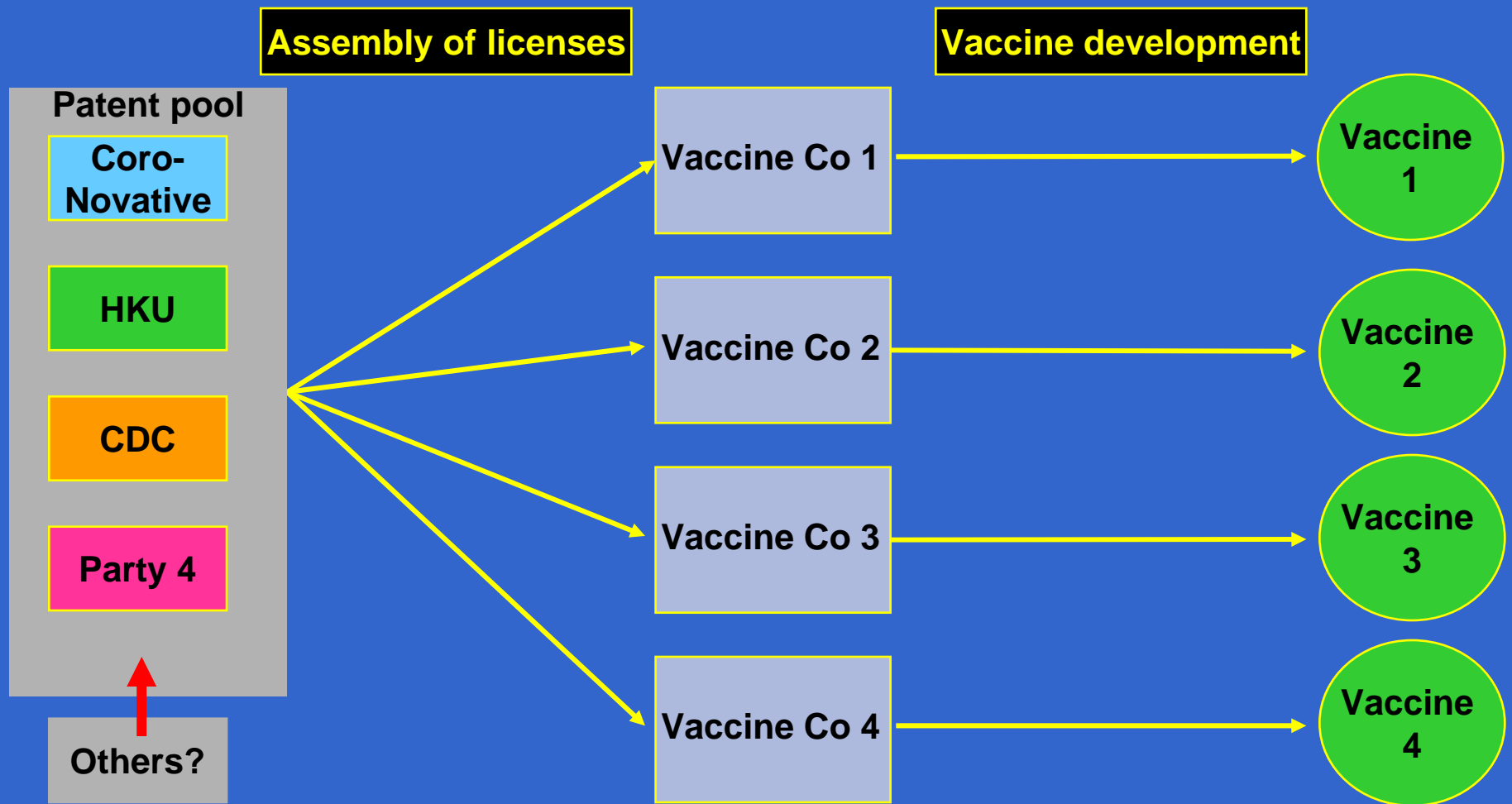
# PATENT POOLS SHOULD NOT BE ANTI-COMPETITIVE

Benefits of patent pools	Criticisms of patent pools
<p><b>Reduced risk</b></p> <ul style="list-style-type: none"><li>• Infringement litigation</li><li>• Blocking patents</li></ul> <p><b>Reduced licensing costs</b></p> <ul style="list-style-type: none"><li>• Stacked royalties</li><li>• Licensing transaction costs</li></ul> <p><b>Stimulates innovation</b></p> <ul style="list-style-type: none"><li>• May remove patents from competition, driving 'downstream' innovation</li><li>• Integrate complementary technology</li><li>• Promotes dissemination of technology</li></ul>	<p><b>Reduce competition by pooling of competitive patents</b></p> <p><b>Create incentives for price fixing and collusion</b></p> <p><b>Shielding of invalid patents</b></p>

**Patent pools are not anti-competitive and benefit the consumer; concerns over anti-competitiveness can be addressed by complying to *IP Guidelines***

# PATENT POOLING MAY BE OPTION FOR SARS

Patents Incorporating Sequence of SARS Could be Pooled



**Create “win-win-win” situation:  
IP holders, vaccine manufacturers and public health all benefit**

# PATENT POOL FORMATION STRATEGY: START SIMPLE

## 1. Basic pool

Patents incorporating genomic sequences of SCV  
that cover vaccines and diagnostics in general

# PATENT POOL FORMATION STRATEGY: START SIMPLE LOOK TO EXPAND IN MODULAR MANNER

## 1. Basic pool

Patents incorporating genomic sequences of SCV  
that cover vaccines and diagnostics in general

If approved

## 2. Complex pools?

Patents incorporating genomic sequences of SCV  
that cover vaccines and diagnostics in general

Live attenuated vaccines?

Sub-unit vaccines?

Serology assays?

# GOOD PROGRESS TO DATE WITH PUTATIVE SARS PATENT POOL

## “SARS IP Working Group” Being Formed

Identify relevant parties:

HKU/Versitech; CDC;  
EMC/CoroNovative; Party 4

Gain agreement between parties

Parties agreed  
to move forward

Letter of Intent

Parties agree  
on LOI

Evaluation  
of patents

Regulatory authority  
approval

Develop operating model

Sign Full  
agreement

Go  
live

Morgan, Lewis  
& Bockius LLP

S. Sammut,  
Wharton

Letter of Intent Agreed; Attorneys and Academic Advisors Working Pro Bono

# **UNIQUE OPPORTUNITY TO SET KEY PRECEDENT FOR MANAGEMENT OF IP IN THE LIFE SCIENCES**

**Key IP owners have agreed to form “SARS IP Working Group”**

**Relevant patent applications at similar stage of maturity**

**Legal advice secured from major firm containing both anti-trust and patent practices and that has experience of patent pools**

**Support from variety of health-related organizations being gathered**

**Funding would accelerate and facilitate process**