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

CIPIIH Lunch Time Seminar

22 October 2004
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

- Bernhard-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

Filing of patent application

Publication of patent applications

Issuance of patents

~1.5 years

>1.5 years

Today

End of 2004/2005

Interference proceedings?

2006 onwards

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?

![Diagram showing vaccine development and assembly of licenses with various entities involved.]

“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

Vaccine development

Vaccine approach 1
Vaccine approach 2
Vaccine approach 3

Assembly of licenses

Vaccine Co 1

Coro-Novative
HKU
CDC
Party 4

Others?

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 OF IP FRAGMENTATION STIFLING DEVELOPMENT: THE MISSING CANCER DNA MICROARRAY

Product Concept

DNA Microarrays

~ 300 cancer-associated genes

DNA chip for diagnosis of cancer

Product development

Simple diagnostic for many types of cancer

Assembly of licenses proved impossible
- too many holders of IP
- excessive cost

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
- DVD pool, MPEG-2 pool, FireWire pool
- Patent holders agree to combine their technologies via a separate entity

3rd Party Aggregation
- Company combines technologies from multiple external sources

Forced Cooperation
- Radio Company of America (RCA)
- Companies required by government to allow combinations of technology
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

Source: USPTO, Raymond James & Assoc., Robert Stephens International Ltd
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

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<thead>
<tr>
<th>Benefits of patent pools</th>
<th>Criticisms of patent pools</th>
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<tr>
<td><strong>Reduced risk</strong></td>
<td><strong>Reduce competition by pooling of competitive patents</strong></td>
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<tr>
<td>• Infringement litigation</td>
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<tr>
<td>• Blocking patents</td>
<td><strong>Create incentives for price fixing and collusion</strong></td>
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<tr>
<td><strong>Reduced licensing costs</strong></td>
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<tr>
<td>• Stacked royalties</td>
<td><strong>Shielding of invalid patents</strong></td>
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<tr>
<td>• Licensing transaction costs</td>
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<td><strong>Stimulates innovation</strong></td>
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<td>• May remove patents from competition, driving ‘downstream’ innovation</td>
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<tr>
<td>• Integrate complementary technology</td>
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<tr>
<td>• Promotes dissemination of technology</td>
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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

Assembly of licenses

Vaccine development

Vaccine Co 1
Vaccine Co 2
Vaccine Co 3
Vaccine Co 4

Vaccine 1
Vaccine 2
Vaccine 3
Vaccine 4

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