Reverse Genetics Technology Patent Landscape

5th Meeting with International Partners on Prospects for Influenza Vaccine Technology Transfer to Developing Country Vaccine Manufacturers
Belgrade, Serbia, 27 – 28 March 2012

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Senior Commercialization Officer

PATH
A catalyst for global health

Photo: Gabe Bienczycki
Overview

• PATH’s interest in reverse genetics technology
• Reverse genetics technology patent portfolio
• Scope of reverse genetics technology patent portfolio
• Rights conferred by reverse genetics technology patent portfolio
• Options
Innovation in influenza vaccine development

PATH is doing its part in the global fight against influenza by implementing a multifaceted strategy to expand influenza vaccine solutions that will be optimal for the developing world.
PATH’s Interest in Reverse Genetics Technology

- PATH collaborates with WHO and private- and public-sector partners to advance the development of influenza vaccines
- In exchange for PATH’s support, our partners commit to global access
  - available, accessible, affordable
  - developing country populations
- Use reverse genetics technology to make influenza viral seed stock
- Restrictions on use of reverse genetics technology may be a potential barrier to achieving PATH’s global access goals
Owners and Licensee

Owners:

- Mt. Sinai School of Medicine (Palese et al.)
- Wisconsin Alumni Research Foundation (Kawaoka et al.)
- St. Jude Children’s Research Hospital (Hoffman)

Licensee:

- Aviron / MedImmune / Astra Zeneca
<table>
<thead>
<tr>
<th>Owner</th>
<th>Claim Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mt. Sinai</td>
<td>Influenza virus with heterologous RNA sequence that is reverse complement of mRNA coding sequence, operatively linked to an influenza viral polymerase binding site.</td>
</tr>
<tr>
<td>WO 2001/04333 July 14, 2000</td>
<td></td>
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<tr>
<td>Owner</td>
<td>Claim Summary</td>
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<tr>
<td>St. Jude</td>
<td>Plurality of bidirectional transcription vectors, each with DNA corresponding to a viral genomic segment between (i) RNA polymerase I promoter and a terminator sequence and (ii) RNA polymerase II promoter and a polyadenylation signal.</td>
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<tr>
<td>WO 2001/083794 April 27, 2001</td>
<td></td>
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<tr>
<td>WARF</td>
<td>Viruses made using of a plurality of expression vectors, each vector has a promoter, DNA encoding an influenza protein, and a transcription termination. No helper virus required.</td>
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<tr>
<td>WO 2000/060050 April 5, 2000</td>
<td></td>
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# Filing Summary

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<tr>
<th>Application Number (Owner)</th>
<th>Brazil</th>
<th>China &amp;/or H.K.</th>
<th>India</th>
<th>Israel</th>
<th>Mexico</th>
<th>Russia</th>
<th>S. Africa</th>
<th>S. Korea</th>
<th>AU/CA /EP/JP/NZ/US</th>
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* ex-US patents expired

** according to MedImmune
Rights Conferred By Patent Portfolio

• Early Mt. Sinai patents expired in 2010
• Other patents potentially expire in 2020 and 2021

• Prevent others from making, selling, using
  • Viral seed stock
  • Vaccine
  • Methods of use

• Patents may exist in other countries
  • Verify at each country’s patent office
Options

• Sublicense

• Authorized laboratories make seed strains available
  o Must comply with MTA terms and patent law

• Locate laboratory and/or factory where no patents exist
  o Limitations

• Design around

• Other?
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