Patent Landscape of H5N1 Influenza Virus

Ben Prickril, PIIPA Advisor

WIPO-FAO Patent Landscaping Symposium

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Prepared for WIPO by Public Interest Intellectual Property Advisors (PIIPA)

Team members:

Ben Prickril, Project Coordinator
Carol Nottenburg – Cougar Patent Law, USA
Steven Price – Oklahoma State University, USA
Suzannah Sundby JD – Smith, Gambrell & Russell LLP, USA
Martin Marcus – EMJAYEM Consulting, Ottawa, Canada
Martin Friede – WHO, Switzerland
David Fedson – Consultant, France

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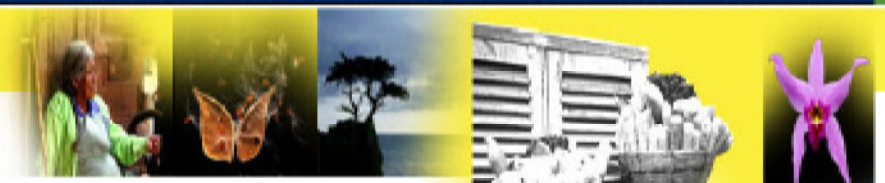

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Goals!

- Produce clear, brief and comprehensive patent landscape and update regularly to reflect current state of play.
- In anticipation of a potential pandemic, provide guidance to stakeholders from government, research community, health professionals, and civil society concerning intellectual property and H5N1.
- Classify patents into related groups or “clades” in order to assess geographic, technological, and other potential patterns.
- Followup preliminary analysis to include patents encompassing vaccines, diagnostics, and pharmaceutical applications.

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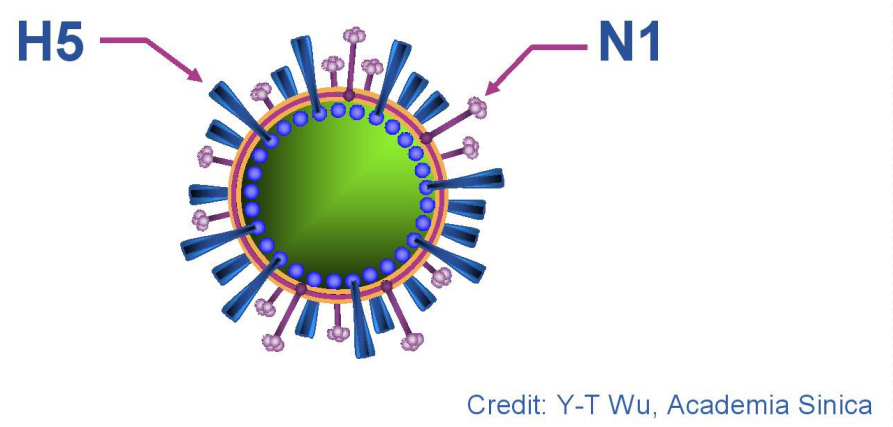
The Science of H5N1

- H5N1 is a <u>single-stranded RNA virus</u>

(Hemagglutinin) (Neuraminidase)



Credit: Y-T Wu, Academia Sinica

- Media reports of "H5N1" or "avian flu" refer to the **h**ighly **p**athogenic **a**vian **i**nfluenza strain "HPAI A(H5N1)"

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Characteristics of H5N1

- Highly pathogenic in birds
- *Epizootic* (an epidemic in nonhumans) and *panzootic* (affecting animals of many species)
- Killed tens of millions of birds and caused culling of hundreds of millions of others to stem its spread.
- H5N1 virus is the world's largest current pandemic threat.

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Intellectual Property Aspects

- **Criteria for inclusion:** Patents and patent applications with one or more:
  - claims to compositions of genes and gene products;
  - claims to vaccines comprising specific gene and gene product sequences that encompass H5N1;

- **Criteria for exclusion:** Patents and patent applications that only have:
  - claims to methods for diagnostics;
  - methods of making vaccines;

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Patent Categories

- Patent documents are divided into three categories:
  - Influenza HA and NA genes and gene products that specifically claim or may encompass H5N1 sequences;
  - Vectors or cells containing influenza genes and vaccines containing influenza gene products;
  - siRNA and antisense directed to H5N1, also oligonucleotides having H5N1 sequences

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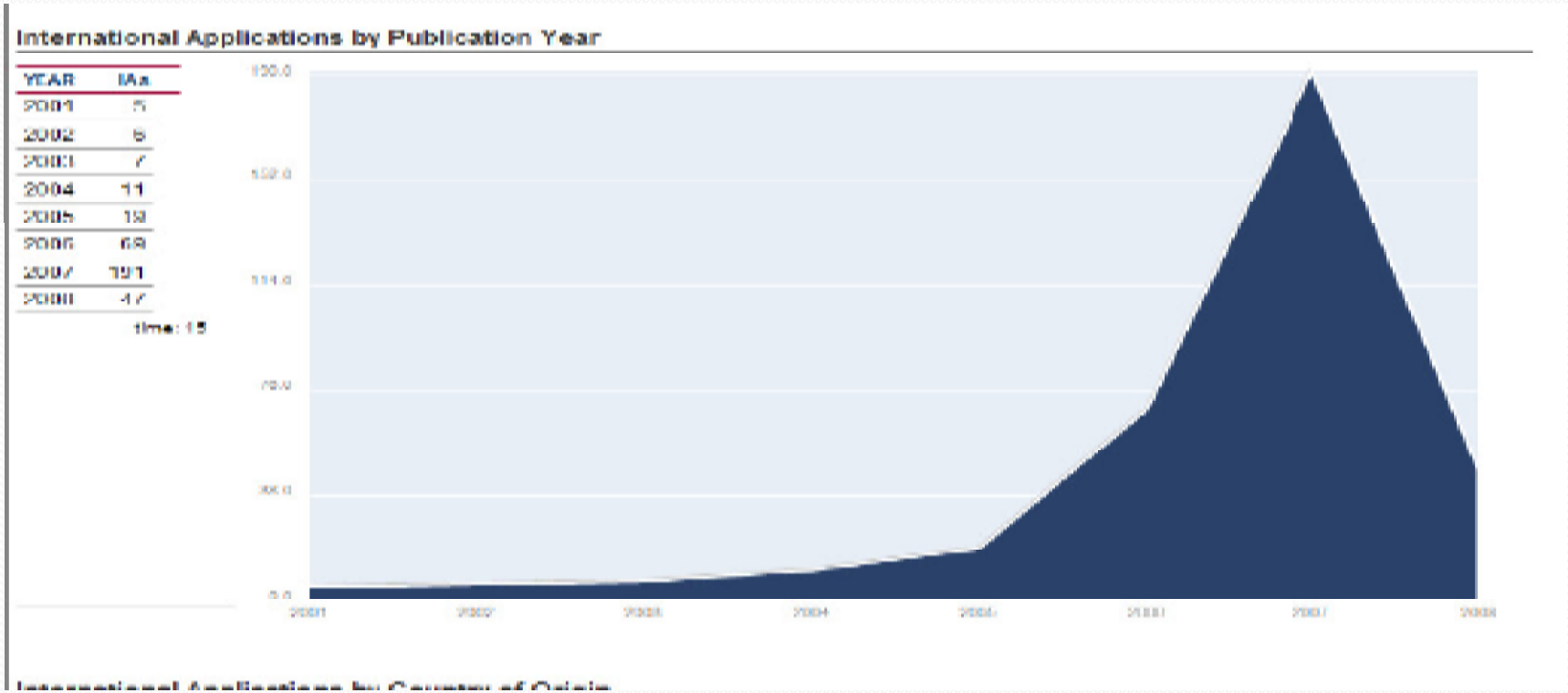
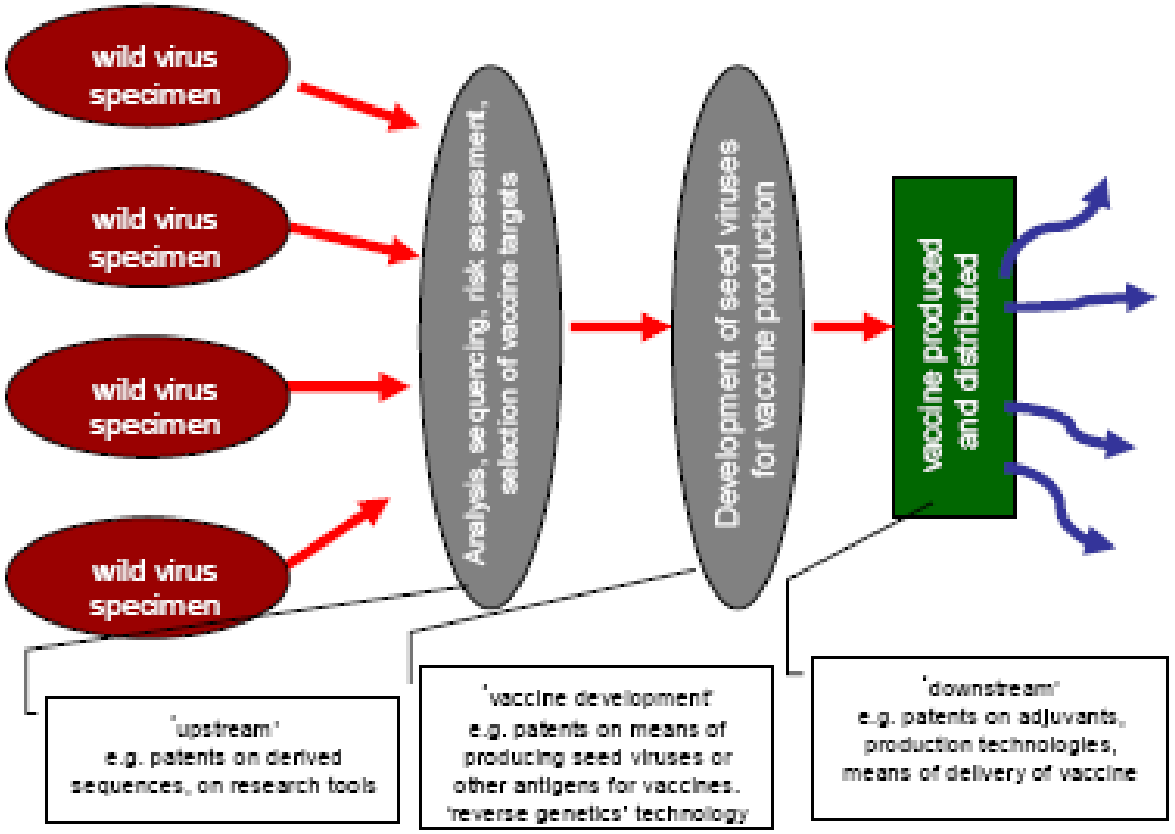
Distribution of Patent Families

CATEGORY	NO. OF PATENT FAMILIES
Influenza HA and NA genes and gene products that specifically claim or may encompass H5N1 sequences	6
Vectors or cells containing influenza genes and vaccines containing influenza gene products	18
siRNA and antisense directed to H5N1, also oligonucleotides having H5N1 sequences	12

“You searched for: (h5n1) (355 IAs)”



Upstream & Downstream Patents



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Influenza HA and NA genes and gene products claiming H5N1 sequences

- *No* applications claim native DNA or protein sequences of H5N1 influenza isolates
- *All* of these six applications are patent *applications*
- Exemplary claim: claim 1 of US 2005/042229 (Medimmune)

  An isolated polypeptide wherein said polypeptide is selected from the group consisting of:

  a) a polypeptide encoded by a polynucleotide sequence of SEQ ID NOS: 1-34;

  b) a polypeptide of SEQ ID NOS:35-68;

  c) a polypeptide encoded by a polynucleotide sequence which hybridizes under highly stringent conditions over substantially the entire length of a polynucleotide sequence encoding (a; and

  d) a polypeptide comprising all or a fragment of (a), (b), or (c), wherein the sequence comprises a hemagglutinin polypeptide, or a fragment thereof, or a neuraminidase polypeptide or a fragment thereof.

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Vectors or cells containing influenza genes and vaccines containing influenza gene products

- 17 patents/applications sub-divided into two groups that claim either 1)constructs and components useful for production of vaccines or 2) vaccines.

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siRNA and antisense directed to H5N1 & oligonucleotides having H5N1 sequences

- Sequences are generally short (15-60 nucleotides), and likely to be chosen from a specific gene or gene region.
  - *Oligonucleotides:* short, single-stranded nucleic acid molecules about 20 bases to 50 bases long.
  - *Antisense molecules:* single-stranded nucleic acid molecules that modify gene expression.
  - *Small interfering RNA (siRNA):* double-stranded ribonucleic acid molecule that inhibits the gene expression.
- ***Antisense* molecules and *siRNAs* can modulate the expression of a given gene**

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Main Conclusions

- We have identified relatively few patents and patent applications specifically directed to H5N1, and a very small number of issued patents. These are grouped according to genetic composition.
- H5N1 Patents & Applications are geographically limited, and concentrated in US, Europe, and Japan
- Patents/Applications related to therapeutics and devices await further analysis

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Search Strategy

- First: Keywords (H5N1, Avian Influenza, etc.)
- Second: BLAST searching of claim sequences specific to H5N1
- Third: Review of titles, abstracts, and claims if available.

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Search Strategy & Patent Data

- Search focused on patents & applications with claims directed to sequences of H5N1
- Several databases searched, including:
  - WIPO's PatentScope PCT database (www.wipo.int/pctdb/en/)
  - USPTO (www.uspto.gov/patft/index.html)
  - Cambia (www.patentlens.net)
  - European Network (esp@cenet)
  - PatBase (all jurisdictions; www.patbase.com)
  - MicroPatent (www.micropat.com)
  - INPADOC (65 countries; through EPO)
  - Other (e.g., Canadian & Australian patent offices)

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Observations

- As patents & applications move further downstream, landscape analysis must evolve in order to maintain relevance.
- Landscape of H5N1 must be “bottom up”, and meet needs of pandemic responders to produce vaccines and other interventions quickly.
- Cambia and other bioinformatics analyses will be used complement present landscape analysis.
- Urgent need remains to provide IP guidance to bolster freedom to operate in fighting potential H5N1 pandemic.

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