

Patent Landscaping for Vaccines:

Patent information, tools and methodologies

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**Innovation, Information, Evidence and
Research (IER)**



**World Health
Organization**

Patent Landscaping within WHO/IER

- To promote the development and production of vaccines
 - Identifying where IP is a barrier to access for vaccines
 - Support research on alternative technologies
 - Negotiate with IP holder on behalf of developing country manufacturers
 - Identify technology areas to promote where IP is not a barrier
- Monitor patenting activities
 - Identify target areas where innovation taking place (or dying off)
 - Identify countries / institutes investing in R&D
 - Are public-sector-supported activities resulting in potential barriers to access: promote best-practices in licensing



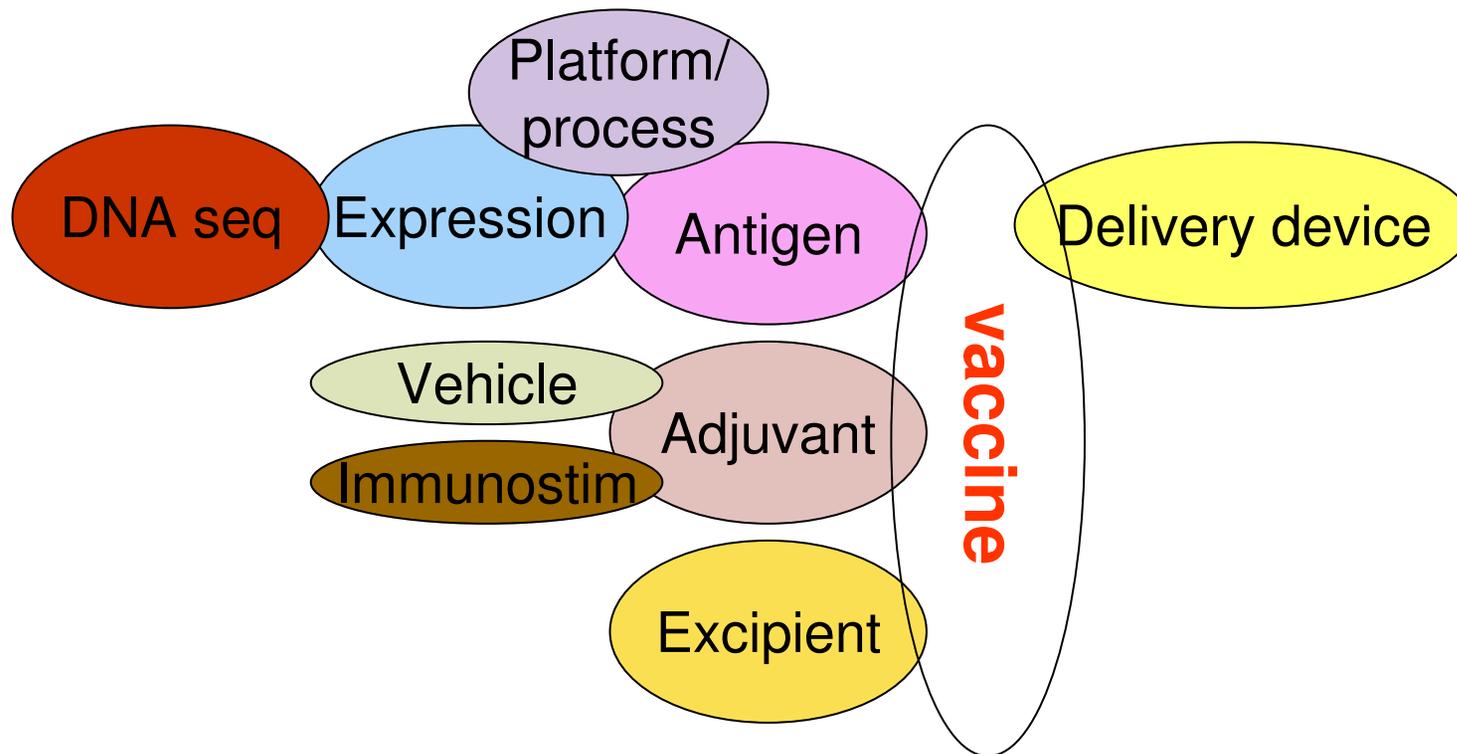
Why vaccines are different to drugs

- True 'generic' vaccines do not exist
- Complex biological drugs: equivalence can not be demonstrated by simple tests. Full clinical safety and efficacy (or surrogate) testing of 'copy' required.



The complexity of vaccine IP

- A modern vaccine is protected by multiple levels of IP often licensed from multiple partners



- Also implies that in many cases 'work arounds' possible

Example: Influenza Vaccine Production Method

http://www.who.int/vaccine_research/diseases/influenza/Mapping_Intellectual_Property_Pandemic_Influenza_Vaccines.pdf

- Objective: identify which influenza vaccine technologies free IP barriers, or identify licensing partner.
- Landscape method:
 - For each known process / composition of matter:
 - Search keywords in claims in EU and US application and granted patents
 - Identify relevant claims, identify legal status in EU / US
 - Search information on filing in developing countries
 - Challenge: legal status in developing/emerging countries
 - DC Manufacturer advised to see if application exists in their country.
- Tool used: Cambia's Patent Lens



Conclusion on influenza vaccine technology landscape

- Methods of making existing influenza vaccines in public domain.
 - Public-sector technology transfer and training centers
 - Patent information very useful to identifying key production steps
- Critical adjuvant technology for pandemic influenza vaccines no IP in developing countries.
 - Public-sector technology transfer and training centers
- One barrier to pandemic vaccines: reverse genetics
 - Research on alternatives
 - Negotiation



Example: Human Papilloma Virus

- Interest from DC vaccine manufacturers to make HPV vaccine for developing countries.
- Landscape method:
 - A) Technical analysis of critical components of existing approved HPV vaccines:
 - Identify minimal set of genes, sequences, combinations etc required.
 - B) Outsourced search (PIIPA)
 - identify IP claiming critical components of approved HPV vaccine
 - Search on claims for HPV gene sequence, vaccine comprising,..
 - look for equivalents in Brazil, Indonesia, Thailand, S. Africa : country office



Issues identified

- Access to patent information from developing/emerging economy countries.
- Databases not reliable (national, inpadoc)
- Machine translation not reliable
 - Example: Peptide for the treatment of cancer with Patrick Pictures million dolphins virus (HPV) of human and other tumor
 - Different results searching database in national language or English.

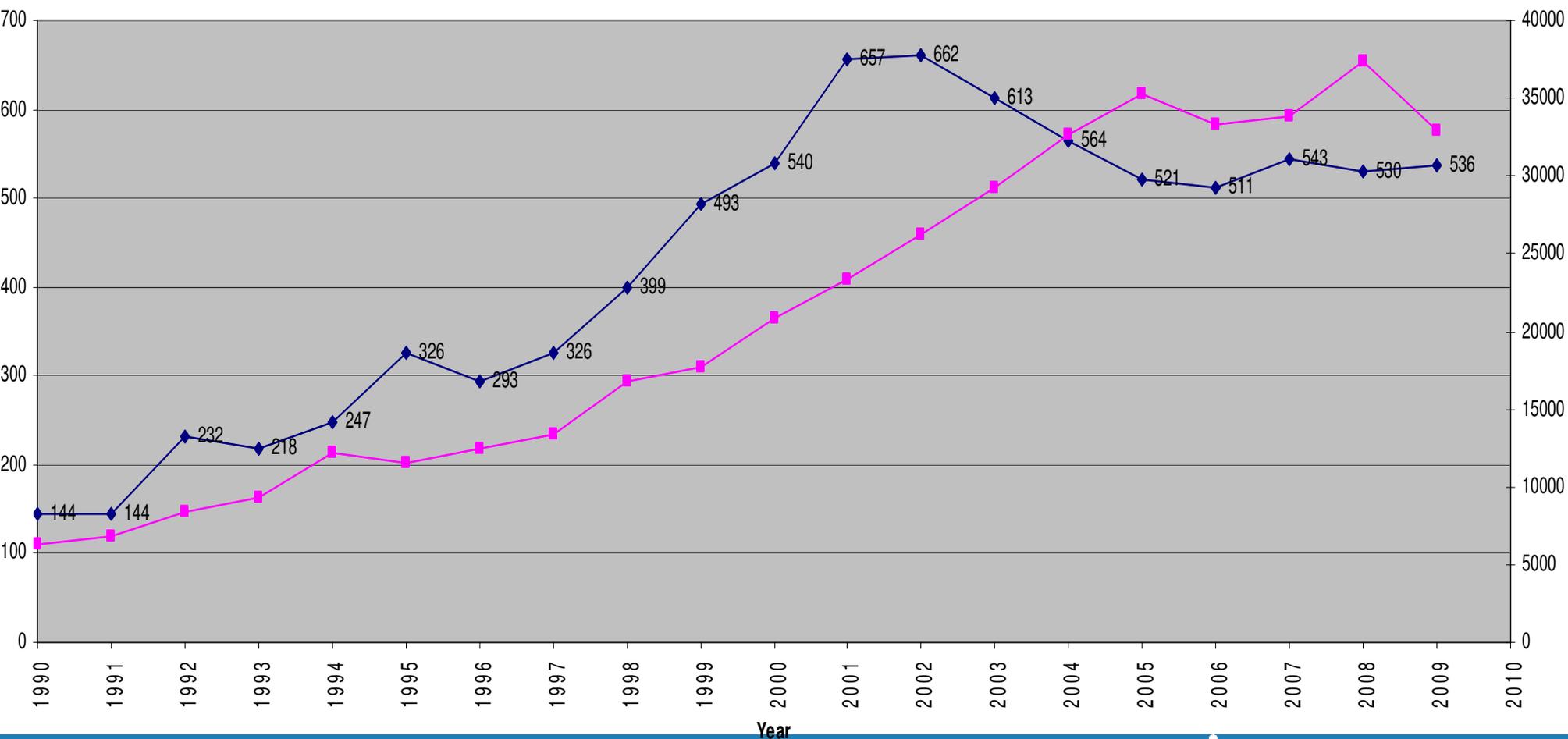


Broad patent landscape on vaccines

- For nearly all approved vaccines, IP is not a barrier.
 - Exception: HPV – significant barriers
- But.... 1990-2010 : ~9000 PCT applications on vaccines ???
 - What vaccines are these applications about ?
 - Who is doing this patenting ?
 - Public / private, which country origin, which country filing
 - Are trends going up, or down ?
- Study being conducted in collaboration with WIPO.

Time-line for applications on Vaccines vs Medicinal products (IC: A61K39+ vs A61K)

Trends in PCT applications for vaccines

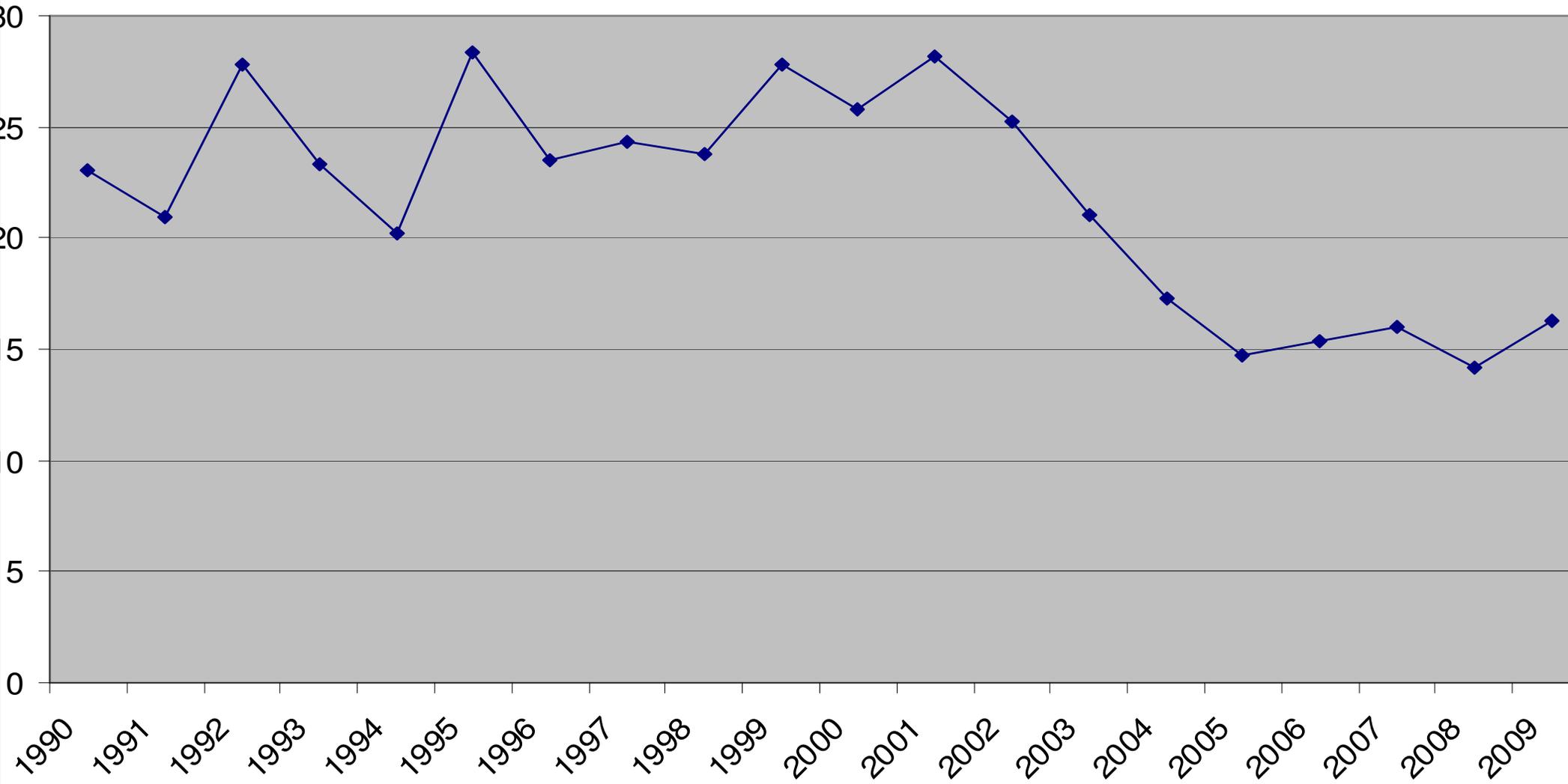


◆ Vaccines (A61K 39/00, C07K 14/00, C12N 15/00 + keywords)
 ■ Preparations for medicinal, dental, or toilet purposes (A61K)



Ratio of vaccine to medicinal product applications over time

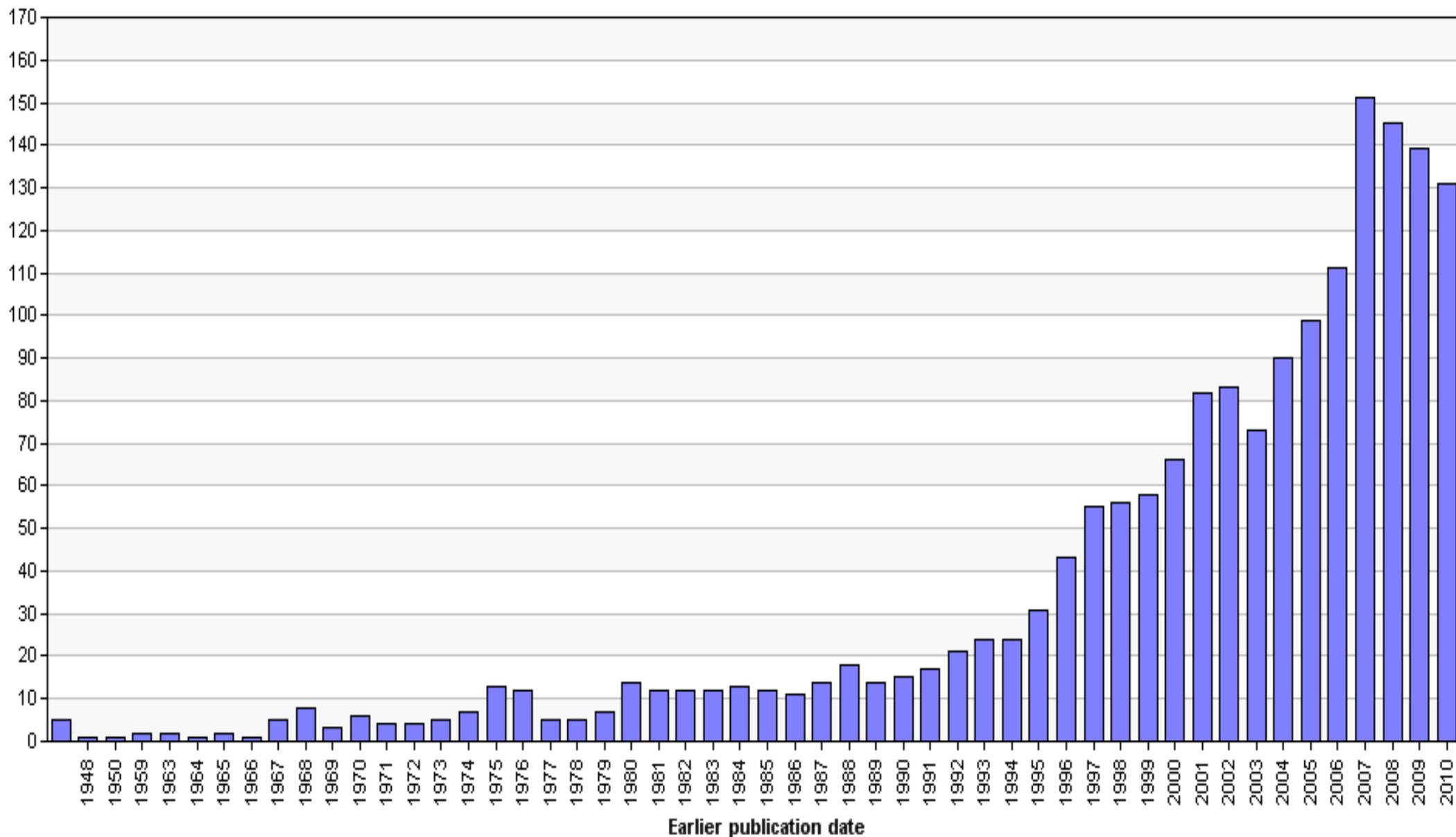
ratio of vaccine patents to medicinal patents



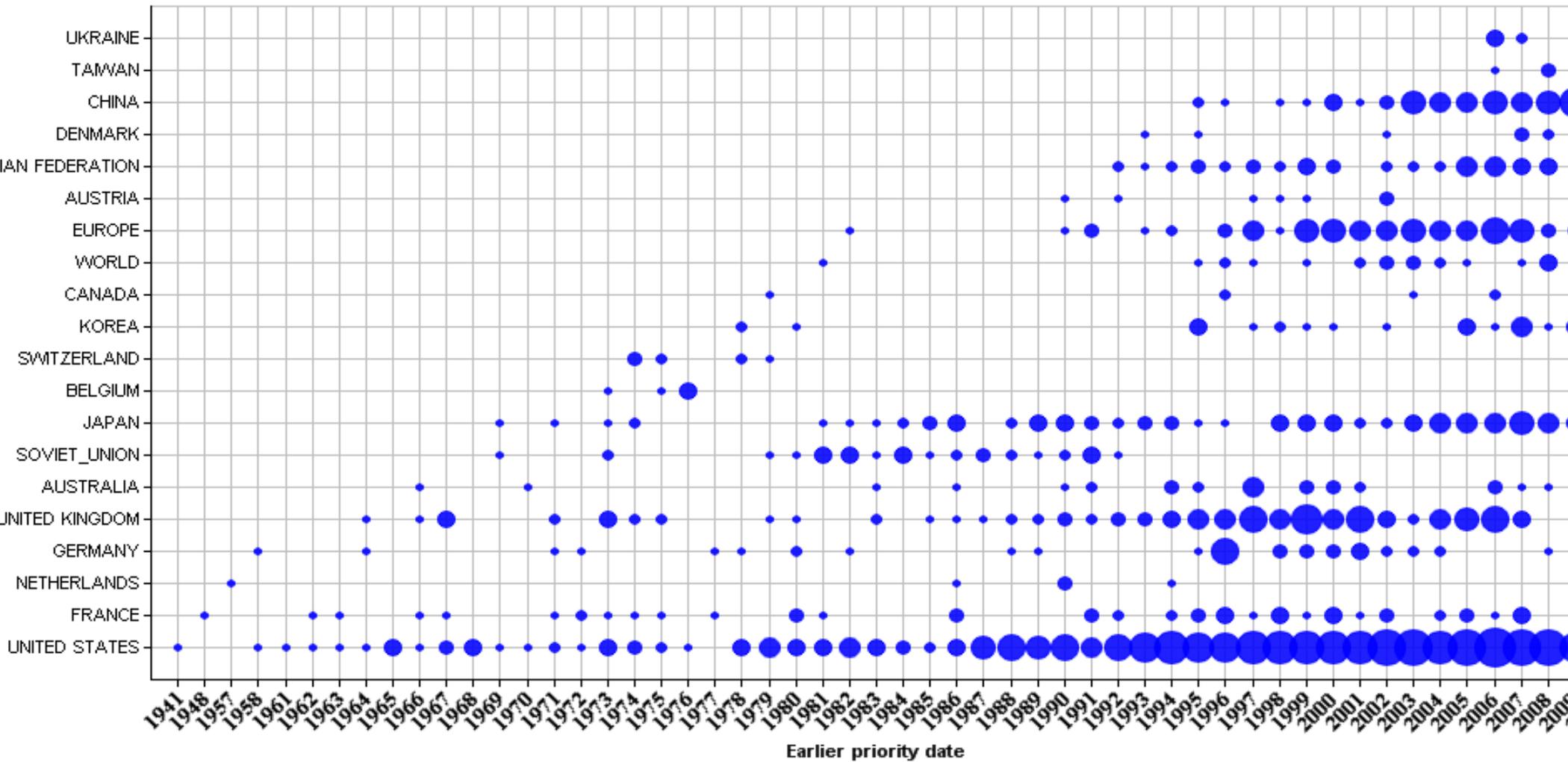
Using IC to search for disease-specific subsets within these applications

- Eg A61K39/145:
 - Medicinal preparations containing antigens or antibodies
 - Orthomyxoviridae: Influenza A, B, C.
- Overcomes language, machine-translation issues.
- But what about diseases such as HPV (discovered after patent classification system) ?

A61K-039/145 Distribution by date



A61K-039/145 Country priority timeline



Challenges identified from these activities

- Access to national legal-status information in developing countries
 - Inpadoc not reliable / up to date.
 - Need in-country evaluation of local IP situation.
 - Country of manufacture, intended countries for export...
- Define the question !!
 - Need close collaboration between technology expert and IP expert



Observations from promoting developing-country vaccine manufacture

- Insufficient capacity in developing countries with respect to:
 - Patent lawyers with understanding of the science behind the technology
 - Scientists with understanding of IP searching and interpreting
- For vaccines, legal FTO is only small part of barrier to access for developing country manufacturers:
 - Other IP: know-how, clinical data, regulatory dossiers
 - Licensing quicker than developing product *ab-initio*.
- Developing alternative processes for process patents requires R&D capacity.
 - DC vaccine manufacturers need to invest in this area.

