Patent Landscaping for Vaccines:

Patent information, tools and methodologies

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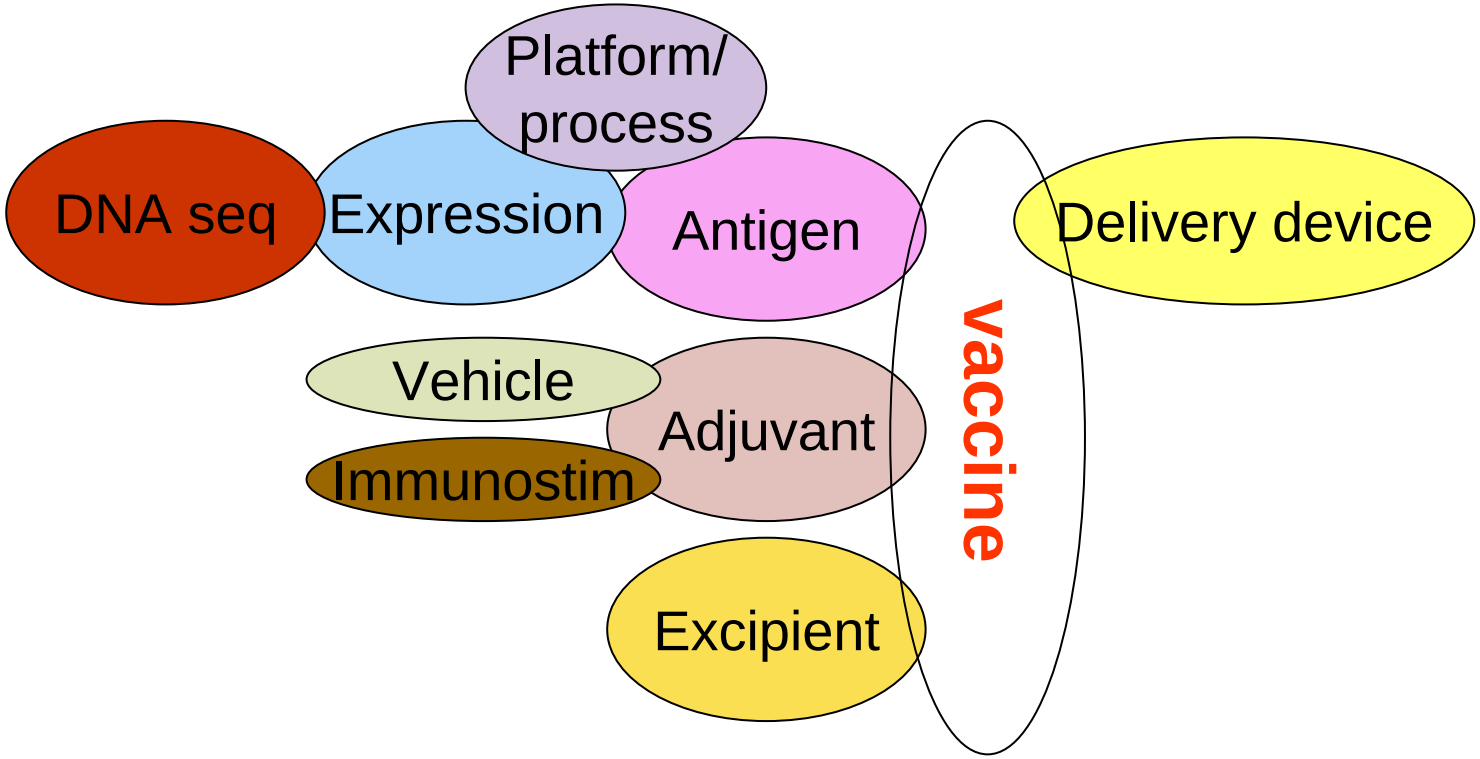
Patent Landscaping within WHO/IVR

- To promote the development and production of vaccines by developing-country vaccine manufacturers.
- Identifying where IP is a barrier to access for vaccines
- Support research on alternative technologies
- Identify technology areas to promote where IP is not a barrier

The complexity of vaccine IP

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



World Health Organization

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.

Top-down or Bottom-up approach ?

- Top-down: landscape entire field (eg. 'Influenza Vaccine')
  - Large number of 'hits'
  - Does not require detailed technical knowledge of topic
  - Value: an idea of where field is going, areas of IP coverage
- Bottom up: search claims on specific concepts
  - Value: identify potential FTO issues.
  - Fewer hits
  - Knowledge intensive: requires detailed technical understanding of topic being researched.
  - Labour intensive: requires reading and interpreting claims

Example: Influenza Production Methods

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

- Objective: assist developing-country vaccine manufacturers identify most appropriate technology or licensing partner.
  - Numerous ways to make influenza vaccines (technical document)
- Landscape method: bottom-up
  - 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 (Inpadoc: EU / US)
    - From PCT application see designated countries
    - DC Manufacturer advised to see if application exists in their country.
- Tool used: Cambia's Patent Lens (search on claims)

Example: Human Papilloma Virus

- Objective: Interest from DC vaccine manufacturers to make HPV vaccine for developing countries. Need to know if such projects viable to fund (FTO issue)

- Landscape method: mix of top-down and bottom-up
  - A) Overview of IP on HPV
    - Outsourced search (Derwent)
  - B) identify IP claiming critical components of approved HPV vaccine
    - Search on claims for HPV gene sequence, vaccine comprising,.. Patent Lens
    - Identify interference/opposition proceedings
  - C) look for equivalents in India, China, Brazil : country office

Issues encountered

Claim analysis

Need to know whether US/EU equivalent in developing country.

- Inpadoc not reliable / up to date.
- Need in-country evaluation of local IP situation.
  - Country of manufacture, intended countries for export…
  - Claims

Analysis of expiry dates critical

- For vaccines development time long
- Policy issue: support R&D on antigens / adjuvants nearing end of pate life.
- Need to consider 'method of use' patent-life extension

Issues encountered

- Country-request is often for FTO identification: legal opinion
  - Can only help with identifying some non-exhaustive IP which should be considered.
- 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

Landscaping Issues

- Define the question !
- Landscaping only as good as description of technology to landscaper
  - Need close collaboration between technology expert and IP expert
- Public health community has inadequate knowledge of IP
  - 'Interpret' patent based on abstract or disclosure, not claims.
  - Often do not realize territorial/ temporal limitation

Observations

- 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 often preferable to developing product *ab-initio*.

- Developing alternative processes for process patents requires R&D capacity.
  - DC vaccine manufacturers need to invest in this area.