Patent Landscape Analyses of Vaccines, Diagnostics and Medicines: Policy and Practical Implications for Global Access

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Director, International Technology Transfer Institute (ITTI)
ITTI promotes science, technology and innovation in developing economies across the globe by building capacity in intellectual property (IP) management, technology transfer (TT) and information access and management in university, government and international research institutions.
Access to information drives innovation: accelerate access to essential, inclusive innovations having broad societal benefit, such as vaccines, medicines, diagnostics, green energy and agricultural technologies.
ITTI students have participated at professional functions, and engaged in high-level discussions with key organizations such as the U.S. Departments of Energy and Commerce, the White House Office of Science and Technology Policy, USAID, the World Bank, WHO, WTO and WIPO.
ITTI Participation, Patent Landscape of EML
Access to Medicines, Patent Information and Freedom to Operate
A Joint Technical Symposium by WHO, WIPO and WTO
February 18, 2011, WHO Headquarters, Geneva
The Engine of International Development: The Role of Intellectual Property (IP)

- IP Education & Training
- IP Capacity: Human & Institutional
- Enhanced Social & Economic Welfare
- Technology Transfer, Patenting, Licensing
- Improved Public Health & Nutrition
- International Partnerships in Product Development
- Widespread Access to Critical Innovations
- Critical Innovations in Health & Agriculture
ITTI Patent Landscape Projects

- HIV Vaccine Technologies
- Dengue Fever Diagnostics
- Chagas Disease Vaccines and Diagnostics
- WHO Model List of Essential Medicines
ITTI Clinic Patent Landscape: Methodology*

E.g., Delphion patent research platform (Thomson Reuters), keyword, assignee and inventor (identified by review of non-patent sources).

*BASIC protocol for ITTI Clinic patent landscape projects (caveats noted).
The foundation of any patent search: Non-patent Literature (NPL)
Publications and patents as information supports have many analogous features for example:

- author/inventor
- institution/assignee
- bibliographic referencing/patent system referencing
- bibliometric classification/official classification
- abstract
- full text
- reference to scientific literature/reference to patent or non-patent literature, etc.
However, there are important caveats!
The two sources of information are neither exclusive nor inclusive, but rather complementary.

When doing patent research, it is important to research both patent and non-patent literature, regardless of the intent, i.e., whether for prior art searching, freedom to operate analysis or patent invalidation research.
HIV Vaccine Patent Landscape: Methodology

HIV Vaccine Patent Landscape: Methodology

Patent search strategies included key-word, assignee, inventor. The initial keyword search encompassed terms and their synonyms, e.g.:

- DNA vaccine = genetic vaccine, nucleic acid vaccine, naked DNA,
- enabling technologies for their production (including expression and purification) and composition (gene sequences, formulations),
- as well as whole vaccines (immunological composition).
HIV Vaccine Patent Landscape: Methodology

Subsequent patent search strategies included key-word, assignee, inventor, patent classification codes, and complex hybrid searches incorporating all of these simultaneously. Searching was iterative and redundant. Patent data collected included patent expiration date, patent abstract, claims, owners (assignees), their country of origin and international patent applications filings.
Broaden & narrow search...

- Unrestricted full text
- Bibliographic file

Try different field restrictors:
- Class
- Spec
- Abstract
- Claims
- Title

Mix & match with keywords
Patent search is an iterative process

• …continuous modification of searches as more information becomes available
• Recheck
• Locate
• Lead
• Tips
Recall & precision

- **Recall** describes the idea of all items which are relevant (useful) to a query. In the real world, only a subset of the relevant items are found.
- **Precision** describes the idea of only those items which are relevant to a query. Again, in the real world, many items which are matched by a query are not really relevant to the question, although they might match the vocabulary.
- In information retrieval, there's a classic tension between recall and precision. Specifying more recall (trying to find all the relevant items), you often get a lot of junk. If you limit your search trying to find only precisely relevant items, you can miss important items because they don't use quite the same vocabulary.
HIV Vaccine Technologies
Patent Landscape
The ITTI Clinic Team assembled a representative HIV vaccine patent landscape for a prime-boost, DNA/adenoviral vaccine platform, to illustrate how patent information can help identify obstacles, maximize opportunities and make informed IP management strategy decisions towards the development and deployment of an efficacious HIV vaccine.
AIDS and HIV infection occur worldwide. At the end of 2008, more than 33 million people were living with HIV/AIDS. Although sub-Saharan Africa remains the most affected part of the world (22.4 million cases), notable increases in HIV infection have occurred from 2001 to 2008 in Eastern Europe and throughout Asia. Ninety-seven percent of new infections come from low- and middle-income countries. (CDC.gov)
Aureka ThemeMap 731 HIV Vaccine Patent Families
Global HIV Vaccine Patenting vs. Occurrence of HIV Infection
HIV Protein Peptide Vaccines
Patent Landscape (with a bit more details)
Patent documents on peptide vaccines generally fall into 11 categories:

(1) Prime Boost
(2) Protein
(3), Peptide
(4) Peptide Formulation
(5) Epitopes
(6) Conjugates
(7) Peptide Screening
(8) Antibodies to HIV
(9) Antibodies Screening Library
(10) Tat-based Vaccine
(11) Therapeutic v. Prophylactic.
The initial keywords used in the four main categories in the subsequent search round were:

1. First category (assigned to search for subunit (envelope) proteins): Protein, vaccine, HIV, human immunodeficiency virus, subunit, sequence, formula, inoculation, immunogen, immunogenic composition, immunological composition, envelope, retrovirus, lentivirus.

2. Second category (assigned to search for patents relating peptide and sub-category formulae, epitope, conjugate and screening method): Protein, peptide, polypeptide, sequence, formula, HIV, vaccine, immune response, epitope*, HIV, human immunodeficiency virus, vaccine, amino acids, vaccines, human immunodeficiency virus, conjugates, screening.

3. Third category (assigned to search for patents relating to antibodies (screening tool)): HIV, human immunodeficiency virus, vaccine, neutralizing antibody, nabs, epitope, screening, peptide, amino acids, cytotoxic, humoral.

HIV Protein/Peptide Vaccines Principal Assignees
HIV Protein/Peptide Vaccines Principal Inventors
HIV Protein/Peptide Vaccines: Patent Doc. Publication Trend
HIV Protein/Peptide Vaccines  IPC Classes

A61K A — Human Necessities; Medical or Veterinary Science 296
C07K C — Chemistry; Metallurgy; Organic Chemistry 285
HIV Protein/Peptide Vaccines  US Classes

530/350  Peptides
424/188.1 Immunodeficiency Virus
Dengue Fever
Diagnostics
Patent Landscape
Dengue Fever Diagnostics Patent Landscape

Dengue fever (DF), a rapidly emerging global health threat, is caused by any of four closely related viruses (serotypes): dengue 1-4. Infection with one serotype does not protect against the others; sequential infections put people at greater risk for dengue hemorrhagic fever (DHF), dengue shock syndrome (DSS). Dengue is transmitted by mosquitoes.
Dengue Fever Diagnostics Patent Landscape

About 2.5 billion people, or 40% of the world’s population, live in areas where there is a risk of dengue transmission. Dengue is endemic in at least 100 countries in Asia, the Pacific, the Americas, Africa, and the Caribbean. The World Health Organization (WHO) estimates 50 to 100 million annual infections, including 500,000 DHF cases and 22,000 deaths, mostly among children.
Dengue, countries or areas at risk, 2010

Countries or areas where dengue has been reported

The contour lines of the January and July isotherms indicate areas at risk, defined by the geographical limits of the northern and southern hemispheres for year-round survival of Aedes aegypti, the principal mosquito vector of dengue viruses.

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Production: Public Health Information and Geographic Information Systems (GIS) World Health Organization

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# Dengue Diagnostic Patent Landscape Keyword Summary

<table>
<thead>
<tr>
<th>Dengue</th>
<th>Diagnostic</th>
<th>Specific Test</th>
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<tbody>
<tr>
<td>Flavivir*</td>
<td>Diagnos*</td>
<td>PCR or Polymerase Chain Reaction</td>
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<tr>
<td>Vir*</td>
<td>Detect*</td>
<td>ELISA or Enzyme-Linked Immunosorbent Assay</td>
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<tr>
<td>IgM</td>
<td>Kit*</td>
<td>NS1* or NS-1*</td>
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<tr>
<td>IgE</td>
<td>Identific*</td>
<td>Immunoglobin</td>
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<tr>
<td>IgG</td>
<td>Mark*</td>
<td>Assay*</td>
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<tr>
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<td>BioMark*</td>
<td>Analyt*</td>
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<tr>
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<td>Immunodetec*</td>
<td>Optic* Biosens*</td>
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</table>
Dengue Diagnostic Patent Landscape
Categorization of Patents:

1. Diagnostic Kit
2. Methods of Diagnosis
3. Compositions of Kits
4. ELISA
5. PCR
6. Luminescence Biosensors
7. Spectroscopy
8. Dengue Specific
9. *Flavivirus* Specific
Dengue Diagnostic Patent Landscape Filing Trend

Source: Thomson Innovation®. www.thomsonscientific.com
# Dengue Diagnostic Patent Landscape: Main US Classes

<table>
<thead>
<tr>
<th>US Class/Sub-Class</th>
<th>Patent Count</th>
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<tbody>
<tr>
<td>435/005 virus or bacteriophage</td>
<td>60</td>
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<tr>
<td>435/006 testing with nucleic acid</td>
<td>35</td>
</tr>
<tr>
<td>424/218.1</td>
<td>16</td>
</tr>
<tr>
<td>435/007.1</td>
<td>15</td>
</tr>
<tr>
<td>530/350</td>
<td>14</td>
</tr>
<tr>
<td>435/235.1</td>
<td>11</td>
</tr>
<tr>
<td>435/069.1</td>
<td>10</td>
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</tbody>
</table>
Filing date of dengue diagnostic patent documents (290 families) in various jurisdictions (including WIPO/PCT and EPO) over 17 years. Patent filing increases in an exponential manner from 1992 in US and WIPO, with a steady increase in all jurisdictions since 2005 (Patent iNSIGHT Pro).
Top Assignees Relevant Dengue Diagnostic Patents
World map of coded relevant and emerging dengue diagnostic

290 patent families, global filing trend

From: http://www.traveldoctor.info/diseases/18.html
Chagas Disease Vaccines and Diagnostics Preliminary Patent Landscape Analysis*

*Also searched various Latin American National Patent Collections via WIPO PatentScope

http://ameliecalot.es/2011/02/08/%C2%BFque-es-el-chagas/
Chagas disease is caused by *Trypanosoma cruzi*, a parasite related to the African trypanosome that causes sleeping sickness. It is spread by reduvid bugs and is one of the major health problems in South America. Due to immigration, the disease also affects people in the United States.
Countries endemic for the Chagas Disease shown in Blue (WHO 2008).
Top Assignees

Number of assigned patents/patent applications

- Abbott Labs
- Corixa/GlaxoSmithKline
- Louis Kirchhoff
- University of Georgia Research
- FIOCRUZ
- Steven G. Reed
- Rockefeller University
- University Federal Minas Gerais
- CONICET
- Osaka Bioscience Institute
Countries endemic for tChagas Disease (flagellate protozoan *Trypanosoma cruzi*) shown in Blue (WHO 2008).

Chagas Disease vaccines/diagnostics, global patent filing trend *(PRELIMINARY DATA)*
WHO Model List of Essential Medicines
Patent Landscape
Essential medicines …satisfy the priority health care needs of the population … selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

Source:
http://www.who.int/topics/essential_medicines/en/
Essential medicines are intended to be available within the context of:

- functioning health systems
- at all times
- in adequate amounts,
- in the appropriate dosage forms
- with assured quality
- adequate information, and
- at a price the individual and the community can afford.

Source: http://www.who.int/topics/essential_medicines/en/
91 Total Medicines

17 Meds From Dr. Attaran 2003 Study
74 Meds From Additions to EML Since 2003

78 Investigated Medicines

After removing 13 Products Having A High Probability of Non-existent Patents or that Were Not Singly Patentable Products

70 Base Patents

Obtained from the 78 Investigated Medicines. Duplicate Patents Were Removed.

166 Unique Patents

After Removing Duplicate Patents Found in Both Base Patents and Orange Book Patents.

152 Orange Book Patents

Obtained from the 78 Investigated Medicines. Duplicate Patents Were Removed.

27568 Family Patents

Generated Using INPADOC, DWPI, and TotalPatent. Family Documents Were Obtained for Each of the 166 Unique Patents.
EML Global Patent Documents. Consolidation of a total of 27568 patents identified for medications on the EML and its related family members. 166 unique patents identified using the ITTI Clinic’s approach were subjected to family data analysis using INPADOC, DWPI, and LexisNexis® TotalPatentTM generating a total of 27568 patents in multiple families. The patents were de-duplicated prior to consolidation. Number of medicines patented per jurisdiction for all years. Regional office filings were detected: ARIP=15, OAPI=17, EAPO=13, EPO=41, WIPO=30.
EML Global Patent Documents. Consolidation of a total of 27568 patents identified for medications on the EML and its related family members. 166 unique patents identified using the ITTI Clinic’s approach were subjected to family data analysis using INPADOC, DWPI, and LexisNexis® TotalPatentTM generating a total of 27568 patents in multiple families. The patents were de-duplicated prior to consolidation. Number of medicines patented per jurisdiction post 1990. Regional office filings were detected: ARIPO=14, OAPI=11, EAPO=14, EPO=34, WIPO=30.
ITTI Patent Landscape Analyses: Practical Implications
Patent information is useful for not only legal purposes, but also business, scientific and policy reasons.

A standardized protocol is a critical tool for identification and analyses of patents appurtenant to advances in health innovations, especially as applicable to developing countries and neglected diseases.

Protocols should be made available, and indeed taught to, all developing countries, with particular focus on the developing nations.

Electronic patent databases (internet) albeit improving, still do not provide reliable coverage of, in particular, developing and emerging regions, e.g., Africa and South America.

In order to evaluate and access innovations crucial for public health in developing countries, an ability to identify what is available, where it is located, and who owns it is fundamental. Patent information mining can help to answer these questions, and facilitate shopping the global innovation marketplace.
Patent landscapes are important and practical tool for making up-front strategic (research) decisions and then formulating appropriate options towards implementation (vaccine development and deployment): what areas to avoid (heavily patented), where to seek licenses, where to seek collaborations and where there is open space (or may soon be as patents expire). Clark et al., Vaccine
Short communication

Patent data mining: A tool for accelerating HIV vaccine innovation

K. Clark, J. Cavicchi, K. Jensen, R. Fitzgerald, A. Bennett, S.P. Kowalski

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ABSTRACT

Global access to advanced vaccine technologies is challenged by the interrelated components of intellectual property (IP) management strategies, technology transfer (legal and technical) capabilities and the capacity necessary for accelerating R&D, commercialization and delivery of vaccines. Due to a negative association with the management of IP, patents are often overlooked as a vast resource of freely available, information akin to scientific journals as well as business and technological information and trends fundamental for formulating policies and IP management strategies. Therefore, a fundamental step towards facilitating global vaccine access will be the assembly, organization and analysis of patent landscapes, to identify the amount of patenting, ownership (assignees) and fields of technology covered. This is critical for making informed decisions (e.g., identifying licensees, building research and product development collaborations, and ascertaining freedom to operate). Such information is of particular interest to the HIV vaccine community where the HIV Vaccine Enterprise, have voiced concern that IP rights (particularly patents and trade secrets) may prevent data and materials sharing, delaying progress in research and development of a HIV vaccine. We have compiled and analyzed a representative HIV vaccine patent landscape for a prime-boost, DNA/adenoviral vaccine platform, as an example for identifying obstacles, maximizing opportunities and making informed IP management strategy decisions towards the development and deployment of an efficacious HIV vaccine.
ITTI Patent Landscape Analyses: Practical Implications
Data presented in the ITTI EML patent study support the proposition that global patenting trends follow economic development and markets; this is a dynamic and fluid situation across the world; patentees will likely file patent applications in more countries as viable economic markets expand accordingly.

- Patents per se might not be a primary obstacle for access to vaccine and diagnostics, and EML pharmaceuticals, in many developing countries, as they are consistently not detected in patent family data from developing nations and regions (yet caution in assessing FTO is always necessary).
- More recent vaccine and diagnostics, and EML pharmaceuticals, appear to have greater global patent filings, which is not inconsistent with generally increasing global trends in patenting activity.
- Countries need to understand that patent information access and management is integral to an overall intellectual property and innovation development agenda.
Acknowledgement
Professor Jon R. Cavicchi, J.D., LL.M., Ph.D. (Hon) has served for almost two decades at Franklin Pierce Law Center as Professor and chief administrator of the only academic Intellectual Property Library in the Western Hemisphere. He teaches a four-semester, seven course curriculum in patent informatics to law and graduate students. He is originator and producer of the highly regarded open source website for IP research, The IP Mall at www.ipmall.info. He is Research Director of ITTI. He is an author and speaker on Intellectual property research tools and strategies.
Questions?
Thank you for attending!
Disclaimer

The patent data and related information presented herein are neither inclusive nor all encompassing, and are presented solely as an informational and educational resource, to facilitate a better understanding of the potential international patent literature landscape with regard to HIV Vaccine Technologies, Dengue Fever Diagnostics, Chagas Disease Vaccines and Diagnostics (Chagas Disease: flagellate protozoan *Trypanosoma cruzi*), and the WHO Model List of Essential Medicines.