University of New Hampshire School of Law Educational Report:
International Technology Transfer Institute (ITTI)
Patent Landscape of Malaria Sporozoite Vaccine and Related Technologies

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Introduction

Executive Summary

Malaria is a common and wide-spread infectious disease that is caused by the mosquito-borne *Plasmodium* parasite.[1] Nearly half of the world's population, especially in developing countries, is at risk for contracting malaria, and over one hundred countries continue to report endemic levels of this disease.[2] Currently, there is no effective malaria vaccine approved for use in humans.[3]

The World Health Organization (WHO) reported over two hundred million cases of malaria in 2010, which resulted in an estimated 655,000 deaths.[4] Children under the age of five represented 86% of all malaria deaths,[5] and six African countries — Nigeria, Democratic Republic of Congo, Burkina Faso, Mozambique, Cote d'Ivoire, and Mali — accounted for 60% of all malaria deaths.[6] Outside of Africa, malaria remains a serious health issue in areas of Southeast Asia, the Middle East, Oceania, and the Americas, particularly South America and the Caribbean.[7]

Malaria is caused by the *Plasmodium* parasite and is transmitted through the bite and feeding of the female *Anopheles* mosquito.[8] Some of the species of *Plasmodium* that can cause human malaria include *P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale, and P. knowlesi*.[9] Out of these, *P. falciparum* is by far the most deadly, disproportionately leading malaria-related deaths in the world.[10]

The purpose of this patent landscape was to search for, identify, and categorize patent documents that are focused on malaria vaccine technology related to structural elements of the *Plasmodium* sporozoite, as a discrete form of protozoa. Additionally, other vaccine technologies that involve sporozoites of other organisms were also included in the scope of the project to help inform sporozoite-based malaria vaccine development. One factor in identifying leaders in

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[1] U.S. Global Health Policy, *The Global Malaria Epidemic: Fact Sheet*, THE HENRY J. KAISER FAMILY FOUNDATION (Mar. 2011), http://www.kff.org/globalhealth/upload/7882-03.pdf.
[2] *Id*. Endemic is defined as "where a constant, measurable number of new cases and natural transmission occurs over time." *Id.*
[3] *Id*.
[4] *World Malaria Report: 2011*, WORLD HEALTH ORGANIZATION, http://www.who.int/malaria/world_malaria_report_2011/9789241564403_eng.pdf (last visited Mar. 15, 2012).
[5] *Id*.
[6] *Id*.
[7] *See* U.S. Global Health Policy, *supra* note 50.
[8] *Id*.
[9] Cyrus Daneshvar et al., *Clinical and Laboratory Features of Human* Plasmodium knowlesi *Infection*, 49 CLINICAL INFECTIOUS DISEASES 852, 852 (2009).
[10] *Battling Malaria Drug Resistance Along the Thai-Cambodian Border*, WORLD HEALTH ORGANIZATION, http://www.who.int/malaria/diagnosis_treatment/arcp/faq/en/index.html (last visited Mar. 15, 2012).

a particular field of research is by the size of a patent portfolio. This report tentatively identifies several key industry leaders within the malaria sporozoite vaccine industry, including:

- New York University (NYU or UNIV New York), located in New York, New York, is one of the largest private universities in the United States.[11] NYU is a major research institution with over 3,100 full-time faculty and awarding more than 25 different degrees.

- GlaxoSmithKline plc. (GSK) is headquartered in the United Kingdom and is one of the largest pharmaceutical companies in the world. GSK is actively researching vaccines for the World Health Organization's three priority diseases – HIV/AIDS, tuberculosis and malaria.[12]

- The United States Navy is very active in research and development of vaccines for diseases endemic in areas where the military are engaged in missions and initiatives.

- Eniricerche SA is an Italian company located in Milan, Italy.

- The United States Department of Health and Human Services (US Health) is the United States government's principal agency for protecting the health of all Americans.[13]US Health includes more than 300 programs affecting the public health.

ITTI commenced an intense three-month iterative search and coding process. Thomson Innovation was the primary patent searching platform, but ITTI also used other resources, including Lexis Total Patent™ and GenomeQuest.

An iterative search strategy utilizing keywords derived from the literature reviewed and initial searches to generate useful search strings (examples of keywords include: sporozoite, malaria, circumsporozoite, and vaccine); the searches also used United States Patent Classifications and International Patent Classifications that were identified through subsequent searches and team meetings. The combinations of keywords and classifications in search strings was useful for parsing the technology into compartments and allowing each team member to generate a different set of search results that keywords alone could not provide. This approach generated a broad set of patents. From here, ITTI used the keywords and classifications generated from this broad set of patents in subsequent rounds of searching. After each round of searching, ITTI would identify the most important keywords and classifications for use in subsequent search strings that became more defined and effective.

[11] http://www.nyu.edu/about.html (last visited May 15, 2012)
[12] http://www.gsk.com/about/company.htm (last visited May 15, 2012)
[13] http://www.hhs.gov/about/ (last visited May 15, 2012)

ITTI also performed nucleic acid and peptide sequence searching on the GenomeQuest platform to corroborate the results from conventional search methods. ITTI performed the sequence searches after searching non-patent literature in NCBI's PubMed which links directly to the Basic Local Alignment Search Tool (BLAST) database. The non-patent literature documents were generally scientific articles containing nucleotide and protein sequences related to the relevant technology. The sequences referenced in the articles were retrieved from BLAST and then inserted into GenomeQuest and ITTI used the BLAST algorithm to perform a search that produced patents with the same or similar nucleotide or protein sequences.

ITTI coded and categorized patent documents for sporozoite based vaccines using four relevancy categories; one category has three subcategories, and another category has four subcategories. The four categories and subcategories are:

1. Sporozoite,
    a. Human Malaria,
        i. Whole,
        ii. Antigen/Protein,
        iii. Nucleic Acid,
    b. Non-human Malaria and Non-plasmodium,
2. Vaccine,
    a. Composition of Matter,
    b. Method of Vaccination,
    c. Method of Production,
3. Methods of sporozoite production, and
4. Adjuvants.

One of these categories, sporozoite, must be found in every relevant document. ITTI coded representative documents from each of 114 INPADOC families determined to be relevant.

Top Inventors for Sporozoite Related Vaccine Technologies

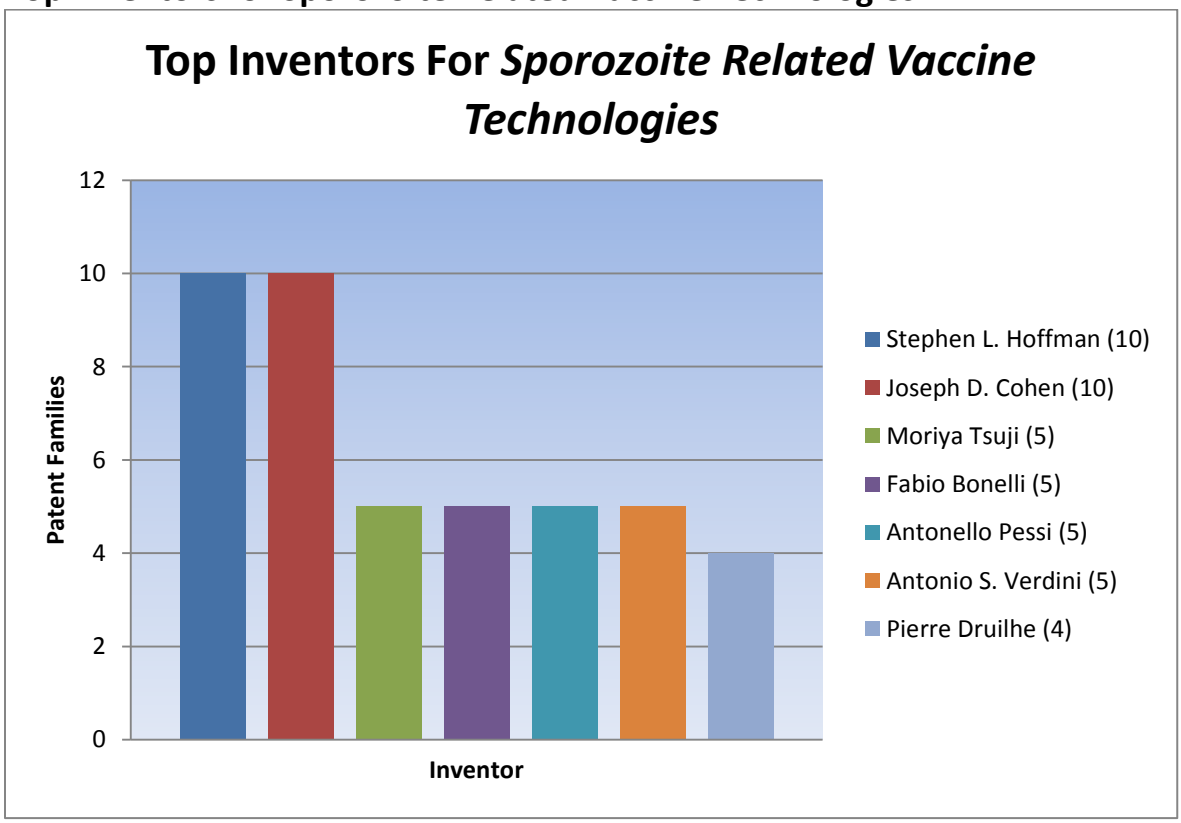


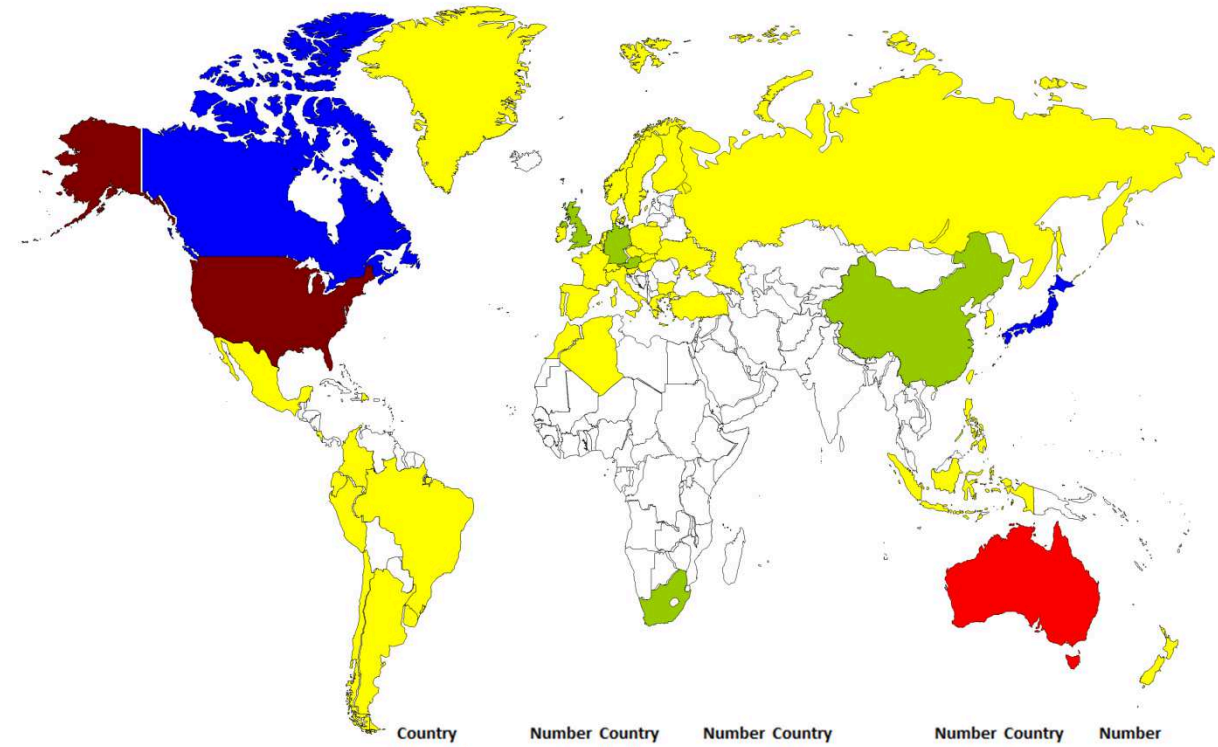
Chart 1: Top Inventors for Sporozoite Related Vaccine Technologies

As per the above graph, Dr. Stephen L. Hoffman and Dr. Joseph "Joe" Cohen are the inventors with the the maximum number of patent families for this technology, i.e. 10 patent families. Dr. Hoffman, founder of Sanaria, holds over 20 years of experience in malaria vaccine research.[3] Many of his patents involve DNA vaccines, and a combination of DNA and peptide vaccines, against malaria. Dr. Cohen, currently working with GlaxoSmithKline on malaria vaccines for the past 20 years, is also one of the original inventors of the RTS,S-technology malaria vaccine.[4] Most of the patents on which Dr. Cohen is an inventor relate to sporozoite antigens, and their combination with Hepatitis B antigens. Other notable inventors in this area include Moriya Tsuji, Fabio Bonelli, Antonello Pessi and Antonio S. Verdini, each named inventors on 5 patent families. Pierre Druilhe owns follows this group as inventor in 4 patent families. Numerous other inventors are named on 3 or less patent families each.

Global Filing Trends for Human Malarial Sporozoite Vaccines

The global filing trends for *Human Malaria Sporozoite Vaccine Technologies* are illustrated in Figure 1. The map was generated using patent family representative documents associated with *Human Malaria Sporozoites Vaccine Technologies*. The below map depicts the number of patent family filings per national jurisdiction, i.e. the number of countries a given patent family has been filed in. Patent family filings in regional patent offices are not illustrated on the map, including: European Patent Office (EPO) 67; Patent Cooperation Treaty (PCT) 80; African

Intellectual Property Organization (OAPI) 9; Eurasian Patent Office (EAPO) 6; and African Regional Intellectual Property Organization (ARIPO) 7.[14]



Country	Number	Country	Number	Country	Number	Country	Number
United States	90	Brazil	13	Peru	5	Russia	2
Australia	60	Korea, Rep	13	Singapore	5	Algeria	1
Canada	52	Greece	9	Costa Rica	4	Bulgaria	1
Japan	43	Mexico	9	Poland	4	Ecuador	1
China	27	Taiwan	9	Uruguay	4	Finland	1
Germany	26	Argentina	8	Belgium	3	Indonesia	1
Austria	25	Norway	8	Colombia	3	Philippines	1
South Africa	24	France	6	Czech Republic	3	Slovakia	1
United Kingdom	22	Hong Kong	6	Dominican Republic	3	Slovenia	1
Ireland	19	Portugal	6	Hungary	3	Turkey	1
Spain	18	Italy	5	Sweden	3	Ukraine	1
Denmark	16	Morocco	5	Switzerland	3		
New Zealand	14	Netherlands	5	Chile	2		

Figure 1: Global Filing Trends

According to the map, United States has the maximum number of patent family filings, i.e. 90. The closest countries after U.S. are Australia (60), Canada (52), and Japan (43). Some European countries have patent family filings in the range of 20-30, namely Austria, Germany and Great Britain. In addition, China and South Africa also have patent family filings in that range.

[14] K. Clark, et al., *Patent data mining: A tool for accelerating HIV vaccine innovation*, 29 VACCINE 4086, (2011). Issue 24. Published 31 May 2011

Brazil and South Korea, along with Denmark, Israel, New Zealand and Spain have patent family filings in the range of 13 to 18. The presence of Asian, Latin American and African countries is noticeable , with China, Hong Kong, Taiwan, Argentina, Peru, Uruguay and South Africa.

Acknowledgements

We would like to take the time to thank those who provided invaluable assistance in the completion of this project.

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We are thankful to Mr. Mark Bauer and Thomson-Reuters for graciously facilitating access to Thomson-Innovation, for providing invaluable guidance, and training on other aspects of patent database mining and research. We also thank LexisNexis®, Innography, and GenomeQuest for providing access to their platforms.

Disclaimer

The patent data and related information presented herein are neither inclusive, comprehensive nor all encompassing, but are presented solely as an informational and educational resource, to facilitate a better understanding of the potential international patent literature landscape with regard to vaccines for sporozoite related vaccine technologies. This report is not a freedom-to-operate opinion (FTO), and the International Technology Transfer Institute (ITTI) Clinic at the Franklin Pierce Center for Intellectual Property (FPCIP) at the University of New Hampshire School of Law (UNH-Law) draws no conclusions, makes no opinions or representations either explicitly or implicitly. Neither the ITTI Clinic nor UNH Law are responsible for any errors, omissions, and limitations of data or search parameters of any data source used for the preparation of this report. Neither the ITTI Clinic nor UNH Law are experts in the field of immunology and/or biotechnology patent law. Therefore no guarantees or opinions are expressed herein with respect to the evaluation of patents and/or related patent information as ITTI Clinic members did not perform claim interpretation. The tight 15-week time frame for report preparation , overall demands faced by the ITTI Clinic Student Team, and limitations imposed by both the search methodology and patent search platforms used affected the level of sophistication and the number of patents found and evaluated. As such, additional patents whether inside or outside the confines of the methodology herein, were not considered. All users of this report should engage a patent professional in all jurisdictions of interest to evaluate any patents listed within this report. Additionally, assay and detection methods,

vaccine delivery methods, and generic expression vectors or adjuvants are not included in the search strategies of this study.

Abbreviations and Definitions

Below is a list of abbreviations and definitions for terms and keywords used throughout the ITTI Spring 2012 report.

Adjuvants – a substance sometimes included in a vaccine formulation to enhance or modify the immune-stimulating properties of a vaccine.[15]

Anopheles – the genus of mosquito that transmits malaria.[16]

Antibody – an infection-fighting protein molecule in blood or secretory fluids that tags, neutralizes, and helps destroy pathogenic microorganisms (e.g., bacteria, viruses) or toxins. Antibodies, known generally as immunoglobulins, are made and secreted by B-lymphocytes in response to stimulation by antigens. Each specific antibody binds only to the specific antigen that stimulated its production.[17]

Antibody-mediated immunity – the immunity that results from the activity of antibodies in blood and lymphoid tissue (also called humoral immunity).[18]

Antigens - (immunogens; substances capable of provoking an immune response) – foreign substances in the body that are capable of causing disease. The presence of antigens in the body triggers an immune response, usually the production of antibodies. Antigens may be soluble substances, such as toxins and foreign proteins, or particulate, such as bacteria and tissue cells; however only the portion of the protein of polysaccharide molecule known as the antigenic determinant combines with antibody or a specific receptor on a lymphocyte[19].

Arm - a group of participants in a clinical trial, all of whom receive the same treatment, intervention, or placebo. The other arm(s) receive(s) a different treatment.[20]

Attenuated - weakened or treated in such a way as to decrease the ability of a microorganism (such as parasite or virus) to cause infection or disease.[21]

Attenuated vaccine - a vaccine in which live bacteria or viruses are weakened through chemical or physical processes in order to produce an immune response without causing the severe effects of the disease. Attenuated vaccines currently licensed in the United States include measles, mumps, rubella, polio, typhoid, yellow fever, and varicella. Also known as a live vaccine. (Irradiated sporozoites delivered via mosquito bite to volunteers was an investigational attenuated vaccine. The ability of this method of immunization to protect volunteers against challenge by infected mosquitoes is the basis for all current efforts to develop a malaria vaccine.)[22]

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[15] http://www.malariavaccine.org/malvac-glossary.php (last visited May 15, 2012)
[16] *Id*.
[17] *Id*.
[18] *Id*.
[19] *Id*.
[20] *Id*.
[21] *Id*.
[22] *Id*.

Attenuation -- established by introduction of a heritable genetic alteration or gene mutation, or by radiation exposure (preferred), chemical exposure or environmental exposure.

B cells – small white blood cells that help the body defend itself against infection. These cells are produced in bone marrow and develop into plasma cells that produce antibodies. Also known as B-lymphocytes.[23]

BLAST – the acronym for Basic Local Alignment Search Tool. This program compares nucleotide or protein sequences to sequence databases and calculates the statistical significance of matches.

Booster – a second or later vaccine dose given after the primary dose(s) to increase the immune response to the original vaccine antigen(s). The vaccine given as the booster dose may or may not be the same as the primary vaccine.[24]

Delivery Systems – a method or system by which a vaccine is delivered to the host body.[25]

DNA (deoxyribonucleic acid) - the double-stranded, helical molecular chain found within the nucleus of each cell. DNA carries the genetic information that encodes proteins and enables cells to reproduce and perform their functions.[26]

DNA vaccine (nucleic acid vaccine) - direct injection of a gene(s) coding for a specific antigenic protein(s), resulting in direct production of such antigen(s) within the vaccine recipient in order to trigger an appropriate immune response.[27]

DWPI – Derwent World Patent Index®. DWPI includes over 20 million patent document families, which covers over 42.5 million patent documents. The DWPI database includes coverage from over 44 worldwide patent authorities.

Effector arm - the part of the immune system that recognizes and responds to infection.[28]

Efficacy - in vaccine research, the ability of a vaccine to produce a desired clinical effect, such as protection against a specific infection or disease, at the optimal dosage and schedule in a given population. A vaccine may be tested for efficacy in Phase 3 trials if it appears to be safe and shows some promise in smaller Phase 1 and 2 trials.[29]

Endemic - the continual, sometimes low-level presence of disease in a community.[30]

Epitope - a specific site on an antigen that stimulates specific immune responses, such as the production of antibodies or activation of immune cells.[31]

Erythrocytic stage - a stage in the life cycle of the malaria parasite found in the red blood cells. Erythrocytic stage parasites cause the symptoms of malaria.[32]

Etiology - origin or cause.[33]

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[23] *Id*.
[24] *Id*.
[25] Crystal Chan, et. al., *Advancing Adjuvants and Vaccine Delivery Systems for Better Vaccination Strategies*, BioPharm Int'l Supplements, Jan. 2, 2010.
[26] http://www.malariavaccine.org/malvac-glossary.php (last visited May 15, 2012)
[27] *Id*.
[28] *Id*.
[29] *Id*.
[30] *Id*.
[31] *Id*.
[32] *Id*.
[33] *Id*.

Exoerythrocytic stage: A stage in the life cycle of the malaria parasite found in liver cells (hepatocytes). Exoerythrocytic stage parasites do not cause symptoms.[34]

Expression system - in genetic engineering, the cells into which a gene has been inserted to manufacture desired proteins.[35]

Functional antibody - an antibody that binds to an antigen and has an effect that can be demonstrated in laboratory tests**.**[36]

Gene – a unit of genetic material (DNA); a segment of DNA encoding a protein molecule; a segment of DNA that contains the information for a specific function.[37]

Genetic transformation - altering the genetic structure of wild-type sporozoites by either transforming the sporozoites with DNA, or otherwise modifying the sporozoites for the purpose of creating sporozoite parasites that fail to cause the disease pathology of malaria. Attenuation is established by introduction of a heritable genetic alteration or gene mutation, or by radiation exposure (preferred), chemical exposure or environmental exposure.

Hepatocyte - liver cell.[38]

Host - a plant or animal harboring another organism.[39]

Immune system - the complex system (network of specialized cells and organs) in the host body responsible for fighting and responding to disease (immune response). Its primary function is to identify foreign substances (antigens of bacteria, viruses, fungi, or parasites) in the body and develop a defense against them. It involves production of protein molecules called antibodies to eliminate these foreign organisms that have invaded the host.[40]

Immunity - a natural or acquired resistance provided by the immune system to a specific disease. Immunity may be partial or complete, specific or nonspecific, long lasting or temporary. Immunity is indicated by the presence of antibodies in the blood and can usually be determined with a laboratory test.[41]

Immunization - the process by which a person or animal becomes protected against a disease; the process of inducing immunity by administering an antigen (vaccine) to allow the immune system to prevent infection or illness when it subsequently encounters the infectious agent. This term is often used interchangeably with vaccination or inoculation.[42]

INPADOC– International Patent Document Center, a patent database maintained by the European Patent Office (EPO), including patent documents from over 98 coutnries

ITTI – International Technology Transfer Institute, an intellectual
property clinic at the Franklin Pierce Center for Intellectual Property at the University of New Hampshire School of Law.

Malaria - See Plasmodium

Malaria Proteins - PbSR, PySR, PfSR, PkSR, or CpSR

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[34] http://www.cdc.gov/malaria/glossary.html (last visited May 15, 2012)
[35] http://www.malariavaccine.org/malvac-glossary.php (last visited May 15, 2012)
[36] *Id*.
[37] *Id*.
[38] *Id*.
[39] *Id*.
[40] *Id*.
[41] *Id*.
[42] *Id*.

NCBI – the acronym for National Center for Biotechnology
Information. NCBI provides access to biomedical and genomic resources, such as BLAST.
Oocyst - a parasite stage within the mosquito, produced by the union of male and female gametes.[43]
Patent document count – the expanded issued patents and patent applications, which include but are not limited to US patents and patent applications, PCT patents and applications, and EPO patents and applications.
Patent family – the collective worldwide application and publications for an invention. Patent protection is country specific and an applicant seeking protection for an invention must file for a patent in each country where patent protection is desired, either by filing national patent applications, or by making the application via one of the multi-national routes (e.g. an EP or a PCT application).
Patent family – one representative patent document of the patent family.
PCT – the Patent Cooperation Treaty, which is an international treaty
aimed at providing a unified procedure for filing patent applications in the contracting states.
A contracting state is a country which has signed onto the treaty. A patent application filed
under the PCT is commonly referred to as an international application, or PCT application.
Pharmaceutical Compositions – the combination of distinct parts or elements to form a whole relating to pharmacy, drugs, or medicine. Can include anything from vitamins, antibodies, antigens, medicaments, and adjuvants.
Plasmodium – the genus of the parasite that causes malaria. The genus includes many species. The four species that naturally infect humans are *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium ovale* and *Plasmodium malariae*. *Plasmodium knowlesi* is a zoonotic species that naturally infects macaques in Southeast Asia and can also infect humans.[44]
Pre-erythrocytic Stage – herein defined as the life cycle stage of plasmodium prior to entering red blood cells.[45]
Prime Boost - See "booster"
Schizogony: - asexual reproductive stage of malaria parasites. In red blood cells, schizogony entails development of a single trophozoite into numerous merozoites. A similar process happens in infected liver cells.[46]
Schizont: - a developmental form of the malaria parasite that contains many merozoites. Schizonts are seen in the liver-stage and blood-stage parasites.[47]
Sporozoite – the infectious form of the malaria parasite, which is injected into people by a feeding mosquito; a spore formed after fertilization; any of the elongated, nucleated cells by division of the encysted zygote of a sporozoon, which undergo multiple fission to give rise to merozoites.[48]
Sporozoite Proteins – CSP, TRAP, as01, MAEBL, NANP, UIS3, Apical surface protein, P36P, ssp2 as01.

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[43] *Id*.
[44] http://www.cdc.gov/malaria/glossary.html (last visited May 15, 2012)
[45] http://www.malariavaccine.org/malvac-glossary.php (last visited May 15, 2012)
[46] http://www.cdc.gov/malaria/glossary.html (last visited May 15, 2012)
[47] *Id*.
[48] http://www.malariavaccine.org/malvac-glossary.php (last visited May 15, 2012)

Vaccine - a preparation that stimulates an immune response that can prevent an infection or create resistance to an infection based upon an antibody response to an antigen.[49]

Background

In this patent landscape project, ITTI has focused on malaria vaccine technology relating to the *Plasmodium* sporozoite. ITTI has also included vaccine technology relating to whole sporozoites of non-*Plasmodium* organisms to help inform on the development of malaria vaccines.

Malaria: The Disease

Malaria is a common and wide-spread infectious disease that is caused by the mosquito-borne *Plasmodium* parasite.[50] Nearly half of the world's population, especially in developing countries, is at risk for contracting malaria, and over one hundred countries continue to report endemic levels of this disease.[51] Currently, there is no effective malaria vaccine approved for use in humans.[52]

The World Health Organization (WHO) reported over two hundred million cases of malaria in 2010, which resulted in an estimated 655,000 deaths.[53] Children under the age of five represented 86% of all malaria deaths,[54] and six African countries — Nigeria, Democratic Republic of Congo, Burkina Faso, Mozambique, Cote d'Ivoire, and Mali — accounted for 60% of all malaria deaths.[55] Outside of Africa, malaria remains a serious health issue in areas of Southeast Asia, the Middle East, Oceania, and the Americas, particularly South America and the Caribbean.[56]

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[49] http://www.cdc.gov/malaria/glossary.html (last visited May 15, 2012)
[50] U.S. Global Health Policy, *The Global Malaria Epidemic: Fact Sheet*, THE HENRY J. KAISER FAMILY FOUNDATION (Mar. 2011), http://www.kff.org/globalhealth/upload/7882-03.pdf (last visited Mar. 15, 2012).
[51] *Id*. Endemic is defined as "where a constant, measurable number of new cases and natural transmission occurs over time." *Id.*
[52] *Id*.
[53] *World Malaria Report: 2011*, WORLD HEALTH ORGANIZATION, http://www.who.int/malaria/world_malaria_report_2011/9789241564403_eng.pdf (last visited Mar. 15, 2012).
[54] *Id*.
[55] *Id*.
[56] *See* U.S. Global Health Policy, *supra* note 50.

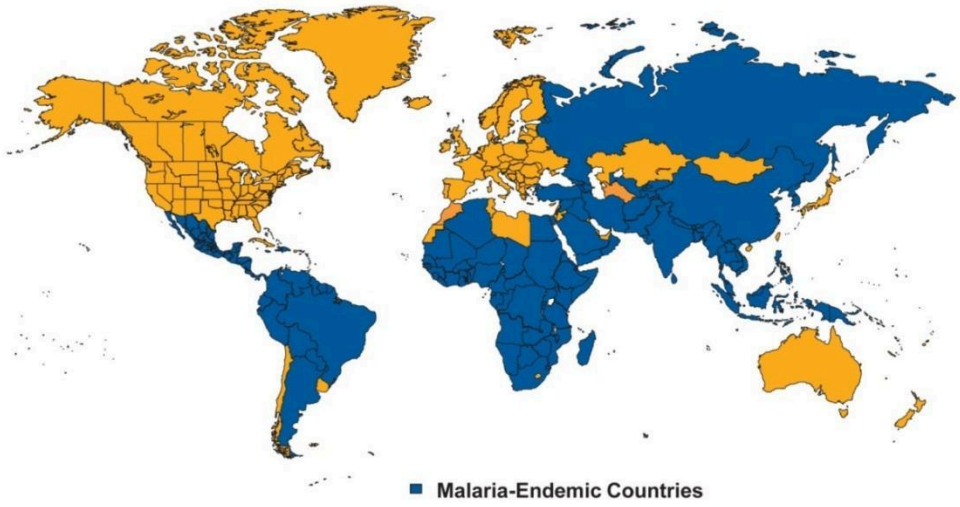


Figure 2: Malaria-Endemic Countries (2009).[57] Countries colored in blue report endemic levels of malaria.

Malaria is caused by the *Plasmodium* parasite and is transmitted through the bite and feeding of the female *Anopheles* mosquito.[58] Some of the species of *Plasmodium* that can cause human malaria include *P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale, and P. knowlesi*.[59] Out of these, *P. falciparum* is by far the most deadly, disproportionately leading malaria-related deaths in the world.[60]

The Plasmodium Life Cycle

The *Plasmodium* parasite has a complex life cycle that requires both an insect vector (the *Anopheles* mosquito) and a vertebrate host (for the focus of our project, the human).[61] The *Plasmodium* parasite moves through several life cycle stages, characterized by cellular varieties of the parasite with distinct morphological and biochemical properties.[62]

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[57] *Id*.
[58] *Id*.
[59] Cyrus Daneshvar et al., *Clinical and Laboratory Features of Human* Plasmodium knowlesi *Infection*, 49 CLINICAL INFECTIOUS DISEASES 852, 852 (2009).
[60] *Battling Malaria Drug Resistance Along the Thai-Cambodian Border*, WORLD HEALTH ORGANIZATION, http://www.who.int/malaria/diagnosis_treatment/arcp/faq/en/index.html (last visited Mar. 15, 2012).
[61] *Life Cycle of the Malaria Parasite*, PATH MALARIA VACCINE INITIATIVE, http://www.malariavaccine.org/malvac-lifecycle.php (last visited Mar. 15, 2012).
[62] *Id*.

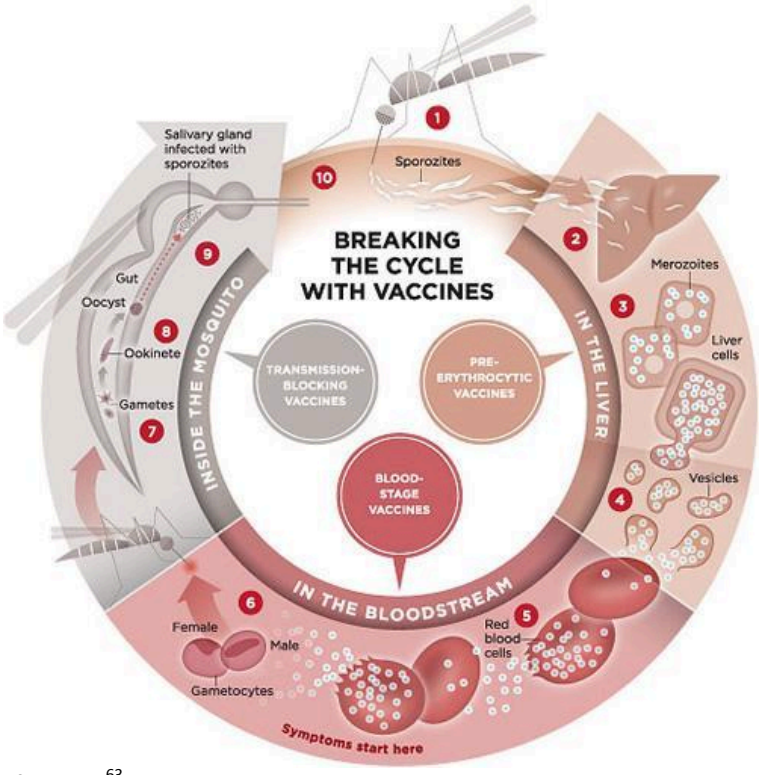


Figure 3: Plasmodium Life Cycle.[63]
(1) Sporozoites migrate from mosquito salivary glands into the host's bloodstream during a blood meal. **(2)** Sporozoites travel to the host liver, infecting liver cells (hepatocytes). **(3)** Asexual reproduction inside hepatocytes creates merozoites which are **(4)** released into the bloodstream. **(5)** Merozoites infect red blood cells (erythrocytes) and rapidly multiply, destroying the erythrocytes and releasing merozoites into the bloodstream. **(6)** Instead of multiplying, some merozoites form gametocytes in erythrocytes. **(7)** Mosquitoes ingest gametocyte-containing erythrocytes during a blood meal from an infected host, and gametocytes develop into gametes in the mosquito gut. **(8)** Gametes fuse to form ookinetes, which bury into the gut and form oocysts. **(9)** Sporozoites develop from the oocyst and migrate to the mosquito salivary glands.

Merozoites are one of the cellular varieties of *Plasmodium*.[64] Merozoites are *Plasmodium* cells found in the bloodstream that can infect red blood cells (erythrocytes).[65] The infection and subsequent destruction of erythrocytes by the merozoites cause fever, chills, and the flu-like symptoms associated with malaria.[66] Other *Plasmodium* cellular varieties include the gametocyte, gamete, ookinete, and oocyst forms.[67] These forms are involved in the transmission stage of malaria, where the *Plasmodium* parasite moves from the human host to the mosquito and undergoes sexual reproduction.[68] Vaccines targeting these cellular varieties and their processes are known as blood-stage vaccines and transmission-blocking vaccines,

[63] *Id*.
[64] *See generally* NATIONAL INSTITUTES OF HEALTH, UNDERSTANDING MALARIA: FIGHTING AN ANCIENT SCOURGE (2007), *available at* http://www.niaid.nih.gov/topics/malaria/documents/malaria.pdf.
[65] *Id*. at 8.
[66] *See id*. at 16; *Life Cycle of the Malaria Parasite*, *supra* note 61.
[67] NATIONAL INSTITUTES OF HEALTH, *supra* note 64, at 9.
[68] *See id*.

respectively.[69] But rather than focusing on these cellular forms of *Plasmodium* relating to the blood-stage or transmission-blocking vaccines, ITTI instead chose to focus the scope of this project to malaria vaccine technology involving structural elements of the *Plasmodium* sporozoite form, and related whole sporozoite vaccine technology from non-*Plasmodium* organisms.

Plasmodium sporozoites are motile cells that develop in oocysts embedded in the mosquito gut.[70] Sporozoites migrate to the mosquito salivary glands where they are transmitted to the human host during a blood meal.[71] Once in the bloodstream, sporozoites quickly travel to the human liver where they invade and infect human liver cells, known as hepatocytes.[72] Once inside the hepatocyte, sporozoites asexually reproduce to form merozoites, which are eventually released into the bloodstream.[73] Vaccines that target the *Plasmodium* life cycle stage occurring in the human host prior to the invasion of erythrocytes by merozoites are known as pre-erythrocytic vaccines.[74] Vaccines relating to whole sporozoites or sporozoite components are considered pre-erythrocytic vaccines.

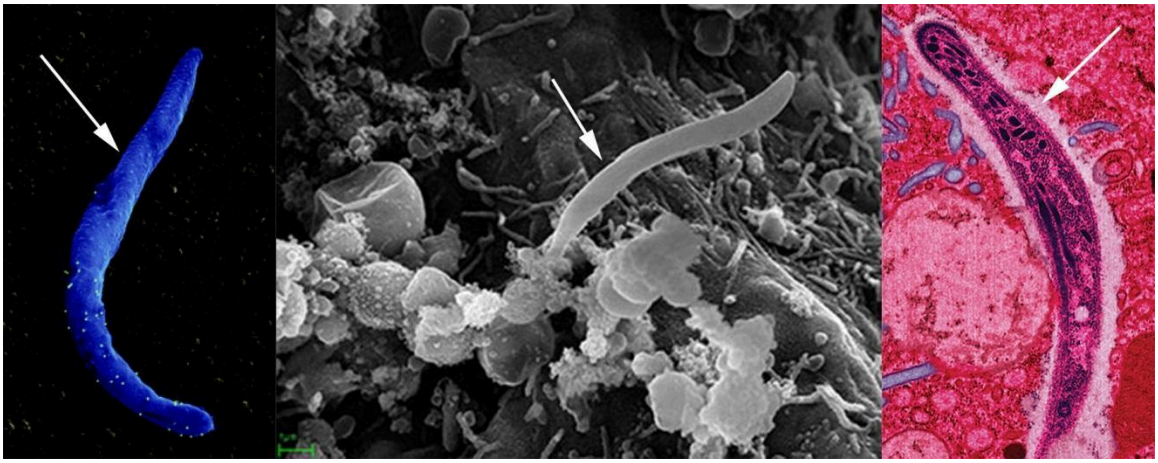


Figure 4: *Plasmodium* Sporozoite Electron Micrographs.
(Left): Scanning Immunoelectron Micrograph of a Malarial Sporozoite.[75] (Middle): Electron Micrograph of Plasmodium sporozoite entering into a human liver cell.[76] (Right): False-colored electron micrograph of

[69] *Life Cycle of the Malaria Parasite*, *supra* note 61.
[70] *See generally* Qian Wang et al., *Exit of* Plasmodium *Sporozoites from Oocysts is an Active Process That Involves the Circumsporozoite Protein*, Vol. 1 Issue 1 PLoS Pathogens 72 (2005).
[71] *Id*. at 72.
[72] *Id*.
[73] *Id*. at 74.
[74] *Parasitic Diseases: Malaria*, WORLD HEALTH ORGANIZATION, http://www.who.int/vaccine_research/diseases/soa_parasitic/en/index4.html (last visited Mar. 15, 2012).
[75] Adapted from Georgina N. Montagna et al., *Critical Role for Heat Shock Protein 20 (HSP20) in Migration of Malarial Sporozoites*, 287 The Journal of Biological Chemistry Cover Image (2012).
[76] Adapted from image courtesy of Volker Brinkmann. *See* Nadia Ramlagan, *Science Translational Medicine: Antibiotics: A Natural Vaccine for Malaria?*, AAAS (July 14, 2010), http://www.aaas.org/news/releases/2010/0714sp_malaria.shtml.

Plasmodium sporozoite migrating through the cytoplasm of midgut epithelia in the mosquito.[77] Added white arrows point to sporozoite.

Pre-erythrocytic malaria vaccines are thought to be an ideal candidate for vaccine development because the symptoms of malaria do not occur until *Plasmodium* merozoites begin to infect and destroy erythrocytes in the blood stage.[78] Vaccines eliciting an immune response capable of neutralizing *Plasmodium* parasites at the pre-erythrocytic stage could prevent symptoms of the clinical disease, while even partially effective vaccines may still reduce the severity of symptoms associated with the blood stage infection and reduce malaria-associated deaths.[79]

Malaria vaccine candidates using whole attenuated *Plasmodium* sporozoites or vaccines targeting components of the *Plasmodium* sporozoite have thus far showed the most promise.[80] RTS,S, one of the leading malaria vaccine candidates that has reached phase III clinical trials, targets the circumsporozoite protein (CSP) expressed by *Plasmodium* sporozoites.[81] Other sporozoite-expressed proteins of interest in malaria vaccine development include: sporozoite surface protein 2 (SSP2 or TRAP), liver-stage antigen 3 (LSA-3), sporozoite and liver stage antigen (SALSA), STARP, and circumsporozoite protein 2 (CSP-2).[82]

Vaccine candidates that use whole attenuated *Plasmodium* sporozoites, such as the PfSPZ vaccine candidate, which has reached phase II clinical trials,[83] have also shown promise. *Plasmodium* sporozoites can be attenuated (weakened) through a variety of means, including exposure to radiation, chemical treatment, or genetic modification/deletions.[84]

Scope of the Project

Malaria vaccine development encompasses a vast and diverse field of technology. To produce a meaningful and manageable patent landscape, ITTI chose to focus on one of the most promising areas within the entire field: malaria vaccine technology relating to the *Plasmodium* sporozoite. Additionally, non-*Plasmodium* whole sporozoite technology was also included in the scope of this project because developments in whole sporozoite technology, regardless of the organism, may provide complementary information applicable to the development of whole attenuated sporozoite malaria vaccine technology.

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[77] Adapted from image courtesy of Ute Frevert & Margaret Shear. *See* Ute Frevert et al., *Intravital Observation of* Plasmodium berghei *Sporozoite Infection of the Liver*, Vol. 3 Issue 6 Pub. Lib. Of Science 1034 (2005).
[78] *Id*.
[79] *Id*.
[80] Balazs Fazekas, *An Eradicating Vaccine for* Plasmodium falciparum*: Possibility or Pipe Dream*?, http://www.cambridgemedicine.org/article/1323558924#2 (last visited Mar. 15, 2012).
[81] *Id*. For a useful website listing clinical trials, including malaria vaccine candidates: http://clinicaltrials.gov/ct2/search.
[82] MALARIA IMMUNOLOGY 99 (P. Perlmann & M. Troye-Blomberg eds., 2nd ed. 2002).
[83] See generally Claudia A. Daubenberger, *First Clinical Trial of Purified, Irradiated Malaria Sporozoites in Humans*, 11 EXPERT REVIEW OF VACCINES 31 (2012).
[84] *See id*. at 32.

Specifically, the scope of this project includes: vaccine technology involving structural elements of the *Plasmodium* sporozoite, including sporozoite-expressed proteins and their corresponding nucleic acid sequences, and vaccine technology relating to whole sporozoites of any organism. ITTI encountered many different types of relevant vaccine technology during the project, including: vaccine compositions, methods of vaccination, and methods of vaccine production, including methods of producing *Plasmodium* and non-*Plasmodium* sporozoites.

Patent Search Methodology

Iterative Process

ITTI identified malaria sporozoite based vaccines and related technology as an ongoing research topic of increasing importance worldwide as a global epidemic affecting millions of children in developing countries.

ITTI, under the direction of Professor Jon Cavicchi and technical supervisor Dr. Stanley Kowalski, began reviewing non-patent literature on the technology relating to malaria sporozoite based vaccines and related technologies for the purpose of immunizing individuals against malaria. ITTI commenced an intense three-month iterative search and coding process. Thomson Innovation was the primary patent searching platform, but ITTI also used other tools, including Lexis Total Patent™, the USPTO website, and GenomeQuest.

The first step in a patent landscape project is to define the scope of the project. ITTI used the non-patent literature to define the scope of the project. non-patentNon-patentNon-patent literature sources include academic journals, books, monographs, trade journals, conference proceedings, encyclopedias, dictionaries, thesis, and technical reports. Publishers of these sources for this project included INSPEC, CAS, COMPDX, BIOSIS, MEDLINE, and FSTA.

Patent and non-patent literature are complimentary sources of information related to author/inventor, institution/assignee, bibliographic referencing/patent system referencing, bibliometric classification/official classification, abstract, full text, and references to additional sources of scientific literature/reference to patent or non-patent literature, etc. These non-patentnon-patent sources of information are often published and provide a large source of non-patent literature which can be mined for pertinent data. The non-patent literature used in this landscape are included in the accompanying DVD.

non-patentnon-patentOne of the advantages of using non-patent literature is to identify basic keywords, which are often missing or obfuscated in patent literature, e.g., a vaccine may be called an immunological composition in a patent document. Academic journals, however, must be informative enough to provide peer viewrs with sufficient detail to determine whether a manuscript is suitable for publication. Therefore, while patents have specific technical information, non-patentnon-patent literature provides a good representation of the general

scope of the field. Examples of keywords found searching the non-patentnon-patent literature are below in Table 1.

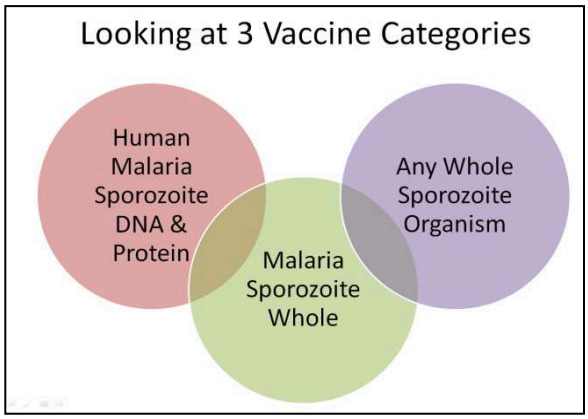
Table 2: Non-patent Literature Keywords

Non-patent Literature 1	Non-patent Literature 2	Non-patent Literature 3
Whole attenuated sporozoite vaccines, irradiated, genetically modified sporozoites; plasmodium falciparum; malaria vaccines; chondroitin sulfate A-binding epitopes PfEMP1; Radiation attenuated sporozoites (RAS); anopheles gambiae; alasmodium falciparum; p. falciparum; anopheles mosquitoes; MAEBL; p. vivax; plasmodium vivax; single-celled eukaryote; sporozoites; inventor-Fairhurst;	immunologenic composition, plasmodium malariae, plasmodium ovale, p. malariae, p. ovale, liver, whole plasmodium, attenuated parasite, plasmodium knowelsi, whole parasite, live parasite, live sporozoite, rts,s/as01, cd8+ t, live-attenuated sporozoite vaccine, Licensee-Sanaria	exo-erythrocyte, erythrocyte, anopheles, asexual reproduction, attenuated malarial parasites, antigens RTS,S, antigen, DNA based vaccine, hepatocytes, anti-CSP antibody, circumsporozoite, exoerythrocyte, subunit vaccine, whole parasite vaccines, SPf66 vaccine, apical membrane antigen (AMA) immunological memory, antigenic polymorphism.

However, this does not mean that one can rely solely on non-patentnon-patent literature. Neither does it mean that these terms would give results that are always relevant to one's project. Indeed, the merozoitic surface protein in column three above would lead a researcher to find vaccines and relevant technology for a different stage of the malaria life cycle. Nor does it imply that one should not mine the patent literature available for more keywords. Instead, these two sources of information are neither exclusive nor inclusive, but rather complimentary and illustrates that iterative searching depends on a dynamic interplay of information resources in order to build a keyword set which will be an effective tool for patent mining and subsequent analysis. Likewise, sequence searching through GenomeQuest, can provide more information about DNA or proteins that might be relevant. Therefore, when doing research, each source can provide valuable information.

The search process doesn't stop there either because the most complete search is not one search but instead, an iterative process requiring a multilevel layered search process providing built-in redundancy which balances precision and recall (see below) and thereby generates a final patent literature data-set with optimal integrity. ITTI first searched for non-patentnon-patent literature that resulted in several key pieces of non-patentnon-patent literature that can be found in full in the appendix. ITTI then used that non-patentnon-patent literature to generate keywords that were felt to be relevant to the scope of the project. Second, ITTI searched for patents using those keywords, and then reviewed the results to generate more keywords, assignees, US classifications, IPC codes, and inventors. ITTI then took this list, which

can be found in the appendix, and cross-referenced with the non-patent literature to generate a list of 'relevant' keywords, assignees, USC codes, IPC codes, and inventors.



ITTI then divided into three areas of investigation to ensure a more thorough investigation into each aspect of malaria sporozoite based vaccines and related technologies. One area of investigation focused on finding vaccines for humans from sporozoite malaria nucleic acids and/or proteins/peptides. The second area of investigation focused on finding vaccines using only whole malaria sporozoites. The third area of investigation focused on finding vaccines using whole sporozoites of any species of organisms. While some overlap was anticipated, the intent was that by including targeted, focused, and broad searches, ITTI would be able to find patents from every field.

Throughout this process, ITTI repeatedly went back to the non-patent literature to verify the relevance of each finding. In order to expedite these searches, ITTI utilized the previously mentioned publishers and the following platforms: LexisNexis TotalPatent®, Thomson Innovation®, Innography®, and GenomeQuest®.

Using these keywords to find relevant patents is not as simple as typing in a title search for "Whole Malaria Sporozoite Vaccine." Patent literature is known to be obfuscated with non-standard terminology and often less-than-clearly articulated language. In the end, misspelling, obfuscation, and mis-categorization all contribute to make even a patent search less than perfect. ITTI also found that searches that included the specification and description fields were generally too broad. Therefore, ITTI focused on searching the fields of title, abstract, and claims or, at times, only the claims field alone.

Precision Recall[85]

The number of patent documents worldwide, including patents (issued, re-issued, and re-examined) and applications, is over 60 million[86]. Selecting relevant documents from such a huge dataset can be difficult, and this type of document retrieval is governed by the mathematical theory of Precision and Recall. Precision is the percentage of retrieved documents that are relevant and is calculated as the number of retrieved relevant documents divided by the total number of retrieved documents. Recall is the fraction of relevant documents retrieved and is

[85] *See also* J. Davis and M. Goadrich, The relationship between precision-recall and ROC curves, Proceedings of the 23rd International Conference on Machine Learning, Pittsburgh, PA, 2006.
[86] Based on data from 2007. http://www.taeus.com/article.php?id=66 (last visited Aug. 14, 2011).

calculated as the number of retrieved relevant documents divided by the total number of existing relevant documents. These concepts are illustrated in Figure 5[87] below.

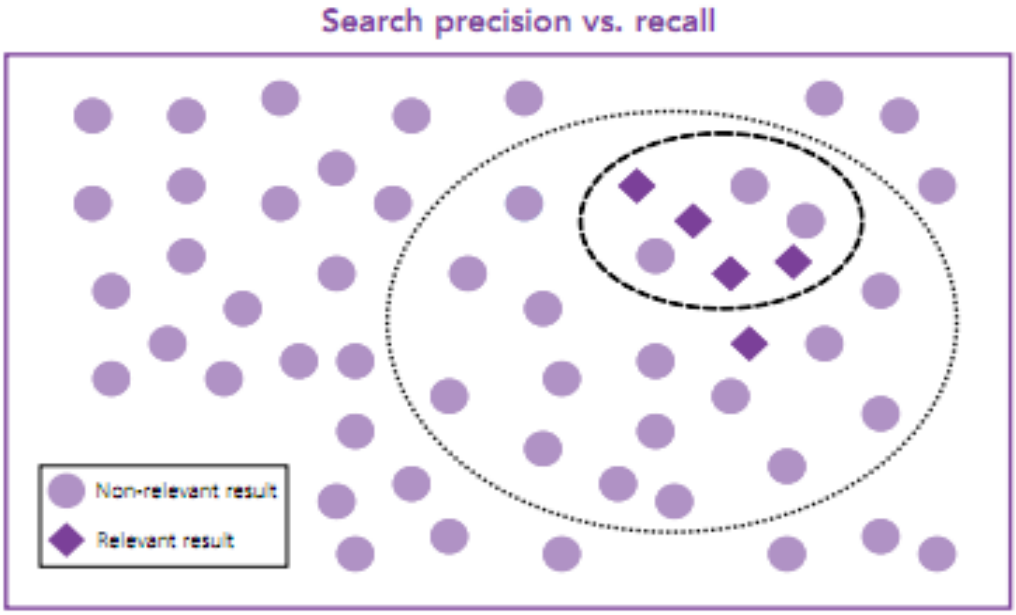


Figure 5: Search Precision v. Recall

Thus, any set of retrieved of documents will always include a certain fraction of irrelevant documents, also termed false positives. As a search attempts to capture an ever higher fraction of relevant documents, the sensitivity of the search will decrease because the proportion of false positives will increase. In the extreme, every relevant document can only be captured if every irrelevant document is also captured, as depicted in Figure 6[88].

[87] http://www.wipo.int/freepublications/en/patents/434/wipo_pub_l434_03.pdf
[88] Precision Recall Graph, Mirrored ROC Curve, www-csli.stanford.edu (last visited Aug. 12, 2011).

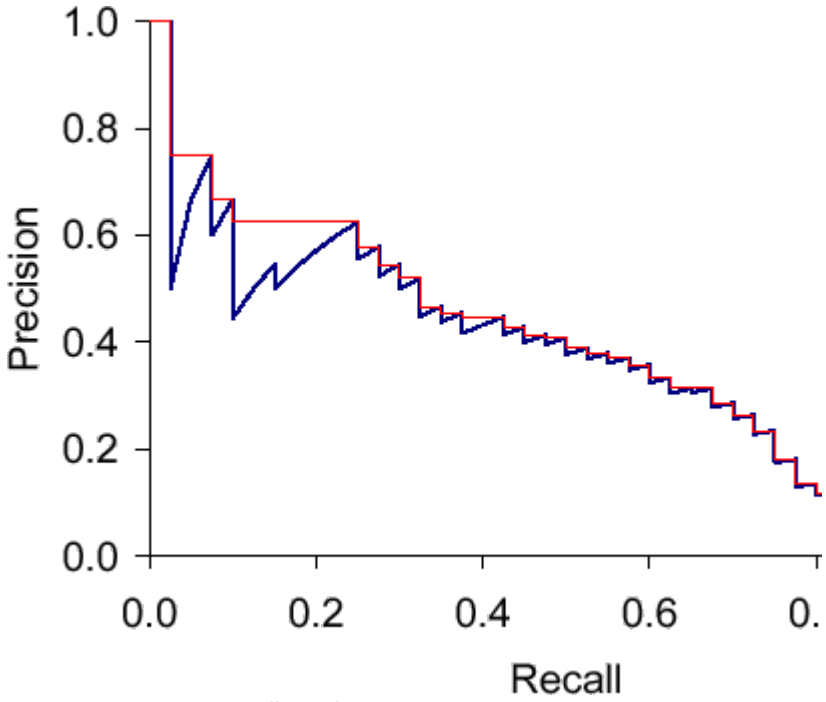


Figure 6: Precision Recall Graph

Stated another way, a high **recall** means you haven't missed anything but you may have a lot of useless results to sift through (which would imply low **precision**). High **precision** means that everything returned was a relevant result, but you might not have found all the relevant items (which would imply low **recall**).[89]

[89] Wikipedia, the free encyclopedia, http://en.wikipedia.org/wiki/Precision_and_recall (last visited Aug. 12, 2011).

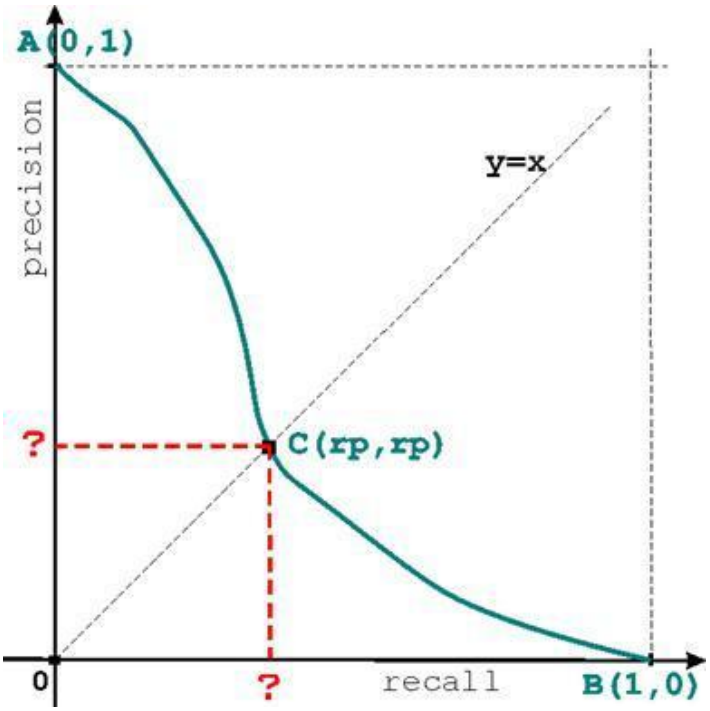


Figure 7: Optimal Balance

An optimal balance, point C in Figure 7[90], must therefore be achieved between precision (degree of relevance of all retrieved documents) and recall (fraction of relevant documents retrieved). In terms of patent searching, and in particular searching for relevant vaccine patents within the malaria sporozoite landscape, one deciding on that balance point must have experience in patent searching in general, knowledge concerning the technology involved, and an understanding of the goal of the search.

The different types of searches conducted for the vaccine patents within the malaria sporozoite landscape had different precision and recall levels. For example, forward citation searching resulted in high levels of recall and low levels of precision. In this search method, the number of patents that were obtained was so high that it was difficult to gauge what among that list was relevant and what was irrelevant. The reason that recall was high was because by definition, forward citation searching is a broad and less specific searching function that covers a lot of area but does not check for accuracy, and in therefore inherently imprecise.

Another search method example that resulted in high levels of recall and low levels of precision is semantic searching. Once again, in this search method, recall was high but precision was low. The reason semantic searching may have been less than effective is that the boundaries that create accuracy in a search, the keywords, were computer generated. Although it is difficult to judge the precision levels of semantic searching based on our limited attempts, this results seem to indicate that the keywords generated by a computer do not result in high levels of precision.

[90] http://www.ccs.neu.edu/home/jaa/CSG339.06F/Homeworks/hw.01.html (last visited Aug. 14, 2011).

High levels of precision were obtained by using other databases. For example, when the search string was controlled and the database being searched was efficient, the results that were obtained were an optimal balance between precision and recall. For example, Derwent is a pre-screened database, where language and classifications are carefully standardized. Therefore, precision is increased due to accuracy and efficiency of searching.

Sources

Thomson Innovation

ITTI utilized Thomson Innovation, a patent search platform that integrates the best of the suite of Thomson tools, Aureka®, Delphion® and MicroPatent®. Thomson Innovation is a single, integrated solution that combines intellectual property, scientific literature, business data and news with analytic, collaboration, and altering tools in a robust platform.

TotalPatent™

ITTI also utilized TotalPatent™, a LexisNexis platform, to search patents and patent applications world-wide. TotalPatent™ provides several additional countries that are not included in other platforms. Also, TotalPatent™ offers useful tools such as semantic searches, the ability to search for subsidiary companies and corporate structure, and analytics.

Sequence Searching

ITTI also performed sequence searching to corroborate the results from conventional search methods. ITTI performed the sequence searches after searching non-patent literature in NCBI's PubMed. The non-patent literature documents were generally scientific articles containing nucleotide and protein sequences related to the relevant technology with corresponding sequences disclosed via hot-links to the NCBI protein and/or nucleic acid sequence databases. The sequences referenced in the articles were inserted into GenomeQuest, and ITTI performed a search that produced patents with the same or similar nucleotide or protein sequences.

The sequence searches were performed concurrently with the conventional search methods. The sequence search results were used to corroborate results and also to ensure that ITTI was not overlooking any patents within the relevant technology field.

Sequence searching using PubMed and GenomeQuest produces an abundance of non-patent literature and provides a way to narrowly search for patents related to the relevant technology. Overall sequence searching allowed ITTI to corroborate its results and suggested that ITTI had not missed any major portions of the relevant technology. However, sequence searching produces results narrowly confined to those nucleotide or protein sequences and thus becomes a tedious search method if used predominantly. ITTI's sequence searching method is thus best used as an initial non-patent literature search or as a way to corroborate search results.

Deduplication Process

The search results from ITTI's secondary patent searches were combined to form a single list of patent documents. The combined search results were then searched on Thompson Innovation® by document number to remove duplicate documents. Then, the results from the Innovation® search were collapsed by INPADOC family to reduce the initial search results into representative family documents. Because ITTI gave preference to US documents, the representative family documents were then re-expanded into the full INPADOC family and collapsed a second time. This second collapsing found all US documents that may not have been in the secondary searches.

After collapsing to representative US documents, all INPADOC family representatives that were not US documents were compiled into a new list. This new list was then searched on other platforms, such as LexisNexis® TotalPatent™, in an attempt to fill in potential gaps in the Innovation® database, such a non-US document is in an INPADOC family with a US document but the Innovation® database does not include the family connection.

Once ITTI investigated the non-US documents, the data was manually collapsed by family to add non-US documents into the INPADOC family represented by the US document. Then, ITTI generated reports using MicroPatent from Thompson Reuters to aid in coding the individual patent documents. Not all of the representative family documents were found in the MicroPatent report. Only documents found in MicroPatent were coded.

The following is a flow outline of the method of how to de-duplicate and collapse the search results using Thomson Innovation®.

(1) Search combined search results via patent number on Thomson Innovation®.
(2) Sort search results by INPADOC Family.
(3) Export search results including the full INPADOC Family.
(4) Search the full INPADOC Family results on Thomson Innovation® to give preference to US Documents.
(5) Sort search results by INPADOC Family with preference to US documents.
(6) Export search results.
(7) Compile a new results list of non-US documents.
(8) Search the list of non-US documents on platforms other than Thomson Innovation® for US documents in the same INPADOC family as the non-US documents.
(9) Manually combine the found US documents and the Thomson Innovation® results.

Relevance

ITTI coded patent documents for sporozoite based vaccines using four relevancy categories; one category has three subcategories, and another category has four subcategories. One of the categories, sporozoite, must be found in every relevant document.

Coding Categorization of Patent Documents

1. Relevant: Relevant patent documents must claim a portion of a sporozoite or the whole sporozoite, and either a vaccine using the sporozoite as an antigen or immunogen or a method of sporozoite production. Additionally, patent documents appearing to primarily relate to an adjuvant, but still claiming a vaccine were denoted in the coding phase as relevant. Documents that list whole sporozoites or portions of a sporozoite in a Markush claim were analyzed on a case-by-case basis to determine whether the claimed method or compound was relevant to sporozoite based vaccines.

2. Irrelevant: Irrelevant patent documents fall entirely outside of the relevant category and do not claim a vaccine or method of sporozoite production. Documents claiming innovations aimed at diagnostic techniques or treatments were classified as irrelevant. Additionally, prophylactic protection against malaria, such as from malarone, was irrelevant because such methods do not induce an immunological response. Also, patent documents claiming vaccine delivery systems and platforms were excluded as being too broad to have specific application with sporozoite vaccines unless the documents also specifically claim a vaccine or a method of sporozoite production. Additionally, patents lacking claims were irrelevant.

The four descriptive categories of relevant patent documents comprise:

I. Sporozoite
Patent documents were relevant if they contained at least one claim relating to a whole sporozoite or to a portion of the sporozoite, such as proteins, peptides, or nucleic acids. Patent documents claiming portions of the sporozoite must be related to human malaria to be relevant. Patent documents claiming whole sporozoites were relevant for any disease caused by a parasite with a sporozoite phase. Patent documents immediately recognized as relevant specified a protein (typically CSP), a nucleotide, or the whole sporozoite in the claims.

II. Vaccine
Patent documents were relevant if they additionally contained at least one claim relating to a vaccine using the whole sporozoite or the portion of the sporozoite. Three forms of vaccine claims were relevant; claims to a vaccine as a composition of matter, claims to a vaccine as a method of vaccination, and claims to a vaccine as a method of vaccine production.

III. Methods of Sporozoite Production
Patent documents were relevant if they contained at least one claim relating to a method of sporozoite production, such as a mosquito cage used to contain mosquitos infected with a malaria causing Plasmodium species.

IV. Adjuvants
Patent documents understood to be primarily related to an adjuvant but still specifically claiming a vaccine using a whole sporozoite or a portion of a sporozoite were relevant

Analysis

Categories of Analysis

ITTI focused on finding Sporozoite stage vaccines for malaria. As discussed in other sections of this report, there are other diseases that have sporozoite stages and often times the work done on finding vaccines for those diseases can shed some light on possible vaccines for malaria as well. While ITTI was not concerned with non-vaccine related patents, in order to have a sporozoite based vaccine, one must first have sporozoites. To that end, ITTI also included patents based on the technology of the production of sporozoites. For clarity and the benefit of our readers, ITTI divided the results of the searching into the following four categories for analytical purposes whenever possible:

Category Title	Truncated Title
Sporozoite Related Vaccine Technologies	Related
Human Malaria Sporozoite Vaccine Technologies	Human
Whole Sporozoite Vaccine Technologies	Whole
Whole Sporozoite Production Methods	Production

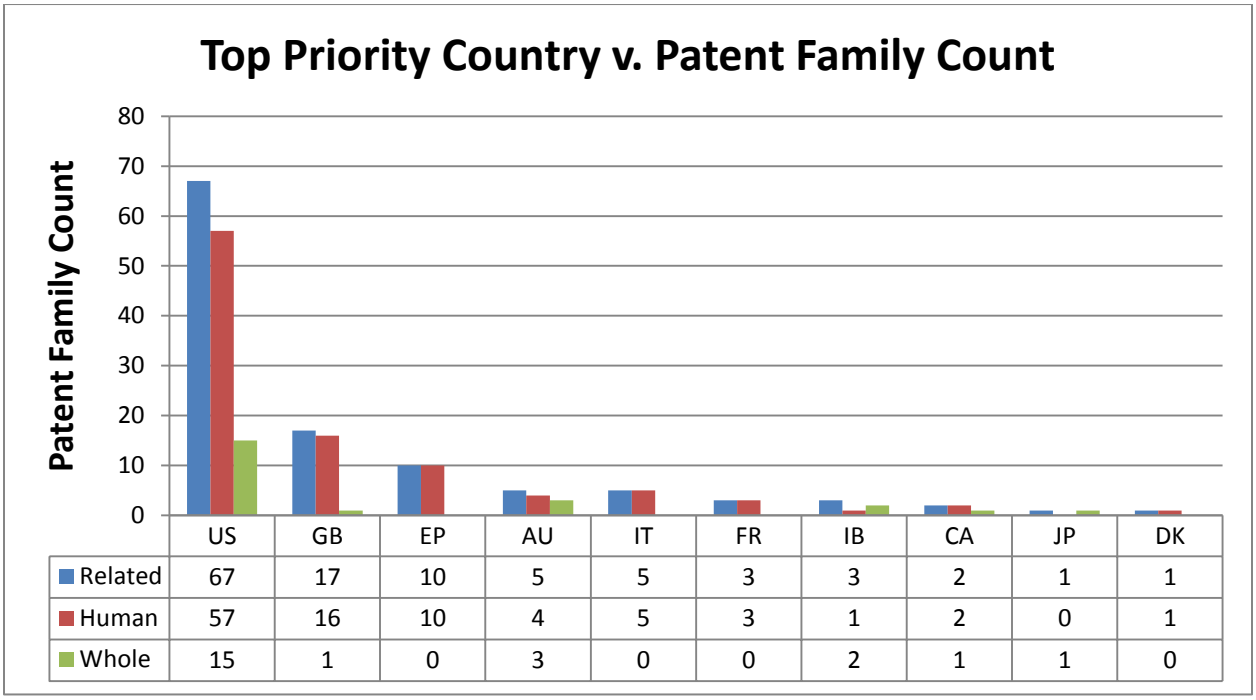
The first category, *Sporozoite Related Vaccine Technologies*, is highlighted blue and includes all of the relevant patents as discussed in previous sections including all of the patents in the three other categories. The second category, *Whole Sporozoite Vaccine Technologies,* is highlighted green and includes patents of vaccines using the whole sporozoite organism of any species. The third category, *Human Malaria Sporozoite Vaccine Technologies,* is highlighted red and contains patents of vaccines using sporozoite whole organisms, protein, or DNA from species that cause Malaria in humans. The fourth category, *Whole Sporozoite Production Methods*, has patents that focus on creating whole sporozoite organisms, and is addressed by itself, separately.

Top Priority Countries

The Priority Country is the country in which the earliest filing of a patent application is filed. Because all members of a patent family share a common priority country designation, ITTI identified the top ten priority country designations by analyzing a representative patent document from each family.

A majority of patent families list the United States as the priority country designation. The priority countries represented in our analysis: United States (US), United Kingdom (GB), European Patent Office (EP), Australia (AU), Italy (IT), France (FR), International Bureau (IB), Canada (CA), Japan (JP), and Denmark (DK). The majority of research and development in the

area of malaria vaccine technology appears to be focused primarily in developed countries. In contrast, the greatest need for such technology is in developing countries. This dichotomy raises issues of how to move and establish malaria vaccine technology in the countries that need it the most.

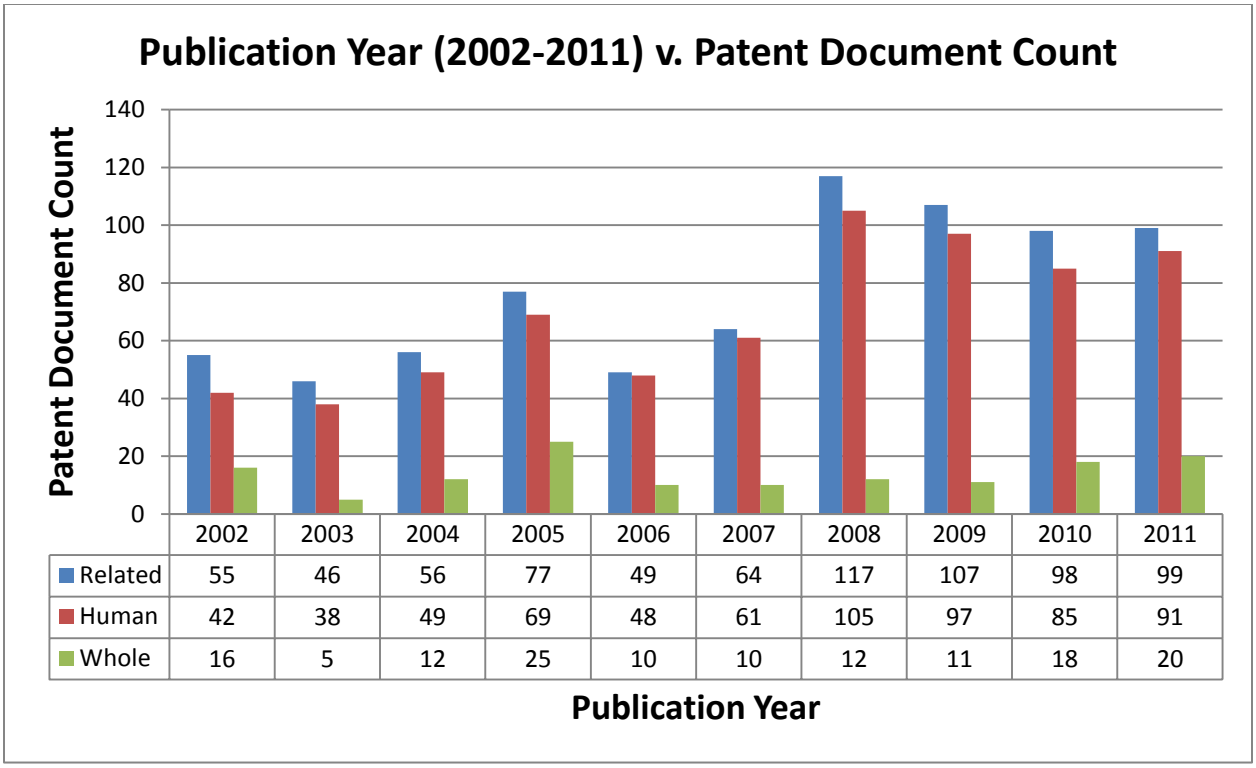


	US	GB	EP	AU	IT	FR	IB	CA	JP	DK
Related	67	17	10	5	5	3	3	2	1	1
Human	57	16	10	4	5	3	1	2	0	1
Whole	15	1	0	3	0	0	2	1	1	0

Chart 2: Top Priority Country v. Patent Family Count

Publication Year v. Patent Documents:

For similar reasons, ITTI used the expanded (INPADOC) patent document count as the column to seek to offer a more significant count difference between years. Besides, instead of offering Top 10 year for patent count, ITTI present patent document counts for the last decade, from 2002 to 2011, chronologically. Interestingly, Top ten data would include the count of, for example, 1989 and 1988. ITTI expected that the technology in year 1989 and 1988 would be quite different from what it is in current age. Thus, ITTI change the strategy to present a quantitative data of chronological trend in the last decade.



	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Related	55	46	56	77	49	64	117	107	98	99
Human	42	38	49	69	48	61	105	97	85	91
Whole	16	5	12	25	10	10	12	11	18	20

Chart 3: Publication Year (2002-2011) v. Patent Document Count

On the graph, for the last decade, the trend of counts for categories *Sporozoite Related Vaccine Technologies* and *Human Malaria Sporozoite Vaccine Technologies* are similar. There is an increase from 2003 to 2005, another increase from 2006 to 2008, and yet another from 2010 to 2011. However, there is a decrease from 2002 to 2003, another from 2005 to 2006, and yet another from 2008 to 2010. The count for year 2008 reached a peak during this decade. Interestingly, the trend for the category *Whole Sporozoite Vaccine Technologies* is similar to the previous two categories, although the trend from year 2008 to 2010 is an increase instead of a decrease.

Top 20 International Filings

Related

The graph for the representative patent documents versus number of jurisdictional filings is shown. This graph helps in understanding the total number of countries in which a representative patent document was filed.

This graph shows that the technologies under the category of *Everything* is originating mostly from the US and have been filed in various countries. The Patent number "US20060292170A1" has most number of international filings (30), owned by GlaxoSmithKline and directed to "an antigen for Malarial Vaccines." The patent US7018640B2 has 23 international filings, owned by Pfizer and directed to "In ovo vaccination against coccidiosis." The other patents in the top 5

are owned by GlaxoSmithKline and Novartis. From this graph it is evident that big multinational companies spend a lot of money in protecting their invention across many countries.

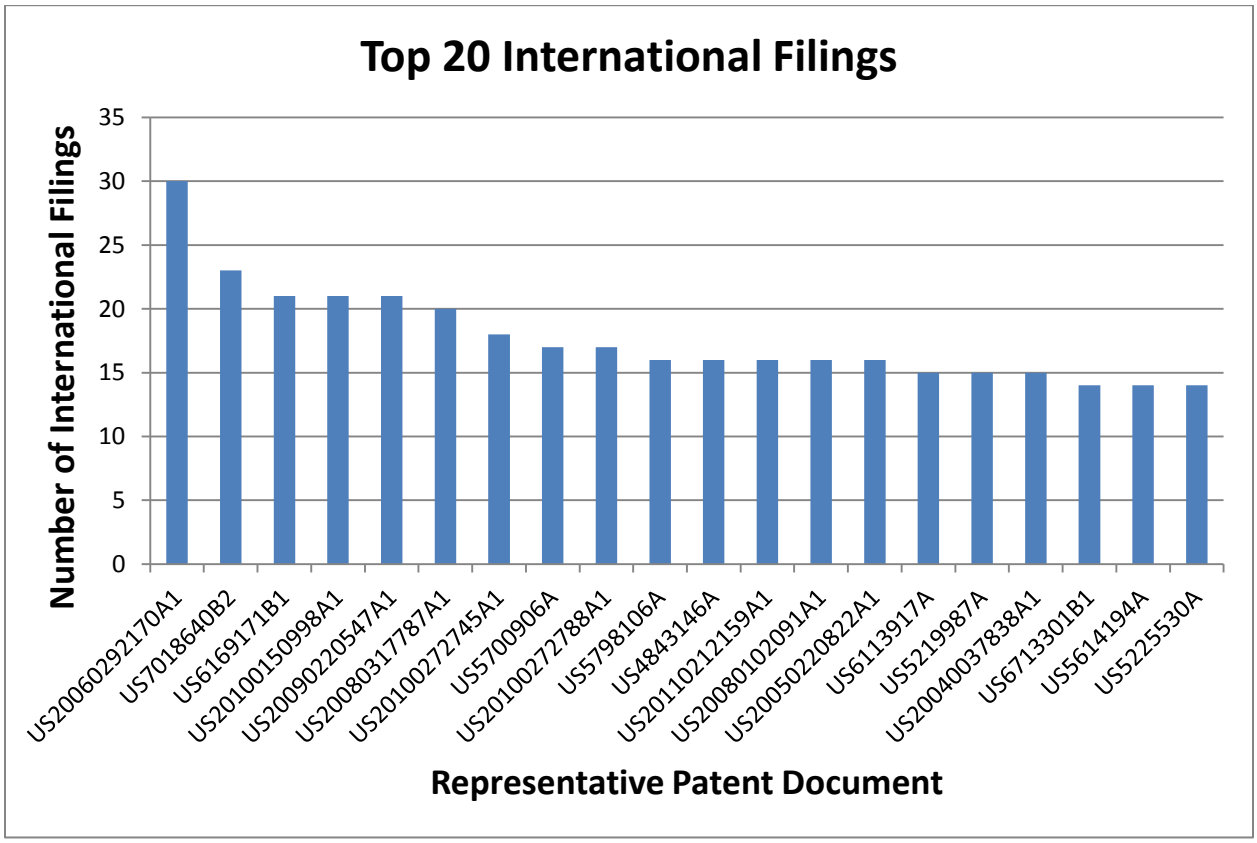


Chart 4: Top 20 International Filings for Related

Whole Sporozoite

The graph for top five international filings is shown. This graph depicts the representative patent documents versus number of jurisdictional filings. This graph helps in understanding the total number of countries in which a representative patent document was filed.

This graph shows that the technologies under the category of *Whole Sporozoites* is originating mostly from the US and have been filed in various countries. The Patent number US7018640B2 has most number of international filings (23), owned by Pfizer and directed to "In ovo vaccination against coccidiosis." The next two in the list are also owned by Pfizer, and they are directed to the similar technology. It is evident from this graph is Pfizer is a big player in *Whole Sporozoite* technology area and has patent protection for their inventions in many countries.

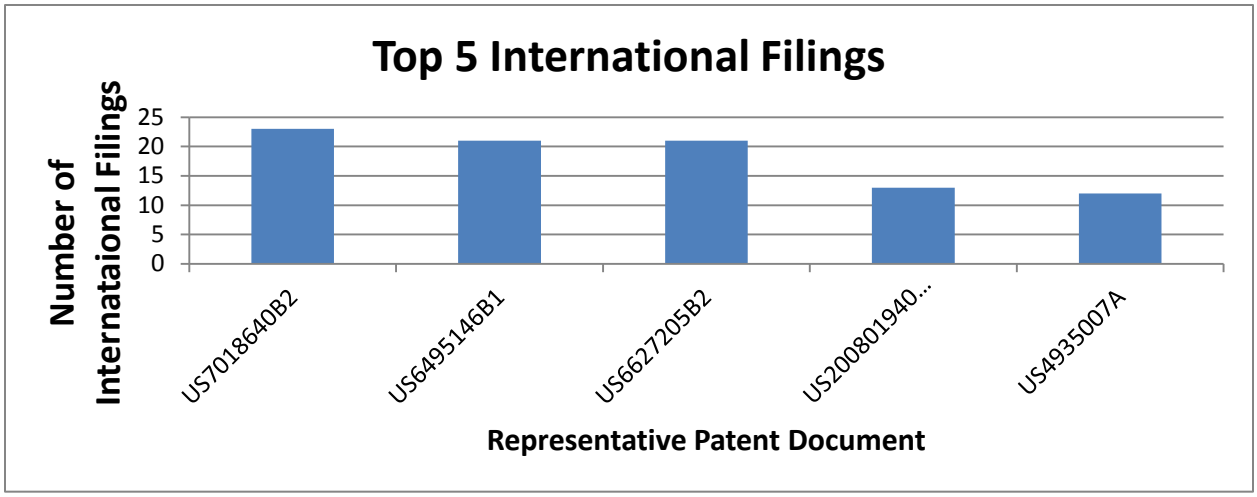


Chart 5: Top 5 International Filings for Whole Sporozoite

All Human Malaria

The graph for top 20 international filings is shown. This graph depicts the representative patent documents versus number of jurisdictional filings. This graph helps in understanding the total number of countries in which a representative patent document was filed.

This graph shows that the technologies under the category of *All Human Malaria* which has a prominent overlap with the technology under the category of *Everything*. The only difference between the two graphs is the patent US7018640B2 which has 23 international filings, owned by Pfizer and it belongs to the category of *Whole Sporozoites.*

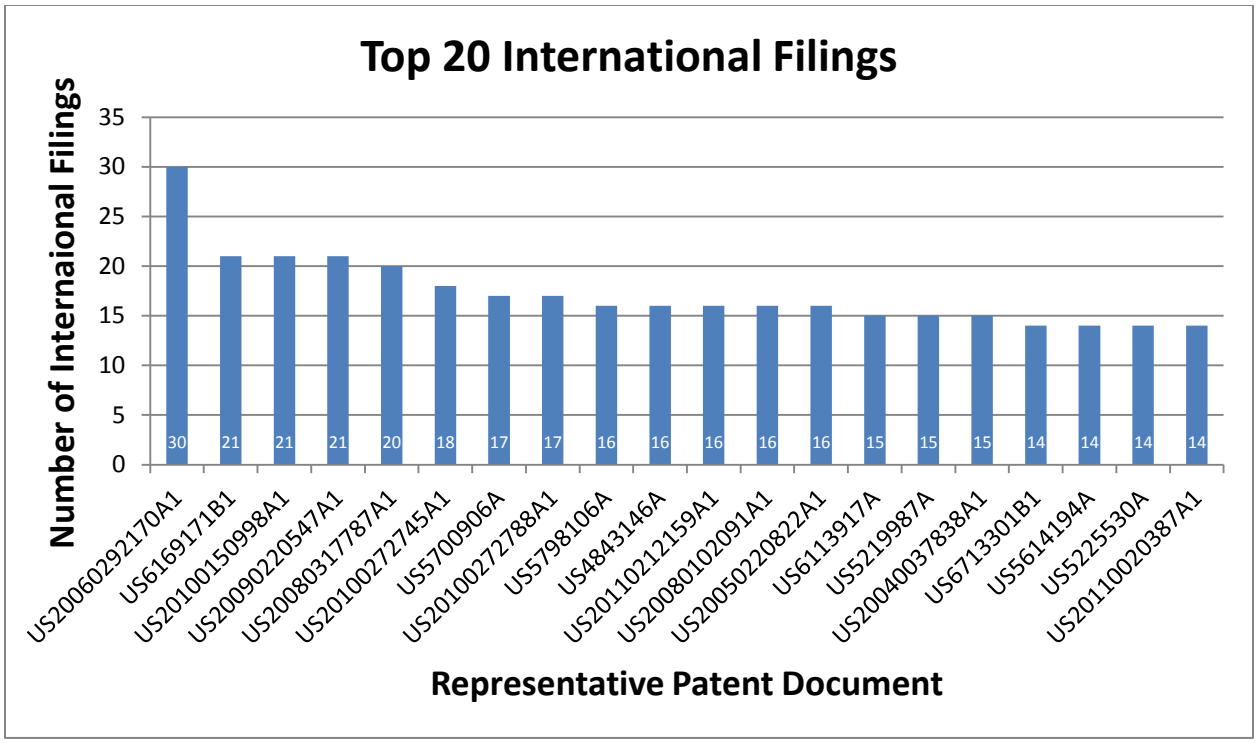


Chart 6: Top 20 International Filings for All Human Malaria

The elaborate data and figures are provided in Table I:

Table I: Patent Number and Number of International Filings:

Patent Number	No of International Filings
US20060292170A1	30
US6169171B1	21
US20100150998A1	21
US20090220547A1	21
US20080317787A1	20
US20100272745A1	18
US5700906A	17
US20100272788A1	17
US5798106A	16
US4843146A	16
US20110212159A1	16
US20080102091A1	16
US20050220822A1	16
US6113917A	15
US5219987A	15
US20040037838A1	15
US6713301B1	14
US5614194A	14
US5225530A	14

U.S. Classification v. Patent Document Count

Any patent document filed with the U.S.P.T.O. receives a U.S. Classification. The classification represents a searchable collection of patents grouped together according to similarly claimed subject matter. Classifications are used both as a tool for finding patents (patentability searches), and for assisting in the assignment of patent applications to examiners for examination purposes. Currently, there are about 450 Classes of invention and about 150,000 subclasses of invention; new classes are created when developments in a particular scientific area have expanded so that a new classification is required. [91]

ITTI completed the U.S. Classification analytics using Thomson Innovation and the 1458 relevant patent documents. The relevant patent documents were analyzed as a whole and then analyzed again when ITTI separated them into two groups: patents claiming *Whole Sporozoite Vaccine Technologies* and patents claiming *Human Malaria Sporozoite Vaccine Technologies*. There is some overlap between the two groups.

Chart 7 shows the analysis of all 1458 patent documents. The top U.S. classification in this analysis is Class 424/272.1 which contains patents relating too: drug, bio-affecting and body treating compositions and subject matter wherein the parasitic protozoan is of the genus *Plasmodium*. Examples of relevant patents documents within this group are: Purified *Plasmodium* and vaccine composition, *Plasmodium falciparum* antigens and methods of use, and *Plasmodium falciparum* antigens and their vaccine and diagnostic applications.

[91] Preface to the Index to the U.S. Patent Classification System, http://www.uspto.gov/web/patents/classification/uspcindex/front_page_preface.pdf (last visited April 16, 2012).

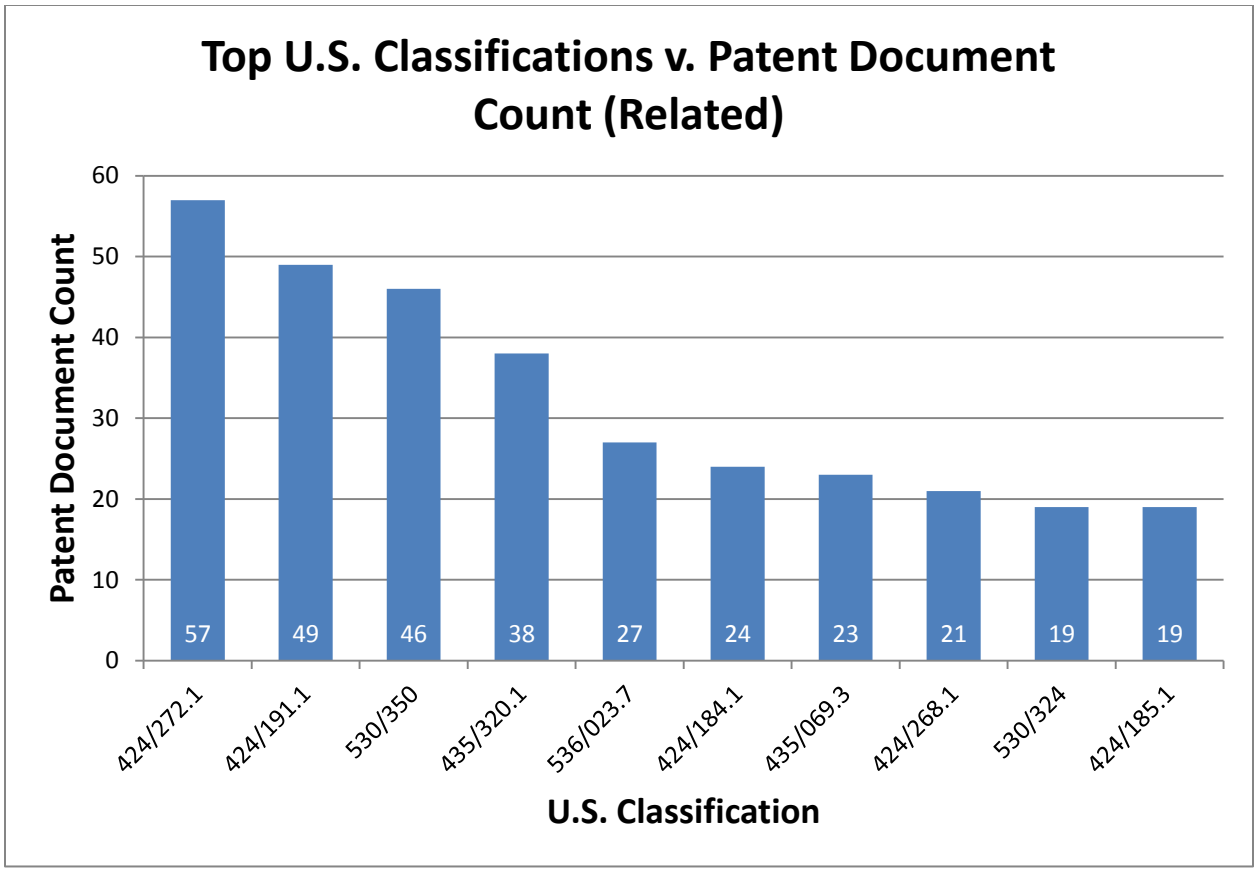


Chart 7: Top U.S. Classifications v. Patent Document Count (Related)

Chart 8 show the analysis of those 1215 patent documents related to *Human Malaria Sporozoite Vaccine Technologies*. The top U.S. classification in this analysis is Class 424/272.1 which contains patents relating too: drug, bio-affecting and body treating compositions and subject matter wherein the parasitic protozoan is of the genus Plasmodium. Examples of relevant patents documents within this group are: purified *Plasmodium* and vaccine composition, *Plasmodium falciparum* antigens and methods of use, and therapeutic target for protozoal diseases.

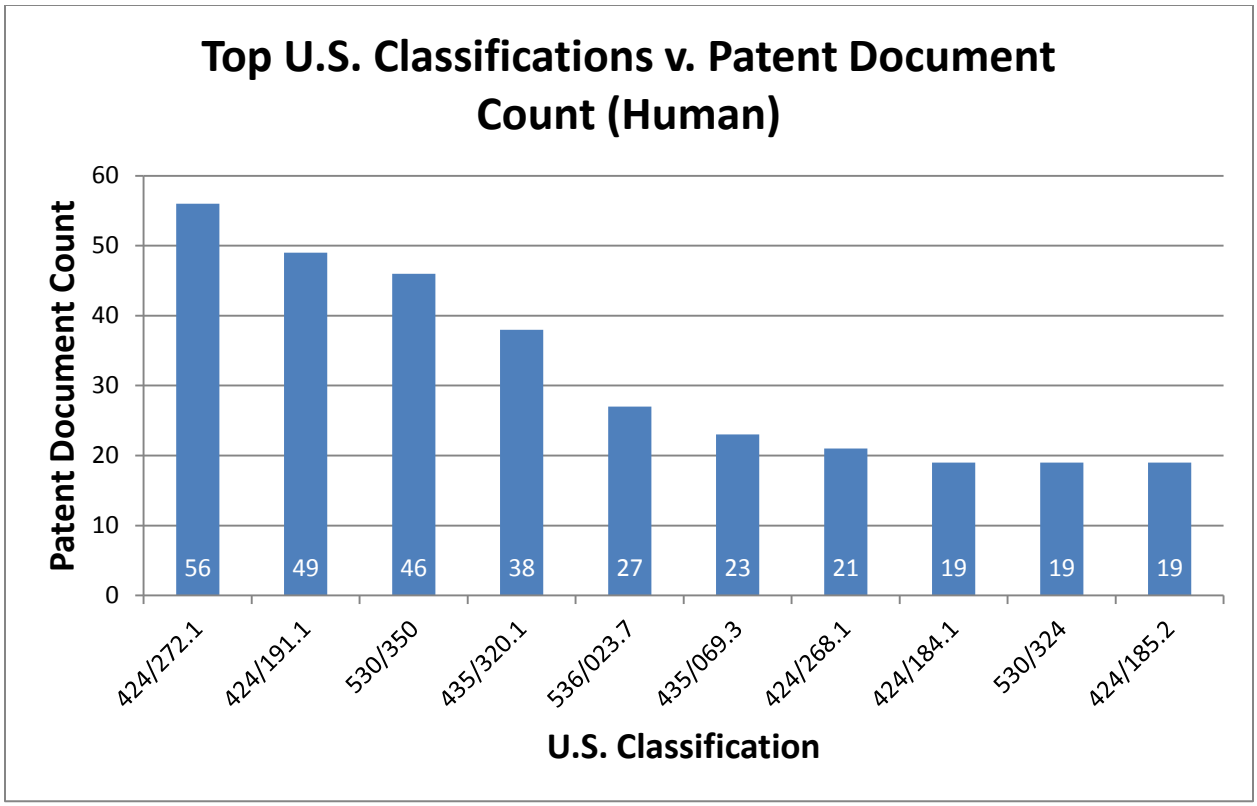


Chart 8: Top U.S. Classifications v. Patent Document Count (Human)

Chart 9 show the analysis of those 315 patent documents related to *Whole Sporozoite Vaccine Technologies*. The top U.S. classification in this analysis is Class 424/271.1, which contains patents relating to: drug, bio-affecting and body treating compositions and subject matter wherein the parasitic protozoan is of the genus *Eimeria*. Examples of relevant patent documents within this group are: In ovo vaccination against coccidiosis, Live vaccine for coccidiosis utilizing coccidial sporozoites, and anticoccidial method.

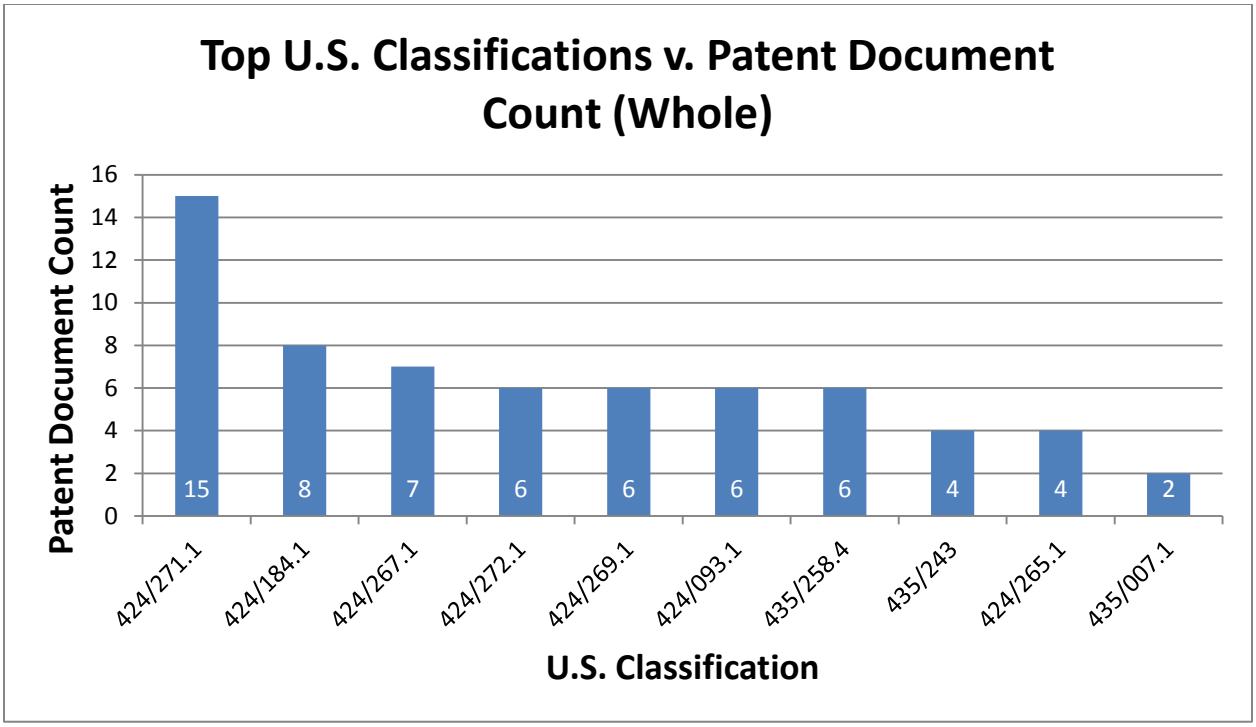


Chart 9: Top U.S. Classifications v. Patent Document Count (Whole)

For a full definition of each of the classes present in this analysis and for example titles of patents found in each group, please see appendix[92]

Top IPC (Current) Codes

In 1971, the World Intellectual Property Organization (WIPO) established the International Patent Classification (IPC) system. The IPC "provides for a hierarchical system of language independent symbols for the classification of patents and utility models according to the different areas of technology to which they pertain."[93] The IPC is contains eight sections with approximately 70,000 subdivisions. Each subdivision is represented by a string of Arabic numerals and letters of the Latin alphabet. WIPO continuously revises the IPC and regularly publishes new versions to keep the classification up-to-date. For this project, ITTI used IPC version 2012/01. The IPC is an indispensable prior-art search tool for patent-issuing authorities, inventors, research & development units, and patent practitioners.

Consistent with the scope of this project, the top IPC codes included class definitions such as "Plasmodium" (C07K 14/445), "Medicinal Preparations Containing Antigens or Antibodies" (A61K 39/00), and "Hemosporidia Antigens" (A61K 39/015). However, ITTI does not recommend class searching as the sole approach for malaria vaccine technology, due to the

[92] Index to the U.S. Patent Classification System, http://www.uspto.gov/web/patents/classification/ (last visited April 17,2012)

[93] World Intellectual Property Organization, *Preface to the International Patent Classification (IPC)*, WIPO IP SERVICES, http://www.wipo.int/classifications/ipc/en/general/preface.html (last visited Apr. 18, 2012).

diversity of IPC codes represented and the broad nature of some of the top IPC codes such as "Recombinant DNA-technology" (C12N 15/09) or "Hybrid peptides" (C07K 19/00).

The following graphs represent the top ten current IPC codes for all relevant patent documents.

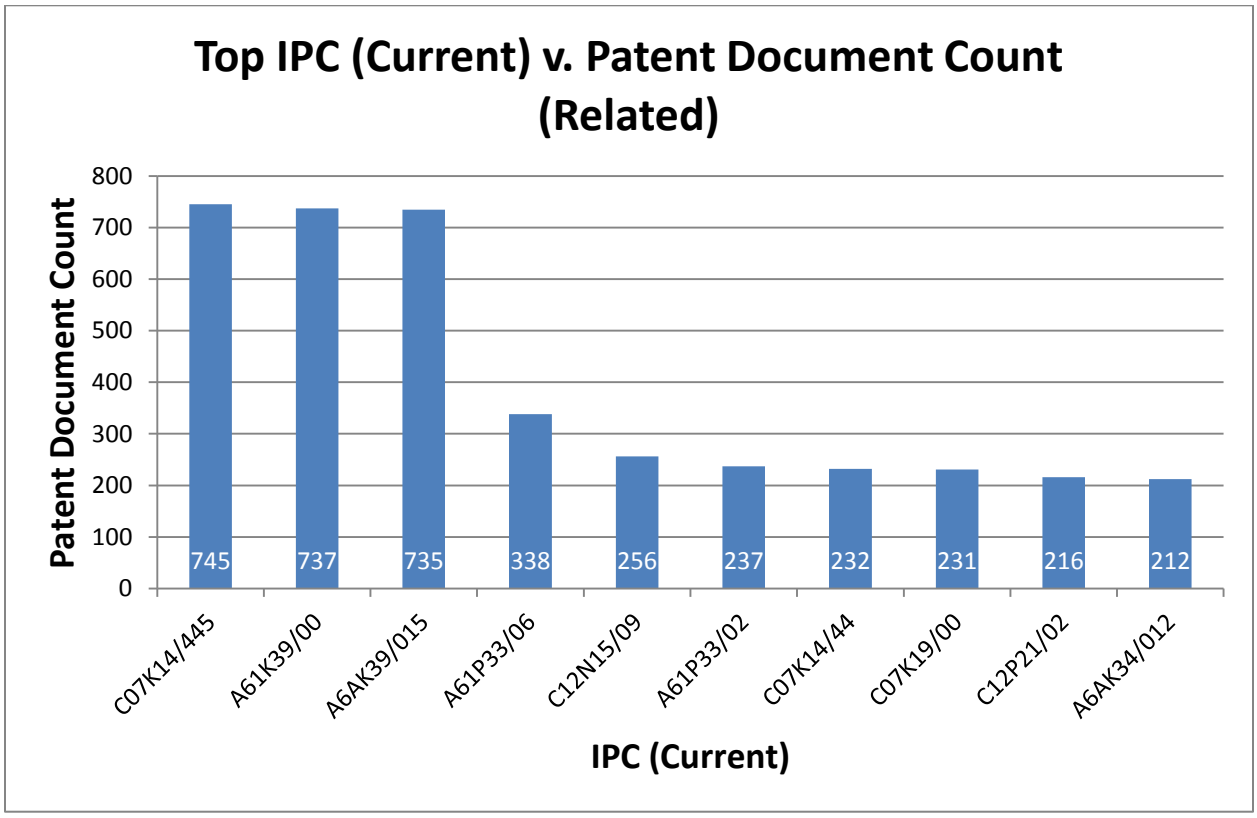


Chart 10: Top IPC (Current) v. Patent Document Count (Related)

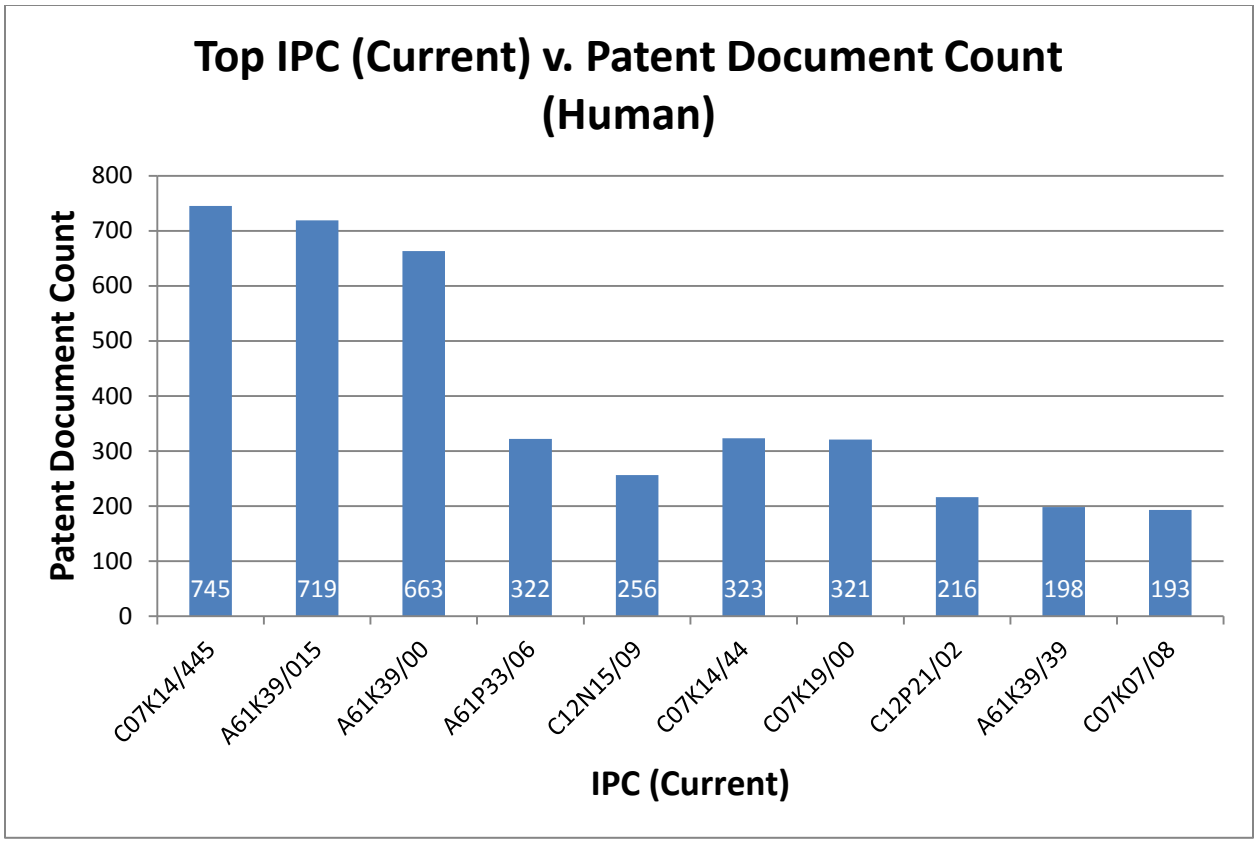


Chart 11: Top IPC (Current) v. Patent Document Count (Human)

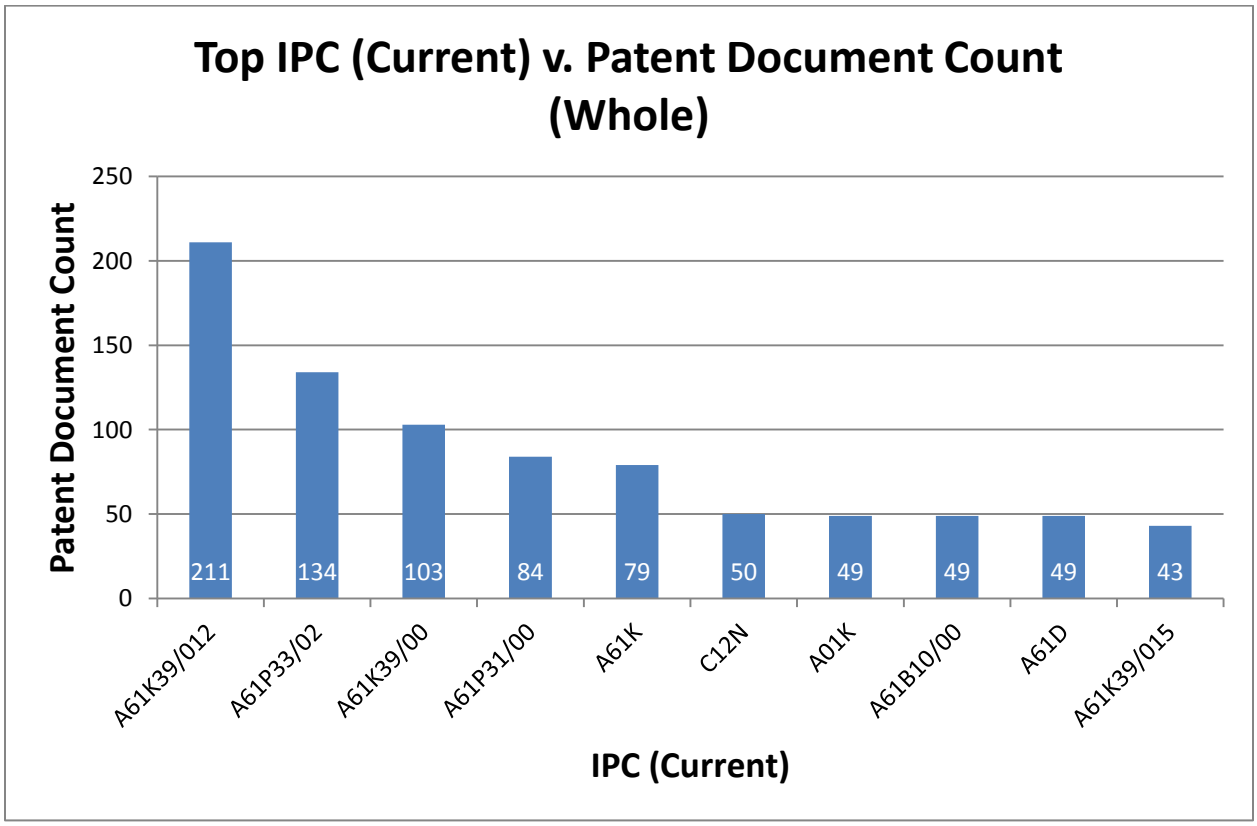


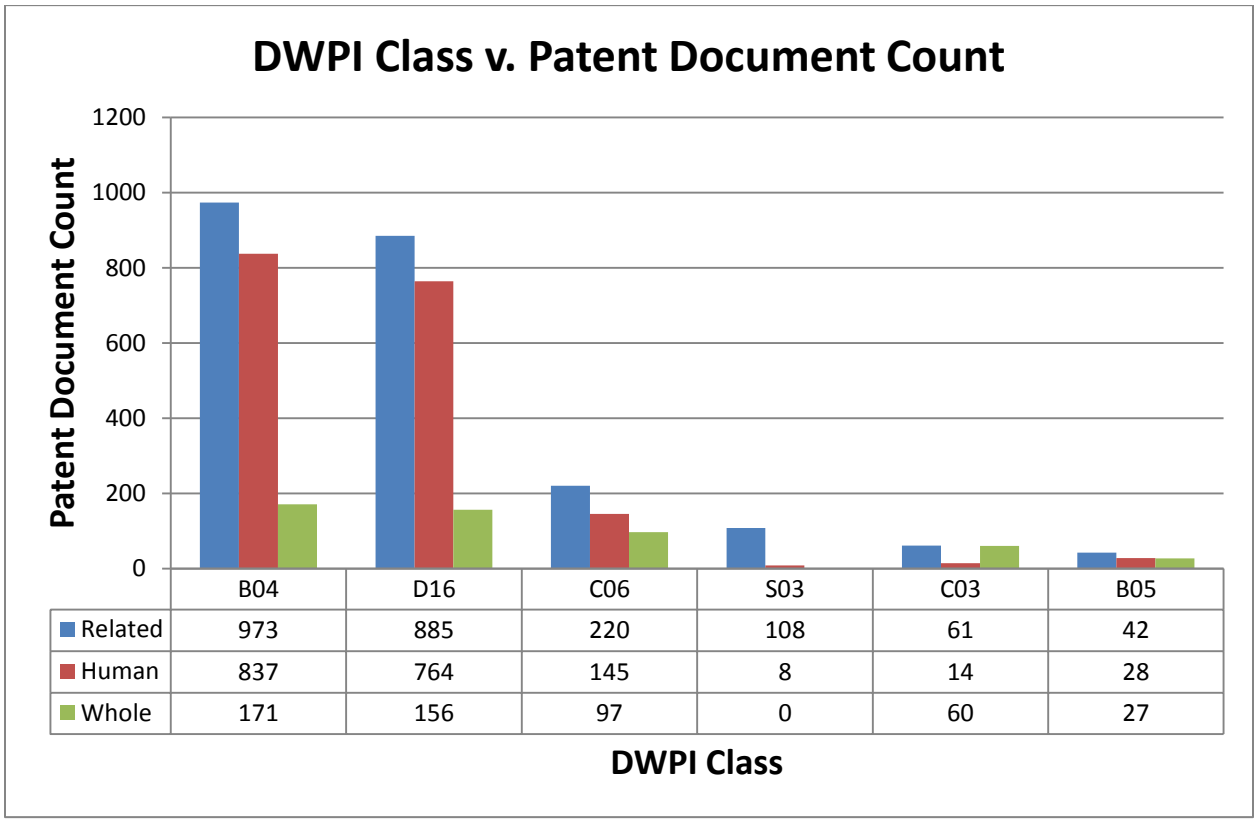
Chart 12: Top IPC (Current) v. Patent Document Count (Whole)

DWPI Class v. Patent Doc Count

DWPI classification system is a unique way of categorizing patent documents using a simple classification system for all technologies. This unique classification is carried by Thomson Scientific subject experts, enabling effective and precise searching in a particular area of technology. As per this system, Patents are broadly divided into three areas: Chemical, Engineering, and Electronic and Electrical Engineering. Each of these is then further divided into Sections and Classes which describe the technical area, or areas, covered by the patent.

The graph for DWPI Class versus patent doc count is shown. It represents the number of patent documents that have been classified under a specified DWPI Class. For the purpose of this graph ITTI used the top 7 DWPI classes, which are described in the below table.

From the above graph, it can be determined that most number of patents relates to the technology of "DNA", "general compositions", "production of vaccines" "genetic engineering" and "Bio-Technology." It can be noticed that 60 patent documents in *Whole Sporozoite Vaccine Technologies* category are classified under "C03 – Other Organic Compounds" because they consists of multiple claims directed to sporozoites as well as some other organic compounds.



	B04	D16	C06	S03	C03	B05
Related	973	885	220	108	61	42
Human	837	764	145	8	14	28
Whole	171	156	97	0	60	27

Chart 13: DWPI Class v. Patent Document Count

Derwent Manual Code v. Patent Documents

The patent family count for the category *Whole Sporozoite Vaccine Technologies* is only 13. The count is too small to offer a significant Top ten ranking, so as to demonstrate a significant count difference from a Code to another. Therefore, instead of using patent families, ITTI used the expanded (INPADOC) patent documents as the column to in order to present a more significant count difference between Codes.

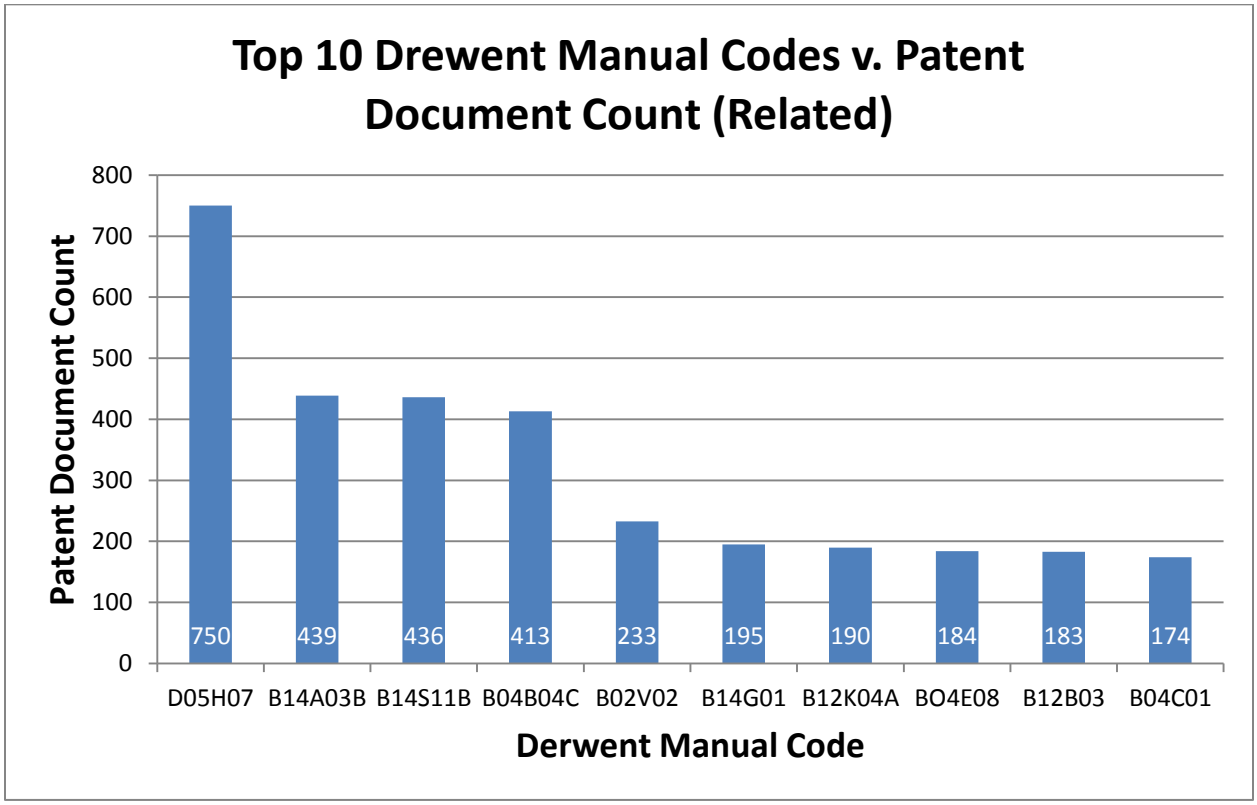


Chart 14: Top 10 Derwent Manual Codes v. Patent Document Count (Related)

The document count being analyzed is 1458 for the category of *Sporozoite Related Vaccine Technologies*. This category has section B Codes and section D Codes representing "Pharmaceuticals," and "Food, Disinfectants, Detergents" respectively. Code D05H07, B14A03B, B14S11B, and B04B04C are the top four Codes presented in the all vaccines category. Each of the count of the top four Codes is, or nearly is, 150 more than the count of the rest six Codes. Viewing the Codes listed in the chart below, the results are consistent with the technology of malaria vaccines, which is the focus of the ITTI's project.

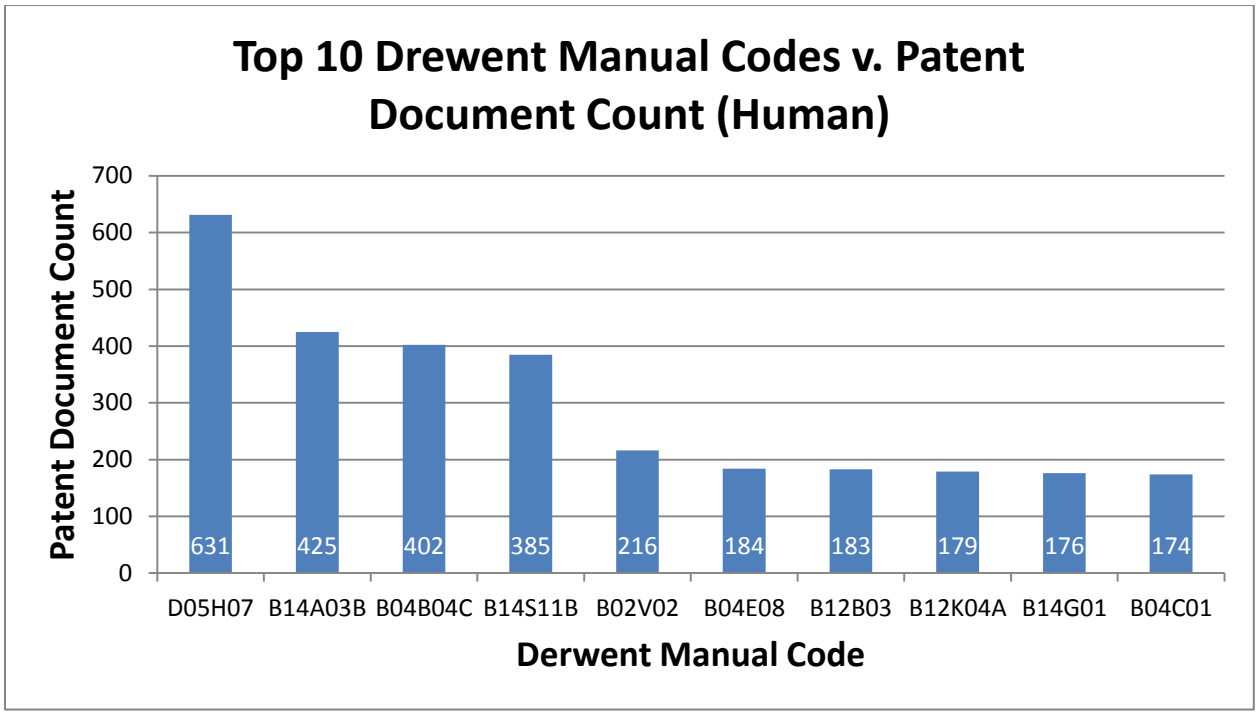


Chart 15: Top 10 Derwent Manual Codes v. Patent Document Count (Human)

The document count being analyzed is 1215. The trend of the graph is alike of the graph for *Sporozoite Related Vaccine Technologies*. All the Codes in this category are conserved as those in category *Sporozoite Related Vaccine Technologies*, even though the order of each Code maybe different. This consistency reflects the fact that the patents we searched in this category take the majority of the main category *Sporozoite Vaccine Related Technology*. The count for the first Code, D05H07, is 631. Each of the counts for second to fourth Codes is twice, or nearly twice, of that of the rest six Codes.

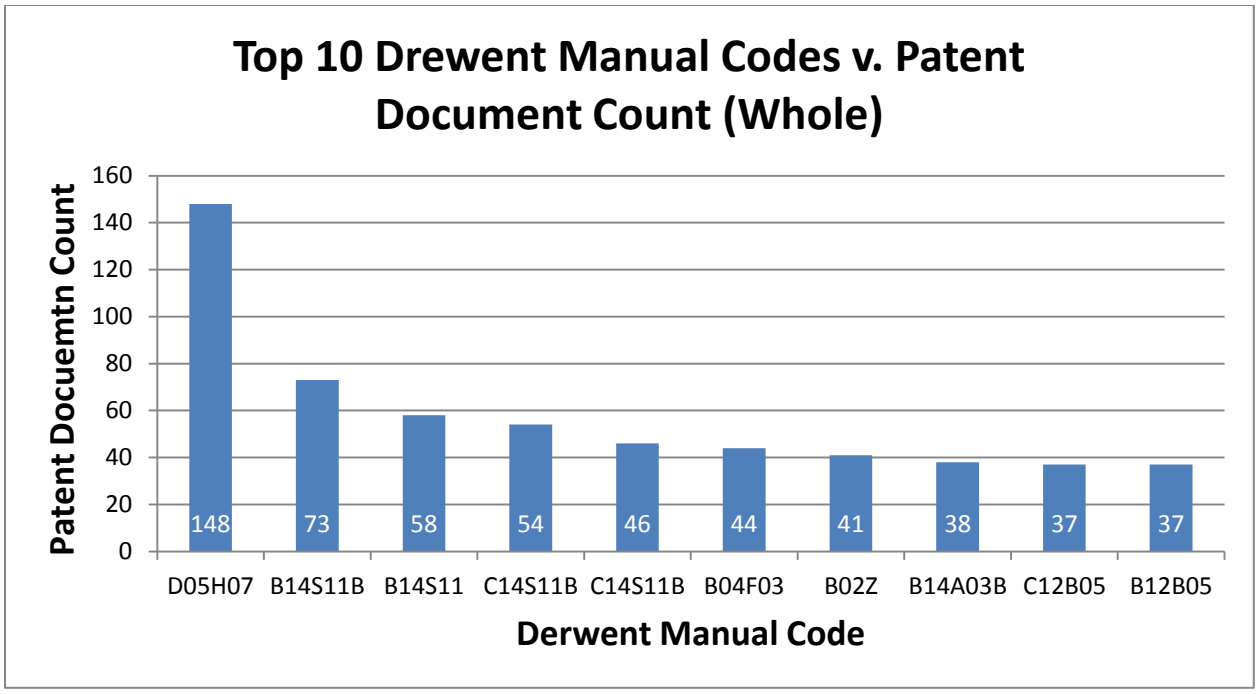


Chart 16: Top 10 Derwent Manual Codes v. Patent Document Count (Whole)

The document count being analyzed is 315. Count for Code D05H07 is more than twice of the count for the second Code B14S11B. Different from the previous two categories which have only section B Codes (9/10) and section D Codes (1/10), this category has 3 section C Codes (C14S11, C14S11B, and C12B05). Section C represents Agricultural chemicals. Besides, Codes which are not human beings involved inventions are presented.

Assignee v. Patent Family

Under 35 U.S.C. §261 patents have the attributes of personal property and are thus assignable. The Assignee of the patent is then the person or entity that owns the rights in the patent.[94] ITTI analyzed the 114 representative patent family documents to determine who the top assignees are in the relevant technology field, malarial vaccines targeting the sporozoite stage.

ITTI completed the assignee analytics using Thomson Innovation. The 114 representative patent family documents were analyzed as a whole and then analyzed again when ITTI separated them into two groups: patents claiming *Whole Sporozoite Vaccine Technologies* and patents claiming *Human Malaria Sporozoite Vaccine Technologies*. There is some overlap between the two groups.

[94] 35 U.S.C. §261, http://www.uspto.gov/web/offices/pac/mpep/documents/appxl_35_U_S_C_261.htm (last visited April 17, 2012).

Chart 17 shows the analysis of all 114 representative patent documents. The top assignee in this area being the University of New York followed by GlaxoSmithKline, the U.S. Navy, Enricerche SPA., and U.S. Health Department.

Chart 18 shows the analysis of the 99 representative patent documents related to *Human Malaria Sporozoite Vaccine Technologies*. The top assignee in this area being the University of New York followed by GlaxoSmithKline, the U.S. Navy, Enricerche SPA., and U.S. Health Department.

Chart 19 shows the analysis of the 23 representative patent documents related to *Whole Sporozoite Vaccine Technologies*. The top assignee in this area is Pfizer followed by the University of New York and Robins Co., Inc.

The analytics in this section do not reflect patent portfolios which have been combined as a result of mergers or acquisitions of Assignees. For example, the patent portfolios of GlaxoSmithKline and SmithKline Beecham were combined as of 2000.

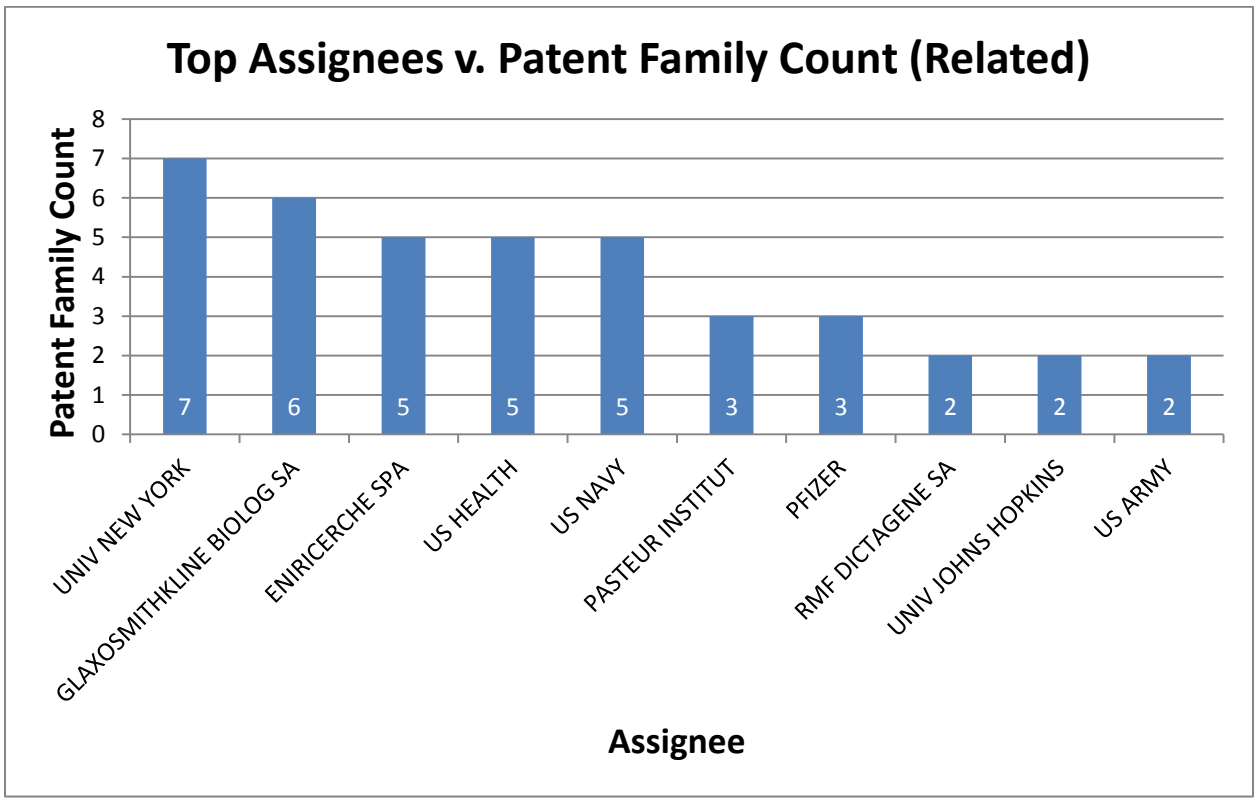


Chart 17: Top Assignees v. Patent Family Count (Related)

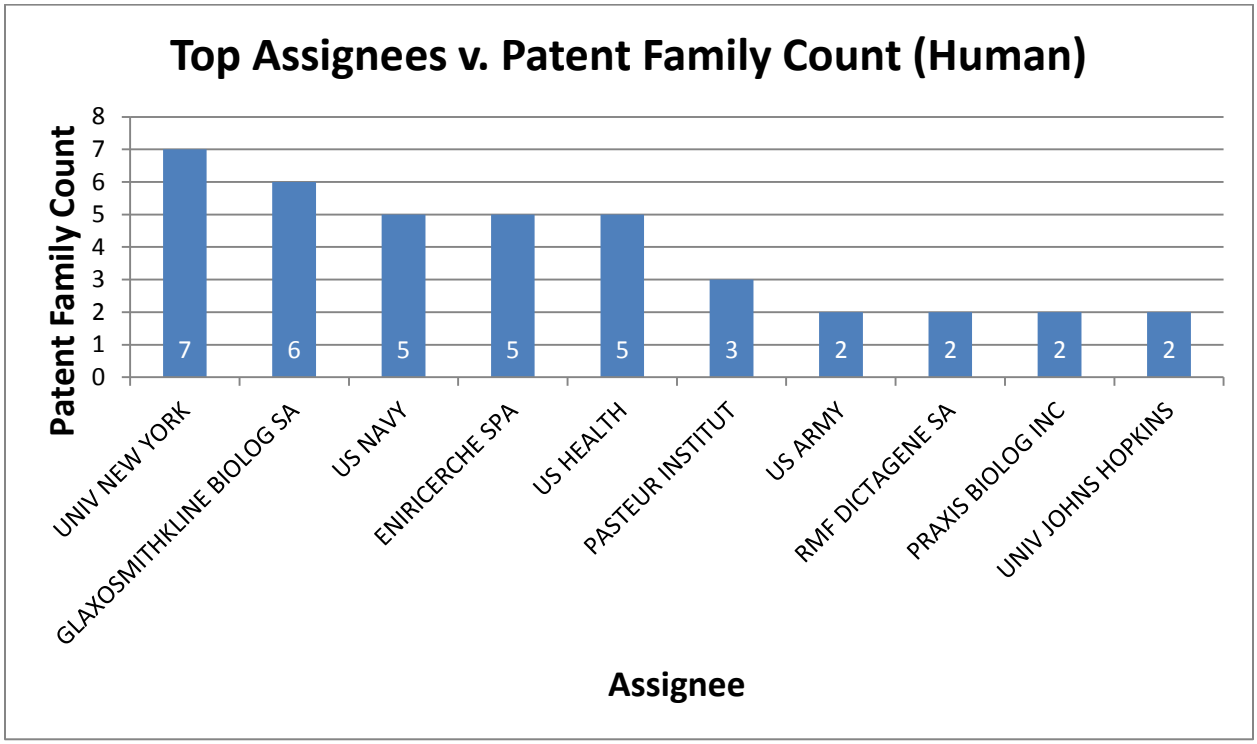


Chart 18: Top Assignees v. Patent Family Count (Human)

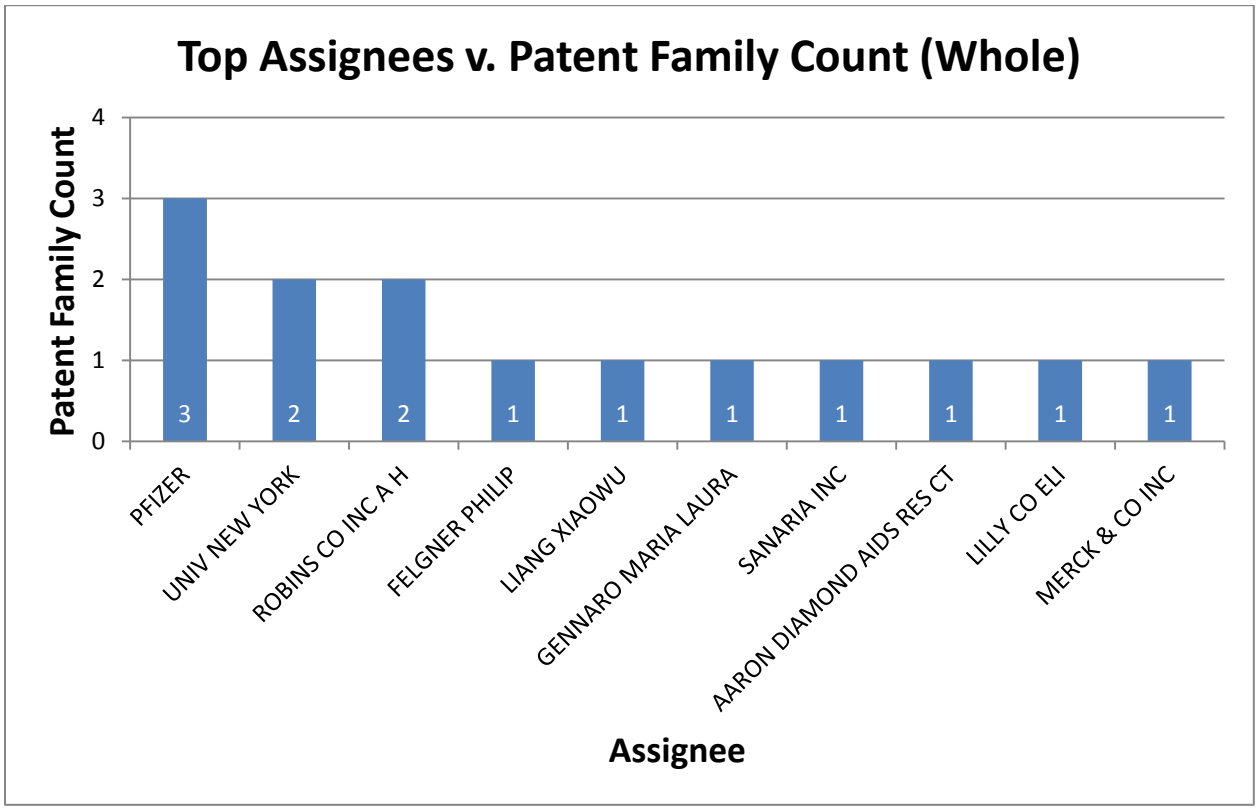


Chart 19: Top Assignees v. Patent Family Count (Whole)

Top Inventors for *Sporozoite Related Vaccine Technologies*

For vaccines technologies involving all technologies of vaccination, including malaria and other Sporozoa-infection diseases such as Eimeria, the top inventors are shown. The graph depicts the number of patent families filed by various top inventors, particularly in the *Sporozoite Related Vaccine Technologies*. Because the inventor remains constant across the various patent documents of a patent family, one representative patent document from each patent family was used for the purpose of this analysis. As discussed earlier, the representative documents belong to either the US jurisdiction or WIPO (PCT) jurisdiction.

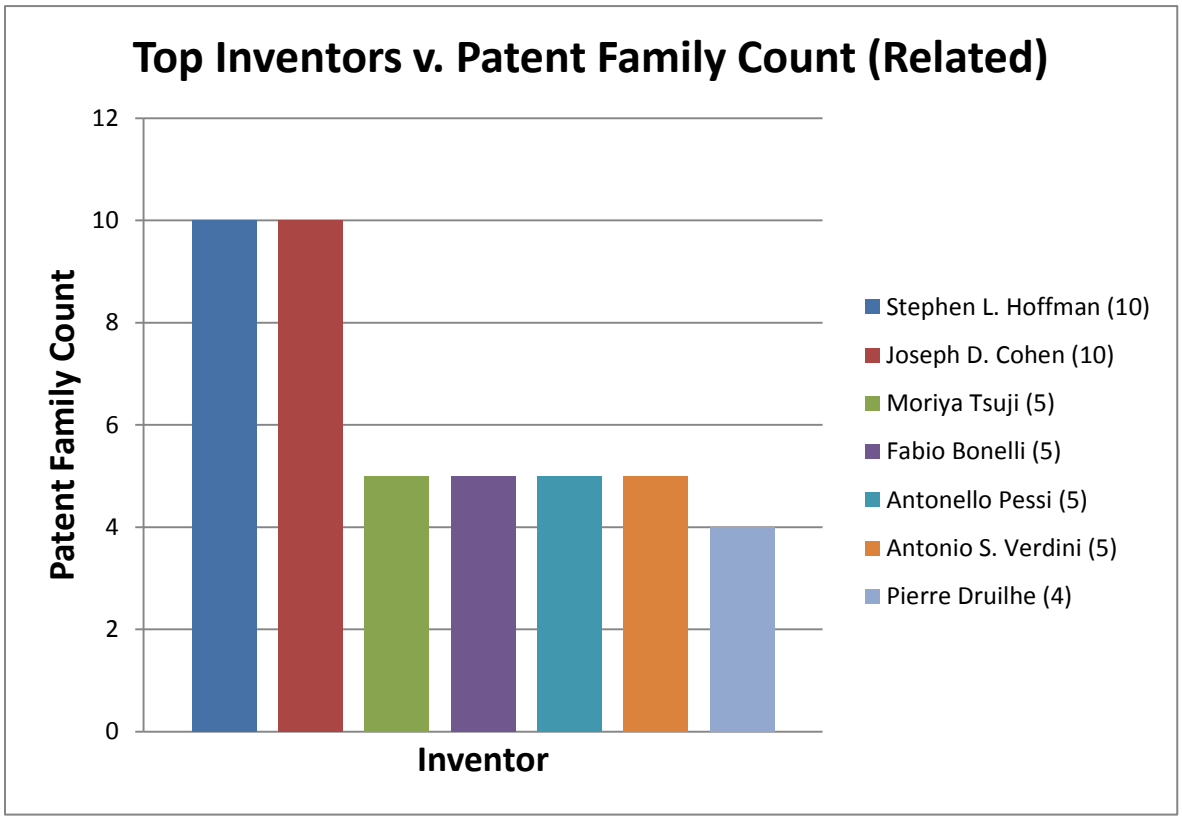


Chart 20: Top Inventors v. Patent Family Count (Related)

As per the above graph, Dr. Stephen L. Hoffman and Dr. Joseph "Joe" Cohen have the maximum number of patent families for this technology, i.e. 10 patent families. Dr. Hoffman, founder of Sanaria, holds over 20 years of experience in malaria vaccine research.[95] The patents he is inventor on mainly involve DNA vaccines, and a combination of DNA and peptide vaccines, against malaria. Dr. Cohen, who is working with GlaxoSmithKline on malaria vaccines since over 20 years, is also one of the original inventors and patent holder of an RTS,S-technology malaria

[95] *Id*.

vaccine.[96] Most of the relevant patents he is inventor on in this report deal with sporozoite antigens, and their combination with Hepatitis B antigens. Following Cohen and Hoffman, some inventors on a number of patent families in the range of 4 to 5. Moriya Tsuji, Fabio Bonelli, Antonello Pessi and Antonio S. Verdini are the inventors of 5 patent families each. Pierre Druilhe is inventor on 4 patent families. Numerous other inventors are inventors of 3 or less patent families each.

Top Inventors for Human Malaria Sporozoite Technologies

For patents in the *Human Malaria Sporozoites Vaccine Technologies*, the top inventors are shown. The graph depicts the number of patent families filed by various top inventors, particularly in the *Human Malaria Sporozoites Vaccine Technologies*. Because the inventor remains constant across the various patent documents of a patent family, one representative patent document from each patent family was used for the purpose of this analysis. As discussed earlier, the representative documents belong to either the US jurisdiction or WIPO (PCT) jurisdiction.

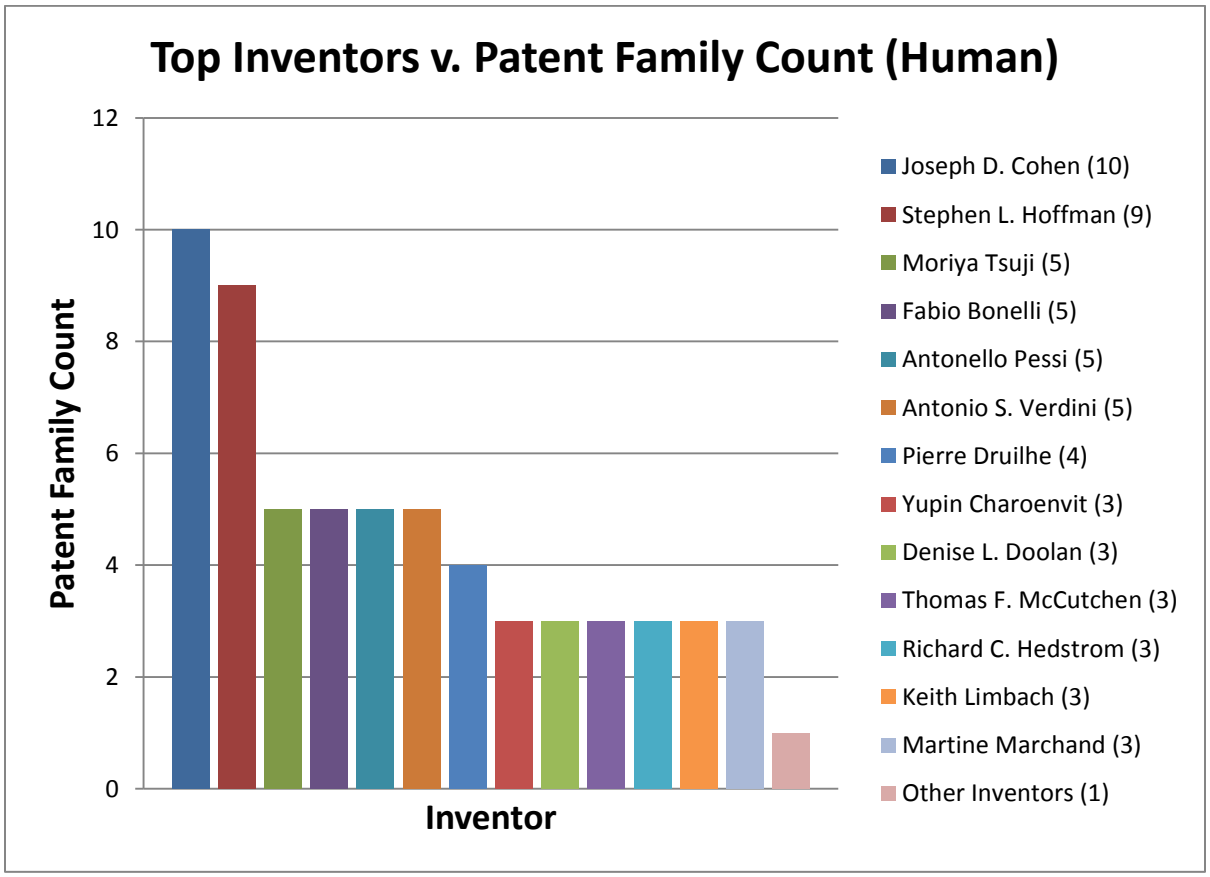


Chart 21: Top Inventors v. Patent Family Count (Human)

[96] http://www.malariavaccine.org/files/Montreaux%20Media%20Briefing/Speaker-bios.htm (last visited May 15, 2012).

As per the above graph, Dr. Joseph "Joe" D. Cohen is inventor on the maximum number of patent families for this technology, i.e. 10 patent families. Dr. Cohen, who is working with GlaxoSmithKline on malaria vaccines since over 20 years, is also one of the original inventors and patent holder of an RTS,S-technology malaria vaccine.[97] Most of the relevant patents he is inventor on in this report deal with sporozoite antigens, and their combination with Hepatitis B antigens. Close to Cohen is Dr. Stephen L. Hoffman with 9 patent families. Dr. Hoffman, founder of Sanaria, holds over 20 years of experience in malaria vaccine research.[98] His patents mainly involve DNA vaccines, and a combination of DNA and peptide vaccines, against malaria. Following Cohen and Hoffman, several inventors are on a number of patent families in the range of 3 to 5. Moriya Tsuji, Fabio Bonelli, Antonello Pessi and Antonio S. Verdini are the inventor on of 5 patent families each. Numerous other inventors are inventors on 1 patent family each.

Top Inventors for *Whole Sporozoite Vaccine Technologies*

Vaccine technologies involving whole sporozoites are for those diseases which are caused by *Sporozoa* species in the sporozoite stage, e.g. malaria (plasmodium), coccidiosis (eimeria) and toxoplasmosis (toxoplasma gondii). The graph depicts the number of patent families filed by various top inventors, particularly in the *Whole Sporozoite Vaccine Technologies*. Because the inventor remains constant across the various patent documents of a patent family, one representative patent document from each patent family was used for the purpose of this analysis. As discussed earlier, the representative documents belong to either the US jurisdiction or WIPO (PCT) jurisdiction.

[97] http://www.malariavaccine.org/files/Montreaux%20Media%20Briefing/Speaker-bios.htm (last visited May 15, 2012).
[98] http://www.molbio1.princeton.edu/NCLB/hoffman.html (last visited May 15, 2012).

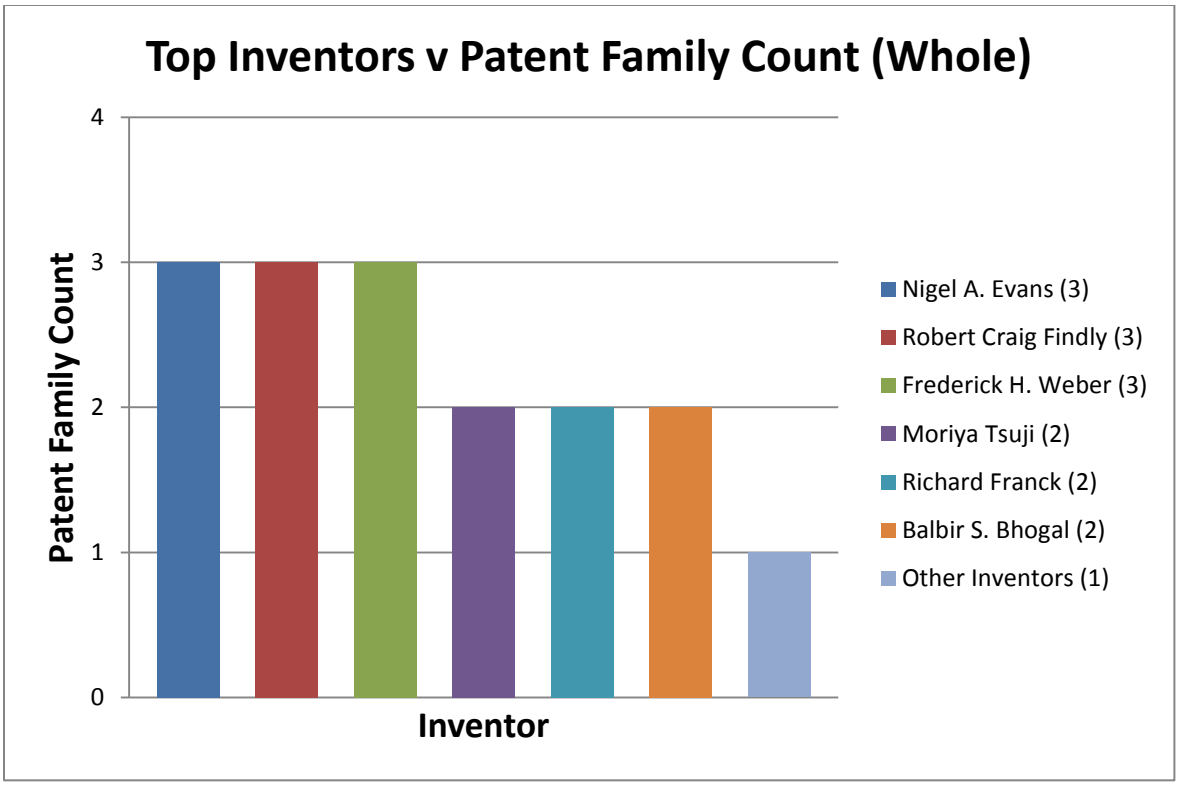


Chart 22: Top Inventors v. Patent Family Count (Whole)

As per the above graph, the maximum number of patent families for this technology are invented by Nigel A. Evans, Robert Craig Findly and Frederick H. Weber, with 3 patent families each. The patents on their inventions revolve around using whole sporozoites for in ovo vaccination against coccidiosis. They are closely followed by Moriya Tsuji (also a notable inventor of human malaria vaccine technology), Richard Franck, and Balbir S. Bhogal, as inventor on 2 patent famililes each. Numerous other inventors are inventors of 1 patent family each.

Themescape Map

Themescape Map is a visual representation tool of Thomson Innovation. It uses all the scientific data including enhanced patent data (DWPI) and scientific literature content. This thematic topographical map enables “at a glance” assessments and is searchable. It is an easy and efficient way to gather, organize, analyze, publish, and maintain large amounts of enterprise information.

Sporozoite Vaccine Related Technology

The below is a themescape map for the *Sporozoite Vaccine Related Technology Category with assignees indicated.* From the map it is evident that New York University has a diversified research for the Malaria. The diversified research includes treating malaria by the help of compounds, species and amino acids. US Navy has their research focused mainly on proteins,

viral vectors and plasmids. US Health also has a much diversified research relating to malaria including all major categories such as compounds, species, amino acids and proteins. SmithKline has their research mainly targeted to Liver Stage malaria. Eniricerche Spa has a very narrow research focusing on pure antimalarial substances.



Figure 8: Related Documents Themescape Map

Assignee Data	Number of Documents	Color
Univ New York	7	Red
US Navy	7	Green
US Health	5	Yellow
SmithKline	5	Pale Blue
Eniricerche Spa	5	Navy Blue

Inventor

The below is a themescape map for the *Sporozoite Vaccine Related Technology Category with inventors on it.* From the map it is evident that Stephen L. Hoffman has the most number of

patents in this category. He has a diversified research that is directed to proteins and amino acids directed to Circumsporozoite. Joseph D. Cohen has a diversified research focusing on oil in water emulsions. Moriya Tsuji also has a diversified research targeted to immuno-augmenting methods. Fabio Bonelli & Antonello Pessi have a narrow research focusing on antigens.



Figure 9: Related Documents Themescape Map – Inventor Abstraction

Inventor	Number of Documents	Color
Hoffman, Stephen L.	8	Red
Cohen Joseph D	7	Green
Tsuji, Moriya	5	Yellow
Bonelli, Fabio	5	Pale Blue
Pessi, Antonello	5	Navy Blue

Human Malaria Sporozoite Technologies

The below is a themescape map for the *Human Malaria Sporozoite Technologies with assignees on it.* From the map it is evident that New York University has a diversified research for the Malaria. The diversified research includes treating malaria by the help of combination of cells,

prime vectors and amino acids. US Navy has their research focused mainly on viral vectors and plasmids. US Health also has a much diversified research relating to malaria including amino acids and proteins. Eniricerche Spa has a very narrow research focusing on priming substances and synthetic Circumsporozoite amino acids. Pasteur Institute has its research focusing on detection methods as well as adenoviral vectors.

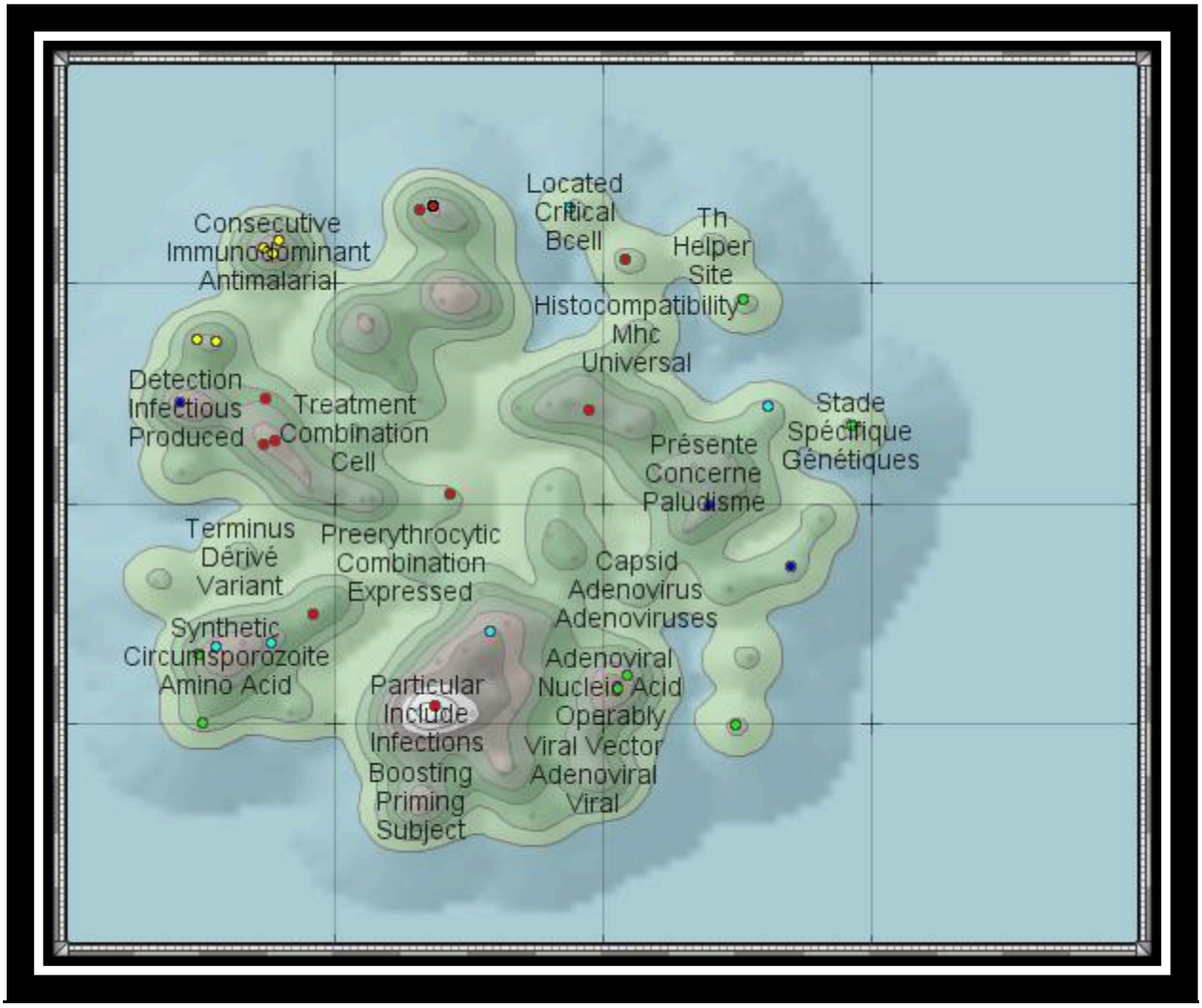


Figure 10: Human Documents Themescape Map

Assignee Data	Number of Documents	Color
Univ New York	10	Red
US Navy	7	Green
Eniricerche Spa	5	Yellow
US Health	5	Pale Blue
Pasteur Instuit	5	Navy Blue

Inventor

The below is a themescape map for the *Human Malaria Sporozoite Technologies with inventors on it.* From the map it is evident that Stephen L. Hoffman has the most number of patents in this category. He has a diversified research that is directed to synthetic amino acids specially Circumsporozoite. Joseph D. Cohenhas a diversified research focusing on pre-erythrocytic stage of Malaria as well as boosting primers. Moriya Tsuji also has a diversified research in the areas of combination cell treatment and adenoviral nucleic acids. Fabio Bonelli & Antonello Pessi has a narrow research focusing on detection methods and other immunostimulants.



Figure 11: Human Documents Themescape Map – Inventor Abstraction

Inventor	Number of Documents	Color
Hoffman, Stephen L.	7	Red
Cohen Joseph D	7	Green
Tsuji, Moriya	5	Yellow
Bonelli, Fabio	5	Pale Blue
Pessi, Antonello	5	Navy Blue

Whole Sporozoite Vaccine Technologies

The below is a themescape map for the *Whole Sporozoite Vaccine Technologies.* From the map it is evident that Pfizer has the most number of patents in this category. Most of the Pfizer's research is directed to In Ovo Vaccination methods against coccidiosis. Robins Co Inc. A H has its research focused on Cellulose Micro Capsule and Polymeric Stabilizers. New York University's research is focused on adjutants. Sanaria has its research focusing on the combination of Whole Sporozoite Vaccine Technologies species.



Figure 12: Whole Documents Themescape Map

Assignee Data	Number of Documents	Color
Pfizer	3	Red
Robins Co Inc. A H	2	Pale Blue
Univ New York	2	Yellow
Sanaria	1	Green

Inventor

The below is a themescape map for the *Whole Sporozoite Vaccine Technologies* with inventors on it. From this map it is evident that most of the inventions under this category have been co-

invented by many inventors. In summary most of the research is directed to adjutants and in ovo methods.



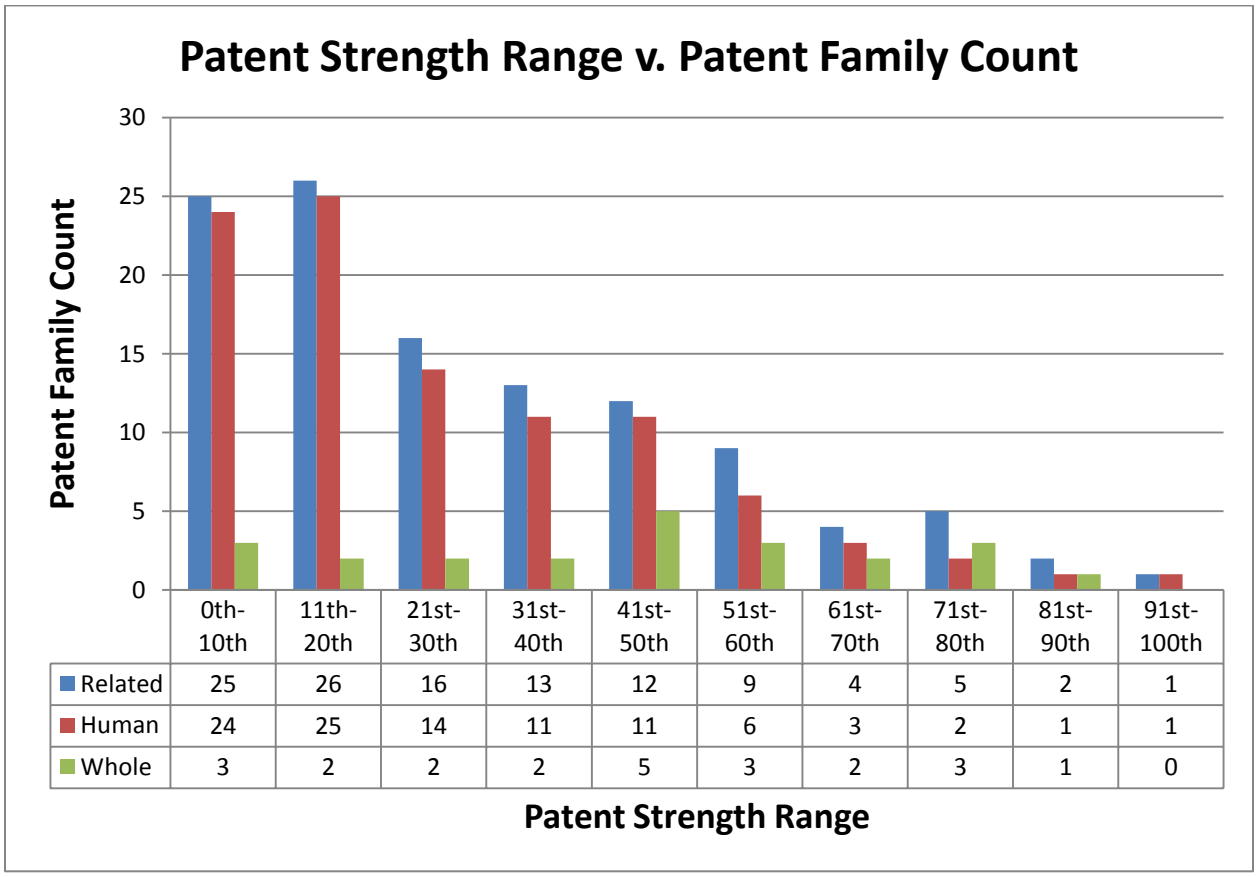
Figure 13: Whole Documents Themescape Map – Inventor Abstraction

Inventor	Number of Documents	Color
Evans, Nigel A.	3	Red
Findly, Robert Craig	3	Pale Blue
Weber, Frederick H.	2	Yellow
Tsuji, Moriya	2	Green

Patent Strength Range versus Patent Family Count

The graph for patent strength versus patent family count is shown. It depicts the number of patent families falling in various ranges of patent strength. The patent strength is taken from the Innography platform, which calculates it on the basis of various parameters, including number of backward and forward citations, amount of time in prosecution, number if claims,

amount of litigation, patent classification, patent age, and other factors.[99] [100] Patent strength can be used for determining litigation risk, making maintenance decisions, for prioritizing results, and for performing relative comparisons. Because the patent strength remains constant across the various patent documents of a patent family, one representative patent document from each patent family was used for the purpose of this analysis. As discussed earlier, the representative documents belong to either the US jurisdiction or WIPO (PCT) jurisdiction.



	0th-10th	11th-20th	21st-30th	31st-40th	41st-50th	51st-60th	61st-70th	71st-80th	81st-90th	91st-100th
Related	25	26	16	13	12	9	4	5	2	1
Human	24	25	14	11	11	6	3	2	1	1
Whole	3	2	2	2	5	3	2	3	1	0

Chart 23: Patent Strength Range v. Patent Family Count

From the above graph, it can be determined that most of the patents for *Sporozoite Related Vaccine Technologies (SVRT)* have low patent strength. About 98 patents lie in the range of 0-50th patent strength, while only about 21 patents have a higher patent strength. Only 1 patent lies in the range of 90-100th patent strength. For patents in the *Human Malaria Sporozoites Vaccine Technologies (HMSVT)*, the situation is quite similar, with most of the patent families lying in the lesser ranges of patent strength. Only about 13 patent family documents lie in and above 50-60th patent strength range. For patents in the *Whole Sporozoite Vaccine Technologies (WSVT)*, there is an even distribution of patent families across various patent strength ranges. The maximum number of patent families lie in the range of 40-50th patent strength range, i.e. 5. However, there is no patent family having 90-100th patent strength.

[99] https://app.innography.com/help/index.htm (last visited May 15, 2012).
[100] http://zuits.zju.edu.cn/attachments/2011-04/07-1302162675-65799.pdf (last visited May 15, 2012).

Patent Strength v. Number of Countries filed for Human Malaria Sporozoite Technologies

For patents in the *Human Malaria Sporozoites Vaccine Technologies*, ITTI performed analytics on the patent strength of a representative patent document in relation with the number of countries where those representative patents falling under that strength range were filed. As discussed earlier, the representative documents belong to either the US jurisdiction or WIPO (PCT) jurisdiction.

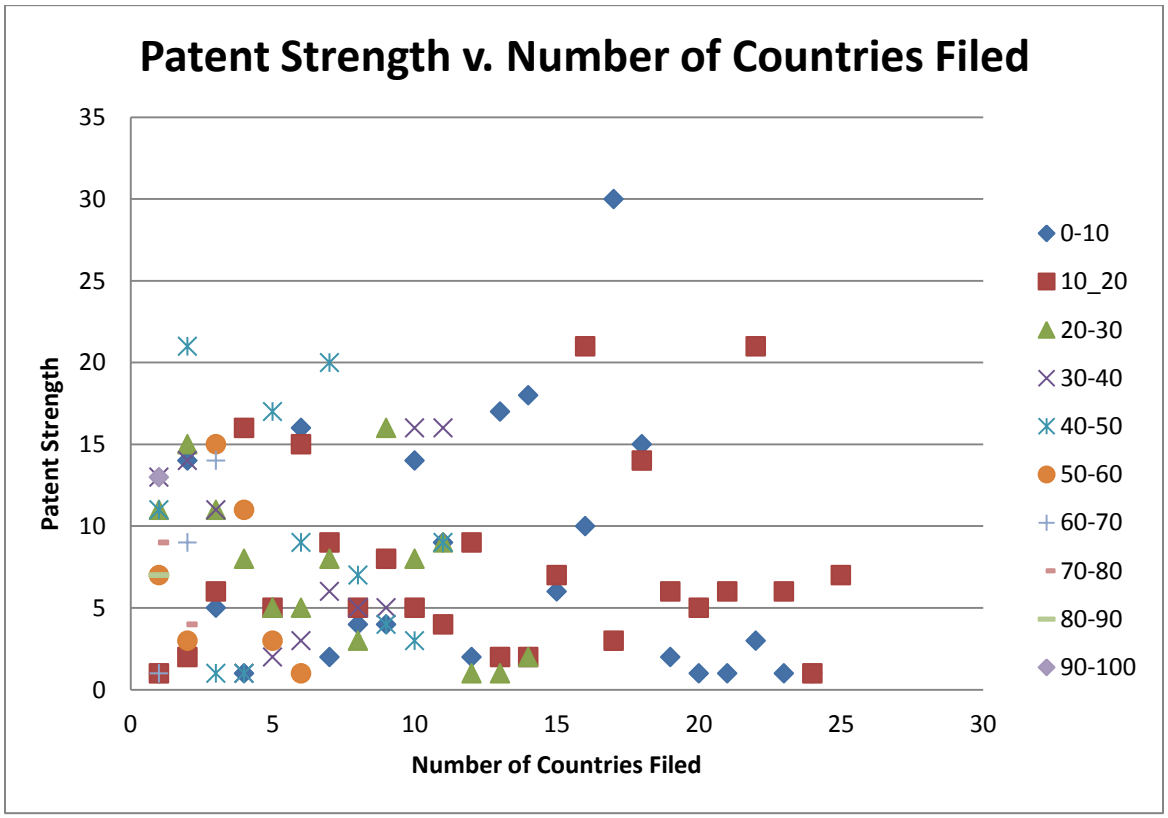


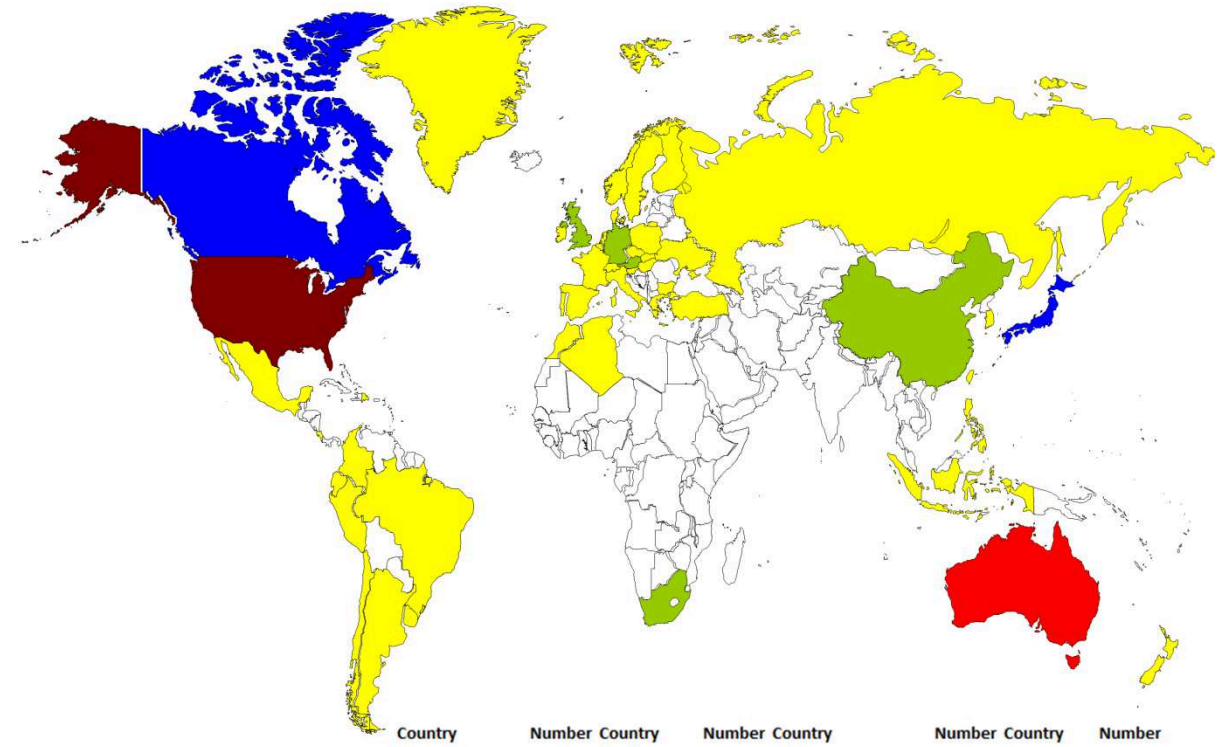
Chart 24: Patent Strength v. Number of Countries Filed

The graph appeared to be scattered and without any pattern. The revelation from such a graph was that there is no relation of patent strength with the number of countries where the patent was filed. Patents This means that the strength of a patent does not appear to depend on how many countries it is filed in.

Global Filing Trends for Human Malarial Sporozoite Vaccines

The global filing trends for *Human Malaria Sporozoites Vaccine Technologies* are shown. Patent family representative documents associated with *Human Malaria Sporozoites Vaccine*

Technologies were used. The above map depicts the number of patent family filings per national jurisdiction, i.e. the number of countries a given patent family has been filed in. The patent families filed through PCT, EPO, ARIPO, EAPO and OAIPO are not shown in this map. Patent family filings in regional patent offices is not illustrated on the map, including: European Patent Office (EPO) 67; Patent Cooperation Treaty (PCT) 80; African Intellectual Property Organization (OAPI) 9; Eurasian Patent Office (EAPO) 6; and African Regional Intellectual Property Organization (ARIPO) 7.[101]



Country	Number	Country	Number	Country	Number	Country	Number
United States	90	Brazil	13	Peru	5	Russia	2
Australia	60	Korea, Rep	13	Singapore	5	Algeria	1
Canada	52	Greece	9	Costa Rica	4	Bulgaria	1
Japan	43	Mexico	9	Poland	4	Ecuador	1
China	27	Taiwan	9	Uruguay	4	Finland	1
Germany	26	Argentina	8	Belgium	3	Indonesia	1
Austria	25	Norway	8	Colombia	3	Philippines	1
South Africa	24	France	6	Czech Republic	3	Slovakia	1
United Kingdom	22	Hong Kong	6	Dominican Republic	3	Slovenia	1
Ireland	19	Portugal	6	Hungary	3	Turkey	1
Spain	18	Italy	5	Sweden	3	Ukraine	1
Denmark	16	Morocco	5	Switzerland	3		
New Zealand	14	Netherlands	5	Chile	2		

Figure 14: Global Filing Trends

According to the map, United States has the maximum number of patent family filings, i.e. 90 of the 114 families in this study. The closest countries after U.S. are Australia (60), Canada (52),

[101] K. Clark *supra* Note 1.

and Japan (43). Some European countries have patent family filings in the range of 20-30, namely Austria, Germany and Great Britain. In addition, China and South Africa also have patent family filings in that range.
Brazil and South Korea, along with Denmark, Israel, New Zealand and Spain have patent family filings in the range of 13 to 18. The presence of Asian, Latin American and African countries can be felt, with Hong Kong, Taiwan, Russia, Argentina, Peru, Uruguay and South Africa.

Text Clustering

Text Clustering analysis is a great tool to organize the data into categorical groupings based on significant phrases that appear in those documents. In general, this analysis is carried out by selecting larger and more closely related the groups of documents will yield the most refined set of text clusters.

Text Cluster analysis has many uses, such as conceptually evaluating a set of patents, providing a quick visual comparison of two or more sets of patents, or identifying key semantic concepts that might not otherwise be apparent in a set of documents.

The Text clusters for three different categories viz. *Sporozoite Related Vaccine Technologies*, *Human Malaria Sporozoites Vaccine Technologies* and *Whole Sporozoite Vaccine Technologies* are shown below. The text cluster for the category of *Sporozoite Related Vaccine Technologies* suggests that the key semantic concepts of the search are Nucleic Acids, Host Cells, DNA Sequences, and Peptides etc. The text cluster for the category of *Whole Sporozoite Vaccine Technologies* suggests that the key concepts of the search include Eimeria and Coccidiosis.

Text Cluster for the category *Sporozoite Related Vaccine Technologies*

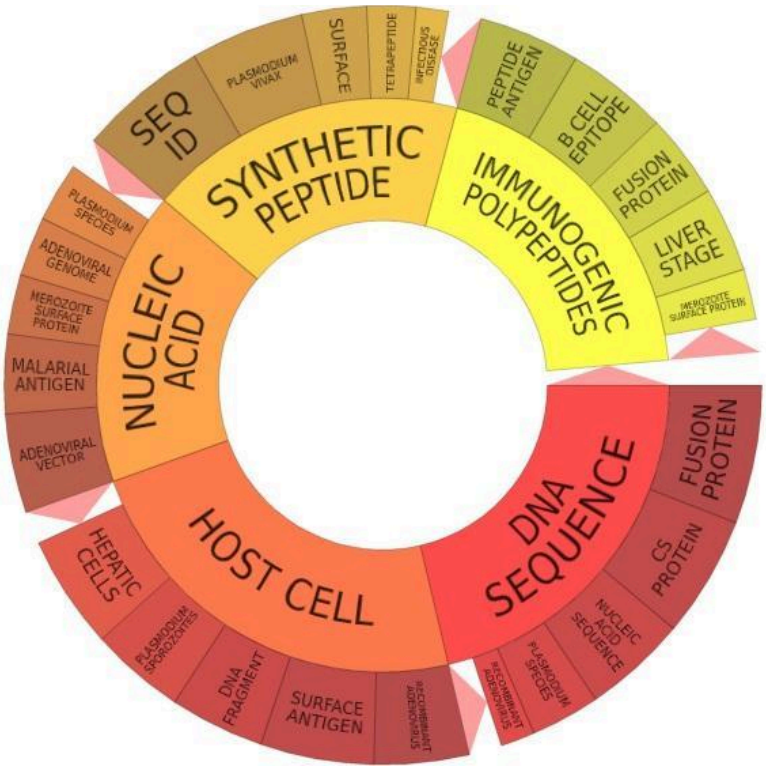


Figure 15: Text Cluster for Related

Text Cluster for *Human Malaria Sporozoites Vaccine Technologies*

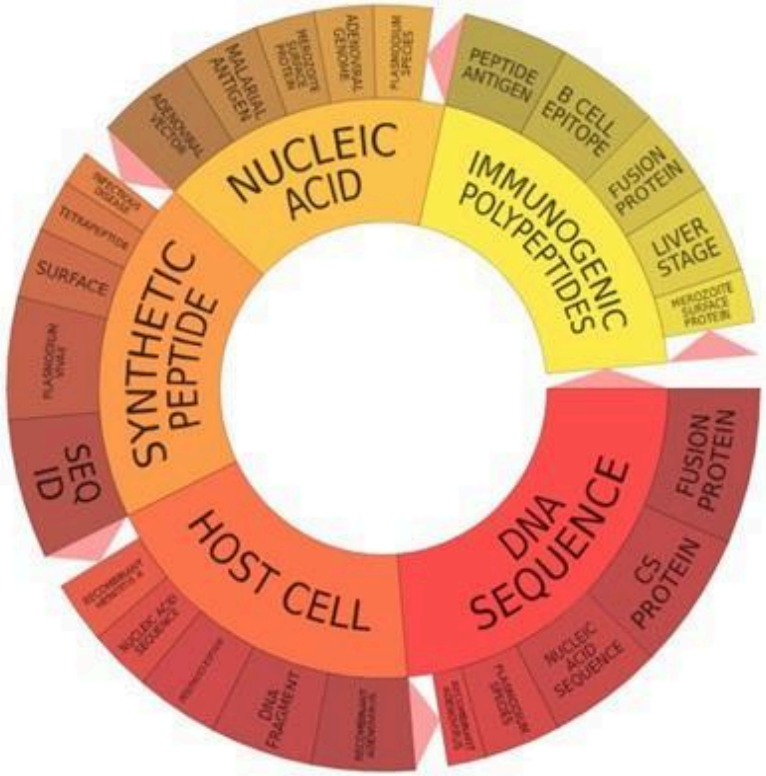


Figure 16: Text Cluster for Human

Text Cluster for *Whole Sporozoite Vaccine Technologies*

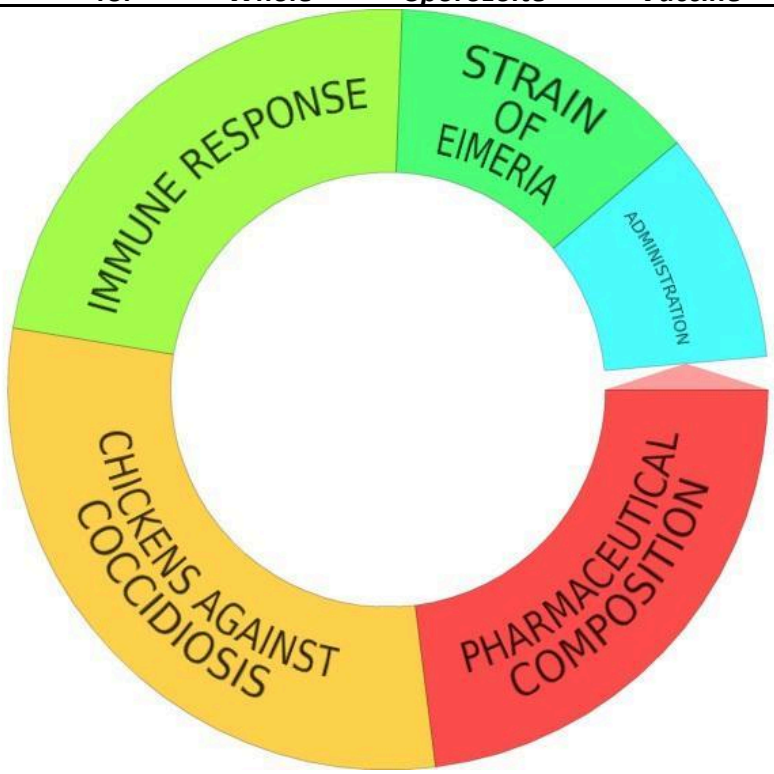


Figure 17: Text Cluster for Whole

Methods of Sporozoite Production

US4438097A – Coccidiosis vaccines

Egg-attenuated strain of Eimeria necatrix suitable for use in live attenuated vaccines is new. Vaccines containing the strain are useful for preventing and controlling coccidiosis in poultry. Such vaccines may contain other strains of Eimeria, esp. attenuated precocious E.acervulina. The vaccines may be included in food and/or drinking water. Dose is up to 5000 oocysts of each strain daily; suitably doses of 10-1000 oocysts of each strain are given daily over 1-5 weeks, or one or two 5000 oocyst doses are given. The vaccinated birds may be kept under conditions permitting access to their litter, to allow re-infection with oocysts derived from the vaccine.

US20080194006A1 – Methods of Releasing Sporocysts from Oocysts using Controlled Shear Forces

Releasing sporocysts from oocysts, involves preparing a solution containing oocysts suspended in it; subjecting the solution to controlled shear forces sufficient to rupture walls of the oocysts and release viable sporocysts from it; and recovering the released viable sporocysts from the solution. ... particularly Eimeria... useful for preparing a vaccine and/or a diagnostic assay (claimed). The method provides improved ways of releasing sporocysts from oocysts and it overcomes the problems associated with conventional methods, which are inefficient and yield

only a fraction of the potential viable sporocysts available. ... Moreover, little damage is done to released sporocysts allowing a high percentage of the recovered sporocysts to remain viable.... Preferred Method... involves treating the oocysts thermally, chemically, and/or enzymatically to weaken their walls prior to subjecting the solution to controlled shear forces. The method further involves cryopreserving the recovered sporocysts; preparing a vaccine and/or a diagnostic assay using the recovered sporocysts; excysting sporozoites from the recovered sporocysts; preparing a vaccine using the excysted sporozoites; determining a percentage of sporocysts released from the oocysts; and determining a percentage of released sporocysts that are viable...

US20080038226A1 – Culture Methods for Cryptosporidium
A host-cell free method for culturing Cryptosporidium comprising introducing Cryptosporidium, at a first lifecycle stage, into a host-cell free medium to enable the Cryptosporidium to progress to a second lifecycle stage or to complete its lifecycle, is new. INDEPENDENT CLAIMS are also included for: a host-cell free method for producing Cryptosporidium biomass from an initial inoculum of Cryptosporidium, comprising putting the inoculum into a host cell free medium, and culturing the Cryptosporidium to increase the Cryptosporidium biomass; a host and/or biphasic host cell free medium capable of maintaining Cryptosporidium or enabling the progress of Cryptosporidium through its lifecycle, comprising a buffered and balanced combination of inorganic salts, amino acids, vitamins and additional constituents; preventing or treating a disease associated with Cryptosporidium infection in a subject, comprising administering to the subject a composition of (4); and detecting Cryptosporidium in a sample, comprising subjecting the sample to the culture method cited, or introducing the sample into a host-cell free medium to enable Cryptosporidium to progress to a further lifecycle stage or to complete its lifecycle, and detecting the Cryptosporidium. ...

US20070169209A1 – Apparatuses and methods for the production of hematophagous organisms and parasites suitable for vaccine production.
A new apparatus useful in producing aseptic insect stage parasites for producing an attenuated Plasmodium sporozoite vaccine that is stable at relatively shallow cryogenic temperatures. A new apparatus for producing aseptic insect stage parasites.... The apparatus comprises: a walled chamber; a reservoir within the chamber for supporting growth of adult insects from surface sterilized insect eggs; and a blood feeding station within the chamber for allowing adult insects to consume blood that is infected with the parasites. INDEPENDENT CLAIMS are also included for the following: a method for the producing aseptic insect stage parasites; an apparatus for assessing the biting behavior of insects; a method for cultivating a hypoallergenic hematophagous insect; a method of cultivating a strain of hematophagous insects capable of an enhanced ability to form insect stage infectious parasites; a method of producing cryopreservation resistant Plasmodium species sporozoites; and an apparatus for the injection of ultra-low volumes of vaccine....

WO2007033398A1 – Cryptosporidium Propagation Systems
Culturing Cryptosporidium comprises introducing a stage in the life cycle of Cryptosporidium into a simple medium and culturing the Cryptosporidium. INDEPENDENT CLAIMS are: a

therapeutic composition comprising a therapeutically effective amount of Cryptosporidium cultured to the method of the present invention and a physiologically acceptable carrier; a method of producing Cryptosporidium antibodies which comprises inoculating a subject with Cryptosporidium cultured according to the present invention that has been neutralized or otherwise attenuated to remove its disease causing ability and isolating antibodies from the subject; a method for detecting Cryptosporidium in a sample; and a method of evaluating a drug. Protozoacide. No biological data given. Vaccine. The Cryptosporidium culture is useful in preparing an immunogenic composition for preventing or treating Cryptosporidium infection in dogs, cats, sheep, domestic animals (especially food producing animals), avian species, wild animals or human (claimed)....

Publication Number	Inventor	Assignee/ Applicant	Priority Country	Priority Year	IPC - Current	US Class
US4438097A	Shirley, Martin W.	National Research Development Corporation, London, GB	GB; US	1980	A61K0039012 C12N000110 C12N000136	4242711 424088 4352584 424093 435258
US20080194006A1	Hutchins, James Earl; Wilson, Kerrianne; Hartman, Angela; Harris, Kelly Michelle	Embrex Inc.	US	2007	C12N000110	4352584
US20080038226A1	Hijjawi, Nawal; Thompson, Andrew R.C.; Ryan, Una M.	Murdoch University, Murdoch, AU Sydney Water Corporation, Sydney, AU	US; AU	2004	A61K003568 A61P003100 C12N000110 C12Q000104 C12Q000168	4240931 43500612 435034 4352581 435006
US20070169209A1	Hoffman, Stephen, L.; Luke, Thomas, C.		US	2003	A01K0067033 C12N000110	800013 4352581
WO2007033398A1	HIJJAWI, Nawal; THOMPSON, Richard, Christopher, Andrew; RYAN, Una, Mary; BOXELL, Annika, Claire	MURDOCH UNIVERSITY, AU; SYDNEY WATER CORPORATION, AU	AU	2005	C12N000110	

Table 2: Methods of Production

Conclusion

Malaria is a common and wide-spread infectious disease that is caused by the mosquito-borne *Plasmodium* parasite.[102] Nearly half of the world's population, especially in developing countries, is at risk for contracting malaria, and over one hundred countries continue to report endemic levels of this disease.[103] Currently, there is no effective malaria vaccine approved for use in humans.[104]

The World Health Organization (WHO) reported over two hundred million cases of malaria in 2010, which resulted in an estimated 655,000 deaths.[105] Children under the age of five represented 86% of all malaria deaths,[106] and six African countries — Nigeria, Democratic Republic of Congo, Burkina Faso, Mozambique, Cote d'Ivoire, and Mali — accounted for 60% of all malaria deaths.[107] Outside of Africa, malaria remains a serious health issue in areas of Southeast Asia, the Middle East, Oceania, and the Americas, particularly South America and the Caribbean.[108]

The purpose of this patent landscape was to search for, identify, and categorize patent documents that are focused on malaria vaccine technology related to structural elements of the *Plasmodium* sporozoite. Additionally, other vaccine technologies that involve sporozoites of other organisms were also included in the scope of the project to help inform on malaria vaccine development. One factor in identifying leaders in a particular field of research is by the size of a patent portfolio. This report tentatively identifies several key industry leaders within the malaria sporozoite vaccine industry, including New York University, GlaxoSmithKline plc., the United States Navy, Eniricerche SA., and the United States Department of Health and Human Services.

Additionally, two major inventors are identified, Dr. Stephen L. Hoffman and Dr. Joseph "Joe" Cohen. Dr. Hoffman is the CEO of Sanaria Inc. and was a research scientist for the U.S. Navy. Dr. Cohen is the Vice President for Research and Development at GlaxoSmithKline.

ITTI commenced an intense three-month iterative search and coding process. Thomson Innovation was the primary patent searching platform, but ITTI also used other tools, including Lexis Total Patent™ and GenomeQuest.

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[102] U.S. Global Health Policy, *The Global Malaria Epidemic: Fact Sheet*, THE HENRY J. KAISER FAMILY FOUNDATION (Mar. 2011), http://www.kff.org/globalhealth/upload/7882-03.pdf.
[103] *Id*. Endemic is defined as "where a constant, measurable number of new cases and natural transmission occurs over time." *Id.*
[104] *Id*.
[105] *World Malaria Report: 2011*, WORLD HEALTH ORGANIZATION, http://www.who.int/malaria/world_malaria_report_2011/9789241564403_eng.pdf (last visited Mar. 15, 2012).
[106] *Id*.
[107] *Id*.
[108] *See* U.S. Global Health Policy, *supra* note 50.

These searches utilized keywords derived from the literature reviewed and initial searches to generate useful search strings; the searches also used United States Patent Classifications and International Patent Classifications that were identified through subsequent searches and team meetings. The combinations of keywords and classifications in search strings was useful for parsing the technology into compartments and allowing each team member to generate a different set of search results that keywords alone could not provide. This approach generated a broad set of patents. From here, ITTI used the keywords and classifications generated from this broad set of patents in subsequent rounds of searching. After each round of searching, ITTI would identify the most important keywords and classifications for use in subsequent search strings that became more defined and effective.

Examples of keywords include:

- Sporozoite
- Malaria
- Circumsporozoite
- Vaccine

ITTI also performed sequence searching to corroborate the results from conventional search methods. ITTI performed the sequence searches after searching non-patent literature in NCBI's PubMed. The non-patent literature documents were generally scientific articles containing nucleotide and protein sequences related to the relevant technology. The sequences referenced in the articles were inserted into GenomeQuest and ITTI used the BLAST algorithm to perform a search that produced patents with the same or similar nucleotide or protein sequences.

ITTI coded patent documents for sporozoite based vaccines using four relevancy categories; one category has three subcategories, and another category has four subcategories. The four categories are sporozoite, vaccine, methods of vaccine production, and adjuvants. One of these categories, sporozoite, must be found in every relevant document. ITTI coded 114 relevant INPADOC families.

APPENDIX A: Table of Relevant Patent Families

Publication Number	Title	Assignee/Applicant	Inventor	Publication Date
US20020058047A1	VACCINES		GARCON, NATHALIE | MOMIN, PATRICIA MARIE CHRISTINE ALINE, FRANCOISE	2002-05-16
US20020136733A1	Malaria peptides		Hill, Adrian, Vivian Sinton | Aidoo, Michael | Allsopp, Catherine, Elizabeth Margaret | Lalvani, Ajit | Plebanski, Magdalena | Whittle, Hilton, Carter	2002-09-26
US20030104003A1	Novel surface protein of the malaria parasite plasmodium falciparum		James, Anthony, A. | Nguyen, Thanh, V.	2003-06-05
US20030185854A1	Use of recombinant hepatitis B core particles to develop vaccines against infectious pathogens and malignancies		Zavala, Fidel | Birkett, Ashley, J.	2003-10-02
US20040037838A1	Malaria vaccine	RMF DICTAGENE S.A.	Corradin, Giampietro | Rogerro, Mario	2004-02-26
US20040176283A1	Methods and compositions for the design of synthetic vaccines		Robinson, John, A. | Pluschke, Gerd | Moehle, Kerstin | Pfeiffer, Bernhard | Zurbriggen, Rinaldo | Glueck, Reinhart	2004-09-09

US20050031592A1	Methods and compositions for inducing immune responses and protective immunity by priming with alpha virus replicon vaccines		Doolan, Denise, L. | Brice, Gary, L. | Dobano Lazaro, Carlota | Chulay, Jeffrey, D. | Kamrud, Kurt, I. | Smith, Jonathan, F.	2005-02-10
US20050208020A1	Enhancement of vaccine-induced immune responses and protection by heterologous boosting with alphavirus replicon vaccines		Doolan, Denise | Brice, Gary | Carucci, Daniel | Kamrud, Kurt | Chulay, Jeffrey | Smith, Jonathan	2005-09-22
US20050208068A1	Malaria immunogen and vaccine		Milich, David | Birkett, Ashley	2005-09-22
US20050220822A1	Methods for the prevention of malaria		Hoffman, Stephen | Luke, Thomas	2005-10-06
US20050222048A1	Novel synthetic C-glycolipids, their synthesis and use to treat infections, cancer and autoimmune diseases	New York University,New York,NY,US | The Research Foundation of The City University of New York,New York,NY,US	Tsuji, Moriya | Franck, Richard | Chen, Guangwu	2005-10-06
US20060188527A1	Methods for vaccinating against malaria		Hoffman, Stephen, L | Wang, Ruobing | Epstein, Judith, E. | Cohen, Joseph, D.	2006-08-24
US20060240033A1	Use of allogenic or syngenic major histocompatibility complex (MHC) molecules as universal adjuvants for vaccines against neoplastic disease,	New York University,New York,NY,US	Tsuji, Moriya	2006-10-26

	infection and autoimmune disease			
US20060292170A1	Vaccine Composition Against Malaria	SmithKline Beecham Biologicals s.a.	Cohen, Joseph	2006-12-28
US20070087021A1	METHOD OF PROTECTING AGAINST CHRONIC INFECTIONS		Lee, Eng Hong	2007-04-19
US20070110771A1	Immunogenic agent and pharmaceutical composition for use against homologous and heterologous pathogens	THE COUNCIL OF THE QUENNESLAND INSTITUTE OF MEDICAL RESEARCH,HERSTON,AU	Good, Michael | Stevenson, Mary, M.	2007-05-17
US20070169209A1	Apparatuses and methods for the production of haematophagous organisms and parasites suitable for vaccine production		Hoffman, Stephen, L. | Luke, Thomas, C.	2007-07-19
US20070196394A1	Immunogenic compositions comprising Liver Stage Malarial Antigens		Cohen, Joe | Druilhe, Pierre	2007-08-23
US20080038226A1	Culture Methods for Cryptosporidium	Murdoch University,Modoch,AU | Sydney Water Corporation,Sydney,AU	Hijjawi, Nawal | Thompson, Andrew R.C. | Ryan, Una M.	2008-02-14
US20080102091A1	Vaccines	GLAXOSMITHKLINE BIOLOGICALS SA,Rixensart,BE	Cohen, Joseph D. | Tornieporth, Nadia Gabriela	2008-05-01

US20080131464A1	VACCINES	Smithkline Beecham Biologicals SA	COHEN, Joseph | Garcon, Nathalie | Voss, Gerald	2008-06-05
US20080194006A1	METHODS OF RELEASING SPOROCYSTS FROM OOCYSTS USING CONTROLLED SHEAR FORCES	Embrex Inc.	Hutchins, James Earl | Wilson, Kerrianne | Hartman, Angela | Harris, Kelly Michelle	2008-08-14
US20080317787A1	Anti-Malaria Vaccine		Cohen, Joseph D.	2008-12-25
US20090110695A1	Compositions Comprising a Recombinant Adenovirus and an Adjuvant		Havenga, Menzo Jans Emko | Radosevic, Katarina	2009-04-30
US20090148477A1	ADENOVIRAL VECTOR-BASED MALARIA VACCINES	GENVEC INC.,Gaithersburg,MD,US	Bruder, Joseph T. | Kovesdi, Imre | King, C. Richter | McVey, Duncan L. | Ettyreddy, Damodar R. | Doolan, Denise Louis | Carucci, Daniel John | Limbach, Keith	2009-06-11
US20090220547A1	Reducing interference between oil-containing adjuvants and surfactant-containing antigens	NOVARTIS VACCINES AND DIAGNOSTICS SRL,Siena,IT	Contorni, Mario	2009-09-03
US20090311285A1	VACCINE	GlaxoSmith Kline Biologicals s.a. a corporation	Biemans, Ralph Leon | Duvivier, Pierre	2009-12-17

US20100015173A1	COILED-COIL LIPOPEPTIDE HELICAL BUNDLES AND SYNTHETIC VIRUS-LIKE PARTICLES	UNIVERSITÄT ZÓRICH PROREKTORAT FORSCHUNG,Zuerich,CH	Boato, Francesca | Freund, Annabelle | Ghasparian, Arin | Moehle, Kerstin | Robinson, John A. | Thomas, Richard M.	2010-01-21
US20100015182A1	COCCIDIOSIS VACCINES	Intervet Inc.	Lang, Marcelo | Broussard, Charles Timothy | Schrader, Joan S.	2010-01-21
US20100040615A1	Digalactolipidic Antigen Exposed on the Surface of Apicomplex Parasites, and Diagnostic and Therapeutic Use Thereof	COMMISSARIAT A L'ENERGIE ATOMIQUE,Paris,FR | CENTRE NATIONAL DE LA RECHERCHE SEIENTIFIQUE,Paris,FR	Botte, Cyrille | Saidani, Nadia | Block, Maryse | Dubremetz, Jean-Francois | Vial, Henri | Cesbron-Delauw, Marie-France | Mercier, Corinne | Marechal, Eric	2010-02-18
US20100055166A1	NOVEL METHOD AND COMPOSITIONS		Voss, Gerald Hermann	2010-03-04
US20100150960A1	COMPOSITIONS AND METHODS FOR CHITOSAN ENHANCED IMMUNE RESPONSE	The United States of America as represented by the Secretary Department of Health and Human Servi,BETHESDA,MD,US	Schlom, Jeffrey | Zaharoff, David A. | Greiner, John W.	2010-06-17
US20100150998A1	VACCINES FOR MALARIA	GLAXOSMITHKLINE BIOLOGICALS S.A.,Rixensart,BE | THE U.S.OFA. AS REPRESENTED BY THE SECRETARY OF THE ARMY,Silver Spring,MD,US	Cohen, Joseph D. | Marchand, Martine | Ockenhouse, Christian F. | Yadava, Anjali	2010-06-17
US20100183590A1	LSA-5 liver stage and blood stage antigen of Plasmodium falciparum, immunogenic composition		Druilhe, Pierre | Brahimi-Zeghidour, Karima	2010-07-22

	comprising said antigen, and vaccines against malaria			
US20100199391A1	ANTI-MALARIA VACCINE COMPOSITIONS AND USES THEREOF	UNIVERSITE DE SCIENCES ET TECHOLOGIES DE LILLE,Villeneuve d'Ascq,FR | CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE (CNRS,Paris,FR	Tomavo, Stanislas | Ball, Steven Graham | D'Hulst, Christophe | Dauvillee, David	2010-08-05
US20100255075A1	CR-2 Binding Peptide P28 as Molecular Adjuvant for DNA Vaccines		Bergmann-Leitner, Elke S. | Angov, Evelina | Tsokos, George C.	2010-10-07
US20100272745A1	VACCINES FOR MALARIA		Lemoine, Dominique Ingrid | Wauters, Florence Emilie Jeanne Francoise	2010-10-28
US20100272753A1	Recombinant Adenovirus Vaccines	The Johns Hopkins University,Baltimore,MD,US	Ketner, Gary W. | Roden, Richard B. | Zavala, Fidel P.	2010-10-28
US20100272786A1	VACCINE		Cohen, Joseph D. | Marchand, Martine	2010-10-28
US20100272788A1	VACCINES FOR MALARIA	GlaxoSmithKline Biologicals s.a.,Rixensart,BE	Cohen, Joseph D. | Marchand, Martine	2010-10-28
US20100278870A1	ADENOVIRAL VECTOR-BASED MALARIA VACCINES	The Henry M. Jackson Foundation for the Advancement of Military Medicine Inc.,Rockville,MD,US	Bruder, Joseph T. | King, C. Richter | Richie, Thomas | Limbach, Keith | Doolan, Denise Louise	2010-11-04

US20100310603A1	TEM8 as an Adjuvant and Uses Thereof		Gregor, Polly | Houghton, Alan	2010-12-09
US20110002916A1	Plasmodium falciparum antigens and their vaccine and diagnostic applications	Institut Pasteur	Druilhe, Pierre | Grüner, Anne-Charlotte	2011-01-06
US20110008383A1	COMPOSITIONS OF TOLL-LIKE RECEPTOR AGONISTS AND MALARIA ANTIGENS AND METHODS OF USE		POWELL, THOMAS J. | NAKAAR, VALERIAN | MCDONALD, WILLIAM F. | NARDIN, ELIZABETH H.	2011-01-13
US20110008414A9	METHOD FOR SYNTHESIZING CONFORMATIONALLY CONSTRAINED PEPTIDES, PEPTIDOMIMETICS AND THE USE THEREOF AS SYNTHETIC VACCINES	Mymetics Corporation,New York,NY,US	Pluschke, Gerd | Kienzl, Ursula | Robinson, John | Zurbriggen, Rinaldo	2011-01-13
US20110020387A1	MALARIA VACCINE	STATENS SERUM INSTITUT,COPENHAGEN S,DK	THEISEN, MICHAEL | JEPSEN, SØREN	2011-01-27
US20110064768A1	Immunogenic Compositions		Draper, Simon | Hill, Adrian | Hill, Fergal	2011-03-17
US20110104195A1	Plasmodium falciparum sporozoite and liver stage antigens		Aguiar, Joao | Limbach, Keith | Sedagah, Martha | Richie, Thomas	2011-05-05

US20110182929A1	MULTICOMPONENT VACCINE FOR MALARIA PROVIDING LONG-LASTING IMMUNE RESPONSES AGAINST PLASMODIA		Schneerson, Rachel | Kubler-Kielb, Joanna | Robbins, John B. | Majadly, Fathy | Mocca, Christopher P. | Keith, Jerry | Biesova, Zuzana | Miller, Louis | Nussenzweig, Ruth | Liu, Darrell T.	2011-07-28
US20110189218A1	Plasmodium vivax hybrid circumsporozoite protein and vaccine		Yadava, Anjali | Ockenhouse, Christian F.	2011-08-04
US20110206714A1	MALARIA VACCINE COMPOSITIONS AND CONSTITUENTS WHICH ELICIT CELL MEDIATED IMMUNITY		Shafferman, Avigdor | Zvi, Anat | Fulkerson, John | Sadoff, Jerald C.	2011-08-25
US20110212159A1	VACCINES		Ballou, William Ripley | Cohen, Joseph D.	2011-09-01
US20110229503A1	Vaccination against malignant melanoma using bcg and/or vaccinia	Goerg-Ausust-Universitat Gottingen Stiftung offentlichen Rechts	Krone, Bernd | Hunsmann, Gerhard	2011-09-22
US20110236468A1	VACCINE COMPOSITIONS		Lorin, Clarisse Marie-Madeleine | Fevrier, Michele | Voss, Gerald Hermann | Tangy, Frederic	2011-09-29
US20110262469A1	MALARIA VACCINE BASED ON FRAGMENTS AND COMBINATION OF FRAGMENTS OF THE CS PROTEIN OF	Centro Internacional De Vacunas,Cali,CO	Herrera Valencia, Socrates | Arevalo-Herrara, Myriam | Corradin, Giampietro	2011-10-27

	PLASMODIUM VIVAX			
US20120015000A1	MALARIA VACCINE OF SELF-ASSEMBLING POLYPEPTIDE NANOPARTICLES		Lanar, David | Burkhard, Peter	2012-01-19
US20120015401A1	PLASMODIUM FALCIPARUM ANTIGENS AND METHODS OF USE	U.S.A as Represented by the Secretary of the Navy Office of Naval Research (Code 00CC),Arlington,VA,US | Epimmune Inc.,San Diego,CA,US	Sette, Alessandro | Doolan, Denise L. | Carucci, Daniel J. | Sidney, John | Southwood, Scott	2012-01-19
US4301148A	Anticocoidial drug	Nisshin Flour Milling Co. Ltd.,Tokyo,JP	Shibata, Kenji | Ozima, Masami	1981-11-17
US4438097A	Coccidiosis vaccines	National Research Development Corporation,London,GB	Shirley, Martin W.	1984-03-20
US4639372A	Coccidiosis vaccine	Merck & Co. Inc.,Rahway,NJ,US	Murray, Peter K. | Galuska, Stefan	1987-01-27
US4693994A	Protective synthetic peptide against malaria and encoding gene	The Government of the United States of America as represented by the Secretary of the Department of Health and Human Services,Washington,DC,US	McCutchan, Thomas F. | Wistar, Jr., Richard	1987-09-15
US4707357A	Immunologically active peptides capable of inducing immunization against malaria and genes encoding therefor	The United States of America as represented by the Secretary of the Army,Washington,DC,US	Dame, John B. | Williams, Jackie L. | McCutchan, Thomas F. | Schneider, Imogene	1987-11-17

US4769235A	Immunodominant epitope of the circumsporozoite surface protein	New York University,New York,NY,US	Schlesinger, David H. | Nussenzweig, Victor N.	1988-09-06
US4808404A	Live vaccine for coccidiosis utilizing coccidial sporozoites	A. H. Robins Company Inc.,Richmond,VA,US	Bhogal, Balbir S.	1989-02-28
US4843146A	Immunologically active polypeptides useful for the preparation of antimalarial vaccines and of diagnostic kits for the detection of antisporozoite antibodies	Eniricerche SA.,Milan,IT	Bernardi, Adriano | Bonelli, Fabio | Pessi, Antonello | Verdini, Antonio S.	1989-06-27
US4886782A	Malarial immunogen	The United States of America as represented by the Department of Health and Human Services,Washington,DC,US	Good, Michael A. | Berzofsky, Jay | Miller, Louis H.	1989-12-12
US4935007A	Anticoccidial method	Eli Lilly and Company,Indianapolis,IN,US	Bafundo, Kenneth W. | Jeffers, Thomas K.	1990-06-19
US4956449A	Immunologically active synthetic peptides useful for preparing an antimalarial vaccine	Eniricerche SA.,Milan,IT	Verdini, Antonio S. | Bonelli, Fabio | Pessi, Antonello	1990-09-11
US5028425A	Synthetic vaccine against P. falciparum malaria	The United States of America as represented by the Department of Health and Human Services,Washington,DC,US	Good, Michael F. | Kumar, Sanjai | Berzofsky, Jay A. | Miller, Louis H.	1991-07-02

US5068104A	Live vaccine for coccidiosis utilizing coccidial sporozoites	A. H. Robins Company Incorporated,Richmond,VA,US	Bhogal, Balbir S. | Williams, Michael G. | Miller, Glenn A.	1991-11-26
US5112749A	Vaccines for the malaria circumsporozoite protein	Praxis Biologics Inc.,Rochester,NY,US	Brey, III, Robert N. | Majarian, William R. | Pillai, Subramonia | Hockmeyer, Wayne T.	1992-05-12
US5114713A	P. falciparum CS-peptides as universal T-cell epitope	Hoffmann La Roche Inc.,Nutley,NJ,US	Sinigaglia, Francesco	1992-05-19
US5116946A	Synthetic, immunologically active peptides useful for the preparation of antimalarial vaccines	Eniricerche SA.,Milan,IT	Verdini, Antonio S. | Pessi, Antonello | Bonelli, Fabio	1992-05-26
US5198535A	Protective malaria sporozoite surface protein immunogen and gene	The United States of America as represented by the Secretary of the Navy,Washington,DC,US	Hoffman, Stephen L. | Charoenvit, Yupin | Hedstrom, Richard | Khusmith, Srisin | Rogers, IV, William O.	1993-03-30
US5219987A	Sequential polypeptides endowed with immunological activity	Eniricerche SA.,Milan,IT	Verdini, Antonio S. | Pessi, Antonello | Bonelli, Fabio	1993-06-15
US5225530A	Polypeptide useful for the preparation of antimalarial vaccines and of diagnostic kits for the detection of malarial affections	Eniricerche SA.,Milan,IT	Bernardi, Adriano | Bonelli, Fabio | Pessi, Antonello | Verdini, Antonio S.	1993-07-06

US5311841A	Administration of medicaments of poultry	THAXTON J PAUL	Thaxton, J. Paul	1994-05-17
US5599543A	Immunogenic four amino acid epitope against Plasmodium vivax	The United States of America as represented by the Secretary of the Navy,Washington,DC,US	Hoffman, Stephen L. | Charoenvit, Yupin | Jones, Trevor R.	1997-02-04
US5614194A	Protective peptide antigen	New York University,New York,NY,US	Colman, David R. | Ellis, Joan | Godson, G. Nigel | Nussenzweig, Ruth S. | Nussenzweig, Victor N. | Svec, Pamela S. | Zavala, Fidel	1997-03-25
US5695957A	Polypeptides and DNA encoding same, associated with human malaria parasites	Imperial Exploitation Limited,London,GB	Robson, Kathryn Jane	1997-12-09
US5700906A	Immunogenic peptide antigen corresponding to plasmodium vivax circumsporozoite protein	New York University,New York,NY,US	Arnot, David E. | Enea, Vincenzo | Nussenzweig, Ruth S. | Nussenzweig, Victor	1997-12-23
US5798106A	Protein	University of Nijmegan,NL	Schoenmakers, Johannes Gerardus Ghislain | Konings, Rudolph Nicholaas Hendrik | Moelans, Inge Irma Maria Dominique	1998-08-25
US5814617A	Protective 17 KDA malaria hepatic and erythrocytic stage immunogen and gene	The United States of America as represented by the Secretary of the Navy,Washington,DC,US	Hoffman, Stephen L. | Charoenvit, Yupin | Hedstrom, Richard C. |	1998-09-29

			Doolan, Denise L.	
US5961983A	Stable pura vectors and uses therefor	Praxis Biologics Inc.,West Henrietta,NJ,US	Brey, Robert N. | Fulginiti, James P. | Anilionis, Algis	1999-10-05
US6066623A	Polynucleotide vaccine protective against malaria, methods of protection and vector for delivering polynucleotide vaccines	The United States of America as represented by the Secretary of the Navy,Washington,DC,US	Hoffman, Stephen L. | Hedstrom, Richard C. | Sedegah, Martha	2000-05-23
US6113917A	Modified polypeptides for enhanced immunogenicity	RMF Dictagene S,CH	Fasel, Nicolas Joseph | Reymond, Christophe Dominique	2000-09-05
US6169171B1	Hybrid protein between CS from plasmodium and HBSAG	SmithKline Beecham Biologicals (s.a.),Rixensart,BE	De Wilde, Michel | Cohen, Joseph	2001-01-02
US6261569B1	Retro-, inverso-and retro-inverso synthetic peptide analogues	Deakin Research Limited,New South Wales,AU	Comis, Alfio | Tyler, Margaret Isabel | Fischer, Peter	2001-07-17
US6495146B1	In ovo vaccination against coccidiosis	Pfizer Incorporated,New York,NY	Evans, Nigel A. | Findly, Robert Craig | Weber, Frederick H.	2002-12-17
US6627205B2	Ovo vaccination against coccidiosis	Pfizer Incorporated,New York,NY	Evans, Nigel A. | Findly, Robert Craig | Weber, Frederick H.	2003-09-30

US6713301B1	Artificial T helper cell epitopes as immune stimulators for synthetic peptide immunogens	United Biomedical Inc.,Hauppauge,NY	Wang, Chang Yi	2004-03-30
US7018640B2	In ovo vaccination against coccidiosis	Pfizer Incorporated,New York,NY,US	Evans, Nigel A. | Findly, Robert Craig | Weber, Frederick H.	2006-03-28
US7211265B2	Vaccination modalities	Rural Industries Research and Development Corporation,AU | Eimeria Pty. Limited,AU | The State of Queensland through the Department of Primary Industries,AU	Richards, David Grant | Jorgensen, Wayne Keith | Stewart, Norman Porter	2007-05-01
US7273605B2	Vaccine	Isis Innovation Limited,Oxford,GB	Laidlaw, Stephen | Skinner, Mike | Hill, Adrian V. S. | Gilbert, Sarah C. | Anderson, Richard	2007-09-25
US7416878B2	Immunogenic compositions including rough phenotype Brucella host strains and complementation DNA fragments	The United States of America as represented by the Secretary of the Army,Washington,DC,US	Nikolich, Mikeljon | Hoover, David	2008-08-26
US7438916B2	Therapeutic target for protozoal diseases	Virginia Tech Intellectual Properties Inc.,Blacksburg,VA,US	Rathore, Dharmendar | Jani, Dewal | Nagarkatti, Rana	2008-10-21
US7438917B2	Peptide sequences specific for the hepatic stages of P. falciparum bearing epitopes capable of stimulating the T lymphocytes	Institut Pasteur,Paris,FR	Guerin-Marchand, Claudine | Druilhe, Pierre	2008-10-21

US7488491B2	Use of glycosylceramides as adjuvants for vaccines against infections and cancer	New York University,New York,NY,US	Tsuji, Moriya | Gonzalez-Aseguinolaza, Gloria | Koezuka, Yasuhiko	2009-02-10
US7550138B1	Plasmodium mutant and vaccines including the mutant	Leiden University Medical Center,Leiden,NL | Stichting Katholieke Universiteit Nijmegen,Nijmegen,NL	Waters, Andrew Paul | Janse, Christofel Jan | van Dijk, Melissa Ruth | Sauerwein, Robert W.	2009-06-23
US7749519B2	Unique DNA and polypeptide sequences based on the circumsporozoite protein of Plasmodium vivax	HOFFMAN STEPHEN | SIM KIM LEE | AREVALO MYRIAM | HERRERA SOCRATES	Sim, Kim Lee | Hoffman, Stephen | Arevalo, Myriam | Herrera, Socrates	2010-07-06
US7771726B2	Use of synthetic glycolipids as universal adjuvants for vaccines against cancer and infectious diseases	New York University,New York,NY,US | The Research Foundation of the City University of New York,New York,NY,US | Aaron Diamond Aids Research Center,New York,NY,US	Tsuji, Moriya | Schmieg, John | Franck, Richard | Huang, Yaoxing	2010-08-10
US8043625B2	Purified plasmodium and vaccine compositions	Sanaria Inc.,Rockville,MD,US	Sim, B. Kim Lee | Li, Minglin | Stafford, Richard E. | Hoffman, Stephen L.	2011-10-25
US8097453B2	Recombinant viral-based malaria vaccines	Crucell Holland B.V.,Leiden,NL	Pau, Maria G. | Holterman, Lennart | Kaspers, Jorn | Stegmann, Antonius J. H.	2012-01-17
US8114614B2	Compositions and methods for immunodominant antigens of Mycobacterium tuberculosis	FELGNER PHILIP | LIANG XIAOWU | GENNARO MARIA LAURA	Felgner, Philip | Liang, Xiaowu | Gennaro, Maria Laura	2012-02-14

WO1994024291A3	COMPOSITIONS OF ANTIGEN CONTAINING RECOMBINANT SALMONELLA, THEIR USE IN ANTI-MALARIAL VACCINES AND METHOD FOR THEIR PREPARATION | COMPOSITIONS DE SALMONELLE RECOMBINEE CONTENANT DES ANTIGENES, LEUR UTILISATION DANS DES VACCINS ANTIPALUDIQUES ET LEUR PROCEDE DE PREPARATION	WASHINGTON UNIVERSITY	CURTISS, Roy, III | SCHODEL, Florian	1994-12-08
WO1999055381A1	METHOD AND PROCESS FOR ESTABLISHMENT OF STAGE SPECIFIC EXPRESSION AND CHARACTERIZATION OF PROTEINS BASED ON MICROBIAL OR HUMAN GENOMIC SEQUENCE DATA | METHODE ET PROCEDE PERMETTANT D'ETABLIR UNE EXPRESSION SPECIFIQUE D'UN STADE ET CARACTERISATION DE PROTEINES SUR LA BASE DE DONNEES DE SEQUENCE GENOMIQUE MICROBIENNE OU HUMAINE	THE UNITED STATES OF AMERICA represented by THE SECRETARY OF THE U.S. DEPARTMENT OF THE NAVY,US	HOFFMAN, Stephen, L. | CARUCCI, Daniel, J.	1999-11-04

WO2001055181A3	RECOMBINANT MULTIVALENT MALARIAL VACCINES AGAINST | VACCINS ANTI-PALUDEENS MULTIVALENTS RECOMBINES CONTRE	THE GOVERNMENT OF THE UNITED STATES OF AMERICA as represented by THE SECRETARY DEPARTMENT OF HEALTH & HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION,US	LAL, Altaf, A. | XIAO, Lihua | ZHOU, Zhiyong	2001-12-20
WO2005063805A1	ANTIBODIES AGAINST THE AMINO TERMINUS REGION OF CIRCUMSPOROZOITE PROTEIN PREVENT THE ONSET OF MALARIA INFECTION | ANTICORPS DIRIGE CONTRE LA ZONE DE TERMINUS AMINO DE LA PROTEINE CIRCUMSPOROZOITE, POUR PREVENIR L'APPARITION D'INFECTIONS PALUDEENNES	THE GOVERNMENT OF THE UNITED STATES OF AMERICA AS REPRESENTED BY THE SECRETARY DEPARTMENT OF HEALTH AND HUMAN SERVICES,US	RATHORE, Dharmendar | MCCUTCHAN, Thomas, F.	2005-07-14
WO2007033398A1	CRYPTOSPORIDIUM PROPAGATION SYSTEMS | SYSTÈMES DE PROPAGATION DE CRYPTOSPORIDIUM	MURDOCH UNIVERSITY,AU | SYDNEY WATER CORPORATION,AU	HIJJAWI, Nawal | THOMPSON, Richard, Christopher, Andrew | RYAN, Una, Mary | BOXELL, Annika, Claire	2007-03-29
WO2010062859A3	RECOMBINANTLY EXPRESSED PLASMODIUM CELTOS ANTIGEN AND METHODS OF USE THEREOF | ANTIGÈNE CELTOS DE PLASMODIUM EXPRIMÉ DE MANIÈRE RECOMBINANTE ET PROCÉDÉS D'UTILISATION DE CELUI-CI	ANGOV Evelina,US | BERGMANN-LEITNER Elke,US | UNITED STATES DEPARTMENT OF THE ARMY AS RESPRESENTED BY THE SECRETARY OF THE ARMY,US | OCKENHOUSE Christian,US	ANGOV, Evelina | BERGMANN-LEITNER, Elke | OCKENHOUSE, Christian	2010-09-30

WO2011022002A1	MODIFICATION OF RECOMBINANT ADENOVIRUS WITH IMMUNOGENIC PLASMODIUM CIRCUMSPOROZOITE PROTEIN EPITOPES | MODIFICATION D'ADÉNOVIRUS RECOMBINANT PAR DES ÉPITOPES IMMUNOGÈNES DE PROTÉINE CIRCUMSPOROZOÏTE DE PLASMODIUM	THE ROCKEFELLER UNIVERSITY,US | SHIRATSUCHI Takayuki | TSUJI Moriya	SHIRATSUCHI, Takayuki | TSUJI, Moriya	2011-02-24
WO2011056877A1	MALARIA TRANSMISSION-BLOCKING VACCINE | VACCIN BLOQUANT LA TRANSMISSION DE LA MALARIA	THE GEORGE WASHINGTON UNIVERSITY,US | JOHN HOPKINS UNIVERSITY,US | ZAHN Bin,US | BOTTAZZI Maria Elena,US | SHAH-BROWN Ami,US | HOTEZ Peter J.,US | DINGLASAN Rhoel Ramos,US | ALBERT B. SABIN VACCINE INSTITUTE,US	DINGLASAN, Rhoel, Ramos | HOTEZ, Peter, J. | SHAH-BROWN, Ami | BOTTAZZI, Maria, Elena | ZAHN, Bin	2011-05-12
WO2011059478A1	TH1/TH2 POLARIZING VACCINES | VACCINS À POLARISATION TH1/TH2	UNITED STATES OF AMERICA AS REPRESENTED BY THE SECRETARY OF THE NAVY,US | CASARES Sofia A.,US | RICHIE Thomas L.,US | BRUMEANU Teodor D.,US	CASARES, Sofia, A. | RICHIE, Thomas, L. | BRUMEANU, Teodor, D.	2011-05-19
WO2011138251A1	LENTIVIRAL VECTOR BASED IMMUNOLOGICAL COMPOUNDS AGAINST MALARIA | VECTEUR LENTIVIRAL À BASE DE COMPOSÉS IMMUNOLOGIQUE CONTRE LA MALARIA	INSTITUT PASTEUR,FR | THERAVECTYS,FR | CHARNEAU PIERRE,FR | COUTANT Frédéric Philippe,FR	CHARNEAU, PIERRE | COUTANT, Frédéric, Philippe	2011-11-10

APPENDIX B: Definitions of US Classifications[109]

The U.S. Patent Classification System is a categorization of all U.S. patent and other technical documents by common subject matter. Each subject matter division includes a class and a

[109] http://www.uspto.gov/web/patents/classification/.

subclass. The Manual of Classification is an ordered listing of all the valid classifications. Classes and subclasses have titles providing a general description of their contents, and definitions providing a more specific description. A definition may contain an explanation of the class or subclass, a glossary, search notes, references to subclasses within a class, and references to other classes and subclasses. The U.S. system contains about 450 classes and about 150,000 subclasses. The classification code is express with 2 numbers separated by a forward slash, for example, 435/134. The first number, 435, represents the class of the invention. The number following the slash, 134, is the subclass of the invention within the preceding class. Patents will always have both a class and a subclass. More explanation and definitions of U.S. patent classifications can be found at, http://www.uspto.gov/web/patents/classification/.

Primary Classifications assigned to patent documents coded as relevant for this report include:

Class 424: Drug, Bio-Affecting And Body Treating Compositions

- 424/093.1 = Whole Live Micro-Organism, Cell, or Virus Containing
- 424/184.1= Antigen, Epitope, or Other Immunospecific Immunoeffector (e.g., Immunospecific Vaccine, Immunospecific Stimulator of Cell-Mediated Immunity, Immunospecific Tolerogen, Immunospecific Immunosupressor, etc.)
- 424/185.1 = Amino acid sequence disclosed in whole or in part; or conjugate, complex, or fusion protein or fusion polypeptide including the same
- 424/191.1 = Disclosed amino acid sequence derived from parasitic organism (e.g., Dirofilaria, Eimeria, Trichinella, etc.)
- 424/267.1 = Eimeria
- 424/268.1 = Plasmodium
- 424/269.1 = Parasitic protozoan (e.g., Trypanosoma, Trichomonas, Leishmania, Entamoeba, etc.)
- 424/271.1 = Eimeria
- 424/272.1 = Toxoplasma

Class 435: Chemistry: Molecular Biology and Microbiology

- 435/007.1 = Involving antigen-antibody binding, specific binding protein assay or specific ligand-receptor binding assay
- 435/069.3 = Antigens
- 435/243 = Micro-Organism, Per Se (e.g., Protozoa, etc.); Compositions Thereof; Process of Propagating, Maintaining or Preserving Micro-Organisms or Compositions Thereof; Process of Preparing or Isolating A Composition Containing A Micro-Organism; Culture Media Therefor
- 435/258.4 = Eimeria
- 435/320.1 = Vector, Per Se (e.g., Plasmid, Hybrid Plasmid, Cosmid, Viral Vector, Bacteriophage Vector, etc.)

Class 530: Chemistry: Natural Resins or Derivatives; Peptides or Proteins; Lignins or Reaction Products Thereof

- 530/324 = 25 or more amino acid residues in defined sequence
- 530/350 = Proteins, i.e., More than 100 Amino Acid Residues

Class 536: Organic Compounds – Part of the Class 532-570 Series

- 536/023.7 = Encodes a microbial polypeptide

APPENDIX C: Definitions of IPC Classifications

International Patent Classification System[110]

- The World Intellectual Property Organization (WIPO) administers the International Patent Classification (IPC) system. IPCs are organized hierarchically and divide technology into eight sections (A through G) with approximately 70,000 subdivisions.
- An IPC is typically expressed as, for example, C12N 15/82, but may also appear as C12N001582.
    - The first letter, C, specifies a Section.
    - The number following the Section indicator, 12, specifies a Class.
    - The letter N specifies a Subclass.
    - The number 15 specifies a Main Group.
    - The number following the slash, 82, specifies a Subgroup.
- WIPO publishes the authentic IPCs versions in English and French languages. Chinese, Croatian, Czech, Dutch German, Hungarian, Japanese, Korean, Polish, Romanian, Russian, Serbian, and Spanish versions are also available.
- More information is available at the WIPO website, http://www.wipo.int/classifications/ipc/en/.

Classification Codes Applicable to this Report[111]

IPC	IPC Classification Definitions
A01K	Animal Husbandry; Care of Birds, Fishes, Insects; Fishing; Rearing or Breeding Animals, Not Otherwise Provided For; New Breeds of Animals
A61B 10/00	Other Methods or Instruments for Diagnosis
A61D	Veterinary Instruments, Implements, Tools, or Methods
A61K	Preparations for Medical, Dental, or Toilet Purposes
A61K 39/00	Medicinal Preparations Containing Antigens or Antibodies
A61K 39/012	Coccidia Antigens
A61K 39/015	Hemosporidia Antigens
A61K 39/015	Reoviridae
A61K 39/39	Characterized by the Immunostimulating Additives (Medicinal Preparations Containing Antigens or Antibodies...)
A61P 31/00	Antiinfectives
A61P 33/02	Antiprotozoals
A61P 33/06	Antimalarials

[110] WIPO, http://www.wipo.int/classifications/ipc/en/ (last visited Apr. 24, 2011).
[111] WIPO, http://www.wipo.int/ipcpub/#refresh=page (version 2011.01) (last visited Apr. 24, 2011).

C07K 07/08	. . . having 12 to 20 Amino Acids (*Linear Peptides Containing Only Normal Peptide Links*)
C07K 14/44	. . . from Protozoa (*Peptides having more than 20 amino acids; Gastrins; Somatostatins; Melanotropins; Derivatives thereof;*)
C07K 14/445	Plasmodium
C07K 19/00	Hybrid peptides
C12N	Micro-Organisms or Enzymes; Compositions Thereof; Propagating, Preserving, or Maintaining Micro-Organisms; Mutation or Genetic Engineering; Culture Media
C12N 15/09	Recombinant DNA-technology
C12P 21/02	. . . preparation of peptides or proteins (*Having a known sequence of two or more amino acids*)

APPENDIX D: Derwent Classifications[112]

Description of Derwent Patent Classifications

- The Derwent World Patent Index (DWPI) classification system categorizes patent documents using a simple classification system for all technologies; consistently applied to all patents by Thomson Scientific subject experts, enabling effective and precise searching in a particular area of technology.
- International Patent Classification (IPC) is an internationally recognized classification system controlled by the World Intellectual Property Organization (WIPO) and assigned to patent documents by various patent offices.
- Where possible Thomson indicated next to the class the equivalent IPC in an abbreviated form (e.g., A47, F23-5). However, this should be used only as a guide since there are areas where the DWPI classes are assigned intellectually by Thomson's subject experts, and no strict correspondence is claimed.

DWPI Class	**Technical Area**
B04	Natural products and polymers. Including testing of body fluids (other than blood typing or cell counting), pharmaceuticals or veterinary compounds of unknown structure, testing of microorganisms for pathogenicity, testing of chemicals for mutagenicity or human toxicity and fermentative production of DNA or RNA. General compositions.
D16	Fermentation industry - including fermentation equipment, brewing, yeast production, production of pharmaceuticals and other chemicals by fermentation, microbiology, production of vaccines and antibodies, cell and tissue culture and genetic engineering.
C06	Biotechnology - including plant genetics and veterinary vaccines.
S03	Scientific Instrumentation (G01J, K, N, T-W) Photometry, calorimetry. Thermometers. Meteorology, geophysics, measurement of nuclear or X-radiation. Investigating chemical or physical properties.
C03	Other organic compounds, inorganic compounds and multi-component mixtures.

[112] *Derwent World Patent Index*, THOMSON CORPORATION, http://science.thomsonreuters.com/m/pdfs/mgr/derwentclass.pdf.

	Polymers and proteins.
B05	Other organics - aromatics, aliphatic, organo-metallics, compounds whose substituents vary such that they would be classified in several of B01 - B05.

Top Codes	**Definition**
D05H07	Production of vaccine and antigens
B14A03B	Antimalarial
B14S11B	Other antimicrobial vaccines
B04B04C	Antigens and general antibodies
B02V02	Vaccines
B14G01	Immunostimulant general and other
B12K04A	Diagnosis of disease or conditions in animal general
B04E08	Vectors, plasmid, cosmids, transposons
B12B03	Antimalarial
B04C01	Polypeptides
B14S11	Vaccine [General]
C14S11B	Other Antimicrobial Vaccine
C14S11	Vaccine [General]
B04F03	Sperm, Ova (Germ cells)
B02Z	Antibiotics beginning with the letter "Z," general
C12B05	Coccidiostat*
B12B05	Coccidiostat*

APPENDIX E: Patent Families

"If there are several applications or publications for an individual invention (in other countries) claiming the same priority or priorities, we talk about a "patent family." All of these "family members" are related to one another by common priority numbers with associated priority dates.
The concept of the patent family first emerged through the Paris Convention on the Protection of Intellectual Property in 1883, while automated systems enabling patent family searching became available through the establishment of the IIB in The Hague in 1947and INPADOC in Vienna in 1972. Since then, patent searching has evolved due to exponential improvements in computing and communication technology.

The term patent family can be defined in a number of ways depending on the relationship between a patent document and its priority or priorities within the meaning of the Paris Convention. The differences only become obvious when the structure of a patent application is complex, i.e. when applications are filed in several countries. Such applications may cite various earlier applications as priorities, or the diverse patent offices involved in the grant process may accept or refuse different patent claims. This results in patents which have different scopes of protection.

An important point when using any database to retrieve information on patent families is that there is never any guarantee that you will find all the corresponding patent documents that

exist. Database producers do what they can to ensure completeness, but they can never guarantee it."[113]

The "Extended" (INPADOC) Patent Family

"The biobibliographic and legal status databases form the basis of the EPO's raw data resources (INPADOC). In February 2008 the bibliographic data included about 60 million bibliographic data sets from almost 80 different countries. The legal status database contains a collection of more than 50 million legal events from 48 countries.

From the beginning, the concept was to cover as many countries and as many publication levels as possible. One of the strongest motives for the integration of INPADOC into the EPO was the wish to combine the particular strengths of INPADOC with the EPO's existing in-house bibliographic database, "DOC-DB."

Following integration of the two databases in the 1990s, the raw data behind both databases is now the same. And since esp@cenet draws on the same pool of data as raw data resources (INPADOC) and DOC-DB, it contains the same documentation.

However, the philosophy of the "extended" (INPADOC) patent family is quite different, and so are the results of family searches. Unlike the "also published as" feature in esp@cenet, which only shows "equivalents," i.e. almost identical documents, an INPADOC family search should retrieve all documents relating in any way to the root document.

Features of INPADOC

When using INPADOC via one of the commercial database host services, it bears all the esp@cenet features, plus the following:

- Standardization of applicant and inventor names
- References to abstracts from Chemical Abstracts and Thomson Scientific Abstracts are made within the patent family
- By including the legal status database additional information is available and additional family links can be established
- National application numbers, international application numbers and domestic relations are included in the family search

For both of the EPO's raw data resources (INPADOC) and esp@cenet, even where no priority has been claimed by the patent application, artificial or "intellectual" links are built in systematic way for the complete PCT minimum documentation. The same is done for older documents (pre-1968) for which the priority information is not complete.

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[113] EUROPEAN PATENT OFFICE, *Patent Families* (Feb. 29, 2008), http://www.epo.org/patents/patent-information/about/families.html.

Definition of the “extended” (INPADOC) patent family

All the documents directly or indirectly linked via a priority document belong to one patent family. In the case shown below, documents D1 to D5 belong to the same patent family, P1.

FAMILY P1

Document D1	Priority P1		
Document D2	Priority P1	Priority P2	
Document D3	Priority P1	Priority P2	
Document D4		Priority P2	Priority P3
Document D5			Priority P5

As mentioned above, national patent application numbers, international application numbers and domestic relations are included in the family search.

In the “extended” (INPADOC) patent family, it does not matter where you start the search. It can be an application number, a priority application number or a publication number.
If the search starts with a publication number, all application numbers, domestic application numbers, priority numbers and international application numbers are used to retrieve additional documents. For all documents found in this step, step one is repeated. This iteration process ends only when no more new documents can be found.

Raw data resources (INPADOC) also use some additional sophisticated rules for certain countries, for example, if publication numbers are used instead of priority numbers in the original documents. This happened rather frequently for older documents, where the priority claims were not treated as carefully as they are now.
The inclusion of legal status information in the patent search also sometimes retrieves additional links, e.g. for divisional applications, continuations, continuations in part or national publications of first filings of PCT (international) applications, where the priority links are often missing.

Limitations of the family search in raw data resources (INPADOC) have to rely on the correctness of the data supplied by the co-operating patent offices and the extent to which it is up to date. In particular, delays in the delivery of bibliographic data can vary significantly depending on the country concerned and the time period covered. Before relying on the completeness of a patent family, users should check where there are gaps or delays in certain areas. You can find this kind of information in the PFS and PRS statistics on the internet, which are updated weekly and contain indications of missing or delayed document series. See raw data resources (INPADOC) useful tables and statistics. To be absolutely sure about the actual status of a patent, users are recommended to contact the appropriate patent issuing authority direct.

Particular care has to be taken in the case of European patents which have entered into the national phase. Here the completeness and accuracy of data can vary significantly from country to country. A good overview of the volume and kind of "post-grant" information available in raw data resources (INPADOC) can be found in the raw data resources (INPADOC) FAQ. For most of the EPO member states, information about the validation, lapse, etc., of European patents is given as part of the legal status information, and as mentioned before is less consistent due to the different quality of data available. Starting from week 50/2007, additional post-grant 172 information is taken from the fee administration system and included in the legal status part of the database.

Example of an "extended" (INPADOC) patent family

The same example is used as for the esp@cenet patent family previously (US5402857). See the example as a PDF document.

As you can see, the iterative INPADOC search retrieves 81 document records, of which esp@cenet displayed only five. The information available includes 323 legal status events (not shown in the example above). This higher recall of documents reflects not only the different philosophies of the two systems, but also the fact that INPADOC displays all publication levels within one country as separate family members."[114]

Thomson Scientific WPI Patent Family (DWPI)

"Patent Families in the Thomson Scientific World Patents Index (WPI) draw together patents covering the same invention. Their relationship is defined by the priority or application details claimed by each document. Thus, in its simplest form, a new document (D1) claiming a unique priority (P1) will be assigned to be the —basic of its own, new patent family in Thomson Scientific WPI.

Subsequently, if a second document (D2) also claiming priority P1 is received by Thomson Scientific this will be added (as an —equivalent) to the patent family already containing document D1. Other documents claiming priority P1 will also be added to this family as —equivalents as they are included in the database. Thus, a patent family may contain anything from a single document to 10 or more. Each patent family represents a single record in the Thomson Scientific WPI database.

The basic document is the first member of a patent family that appears in Thomson Scientific WPI, so it may not necessarily be the first one published for that invention. Differences in the speed that patenting authorities supply data to Thomson Scientific and in the processing time for documents from different countries may affect which document appears in Thomson Scientific WPI first and becomes basic.

[114] *Id*.

Patents often claim more than a single priority and these must match before any equivalent is added to a family. This means that if a basic document (D3) claims priorities P2, P3 & P4, a subsequent document (D4) claiming priorities P2 & P3 will be added to the family as an equivalent, whereas patent D5 which claims priorities P2, P3 and a unique priority (P5) will form the basis of a new, but related patent family. In cases such as this, the accession number of any related family is included in the cross-reference field of each relevant Thomson Scientific WPI record.

Divisions and continuation patents maintain the same status as the original specification. This means that if GB1 is a basic, and GB2 is divisional to GB1, then GB2 will also be a basic (in its own family). However, if GB1 is equivalent to another document already in the Thomson Scientific WPI database, then GB2 will also join this family as an equivalent. It should be noted that family relationships will be defined by the order in which patents appear in Thomson Scientific WPI.

Thomson Scientific also puts a lot of resources into including patents in families even when no foreign priority is claimed, e.g. when an application has been made beyond the 12 months defined by the Paris Convention. Thomson Scientific identifies these "non-convention" equivalents by the presence of foreign nationals and addresses in the Inventor field in the absence of priority data other than the local filing details. Equivalency is determined through a time-consuming manual check of inventors, subject matter, etc.

In this way Thomson Scientific attempts to make patent families in Thomson Scientific PI as comprehensive as possible. However, because of the incidence of multiple priorities, and patent divisions and continuations (especially continuing applications in US documents), it is important to retrieve all related families through their common priorities in order to have a comprehensive overview of patent family relationships."[115]

[115] *Id*.

Appendix F: Authors' Resumes

JOSIAH B. BARBOUR

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EDUCATION

UNIVERSITY OF NEW HAMPSHIRE SCHOOL OF LAW ▪ Concord, NH (expected) 2013
Juris Doctorate Candidate
Member of: Phi Alpha Delta Fraternity, Student Intellectual Property Law Association, Patent Law Forum, International Intellectual Property Organization

UNIVERSITY OF COLORADO AT BOULDER ▪ Boulder, CO 2006
Master of Science in Chemistry
Member, American Chemical Society

ELON UNIVERSITY ▪ Elon, NC 2004
Bachelor of Science in Chemistry

LEGAL EXPERIENCE & RELEVANT COURSEWORK

Student Co-Director for International Technology Transfer Institute 2012
UNIVERSITY OF NEW HAMPSHIRE SCHOOL OF LAW ▪ CONCORD, NH

- Managed students' searching and analysis of global patent landscape related to vaccines for Malaria and other diseases
- Prepared patent landscape report

International Technology Transfer Institute 2011
UNIVERSITY OF NEW HAMPSHIRE SCHOOL OF LAW ▪ CONCORD, NH

- Searched and analyzed global patent landscape related to vaccines and diagnostics for Chagas Disease
- Prepared patent landscape report

Research Assistant 2011
UNIVERSITY OF NEW HAMPSHIRE SCHOOL OF LAW ▪ CONCORD, NH

- Researched voting rights in the several states
- Resulted in publication 112 COLUM. L. REV. SIDEBAR 63 (2012)

Coursework (to be completed by May 2012) 2010-2012
UNIVERSITY OF NEW HAMPSHIRE SCHOOL OF LAW ▪ CONCORD, NH

- Patent Law, Patent Practice & Procedure I, Patent Practice & Procedure II, Copyright Law, Mining Patent Information in the Digital Age, Financial Principles of Intellectual Property Management, Fundamentals of Intellectual Property, Professional Responsibility

SCIENTIFIC EXPERIENCE

Pharmaceutical Chemist 2008
PHARMATEK LABORATORIES, INC. ▪ San Diego, CA
- Developed, optimized, and validated analytical methods for preclinical drug trials
- Exercised technical discretion in the design, execution, and interpretation of experiments
- Directed client interactions for potential and present clients

Contract Synthetic Organic Chemist 2007
NITTO DENKO TECHNICAL ▪ Oceanside, CA
- Synthesized chromophores for potential patentability

Graduate Research 2005-2006
UNIVERSITY OF COLORADO AT BOULDER ▪ Boulder, CO
- Synthesized carboranes and their derivatives
- Modeled the kinetics of decomposition of di-*t*-butlyperoxide in the presence of catalytic Li^+ ion
- Analyzed polymers of simple terminal alkenes and alkynes formed by Li^+-catalyzed radical polymerization

PUBLICATIONS

Vyakaranam, Kamesh; **Barbour, Josiah B.**; Michl, Josef. Catalysis of radical reactions by "naked" lithium cation. Abstracts of Papers, 231st ACS National Meeting, Atlanta, GA, March 26-30, 2006 (2006), ORGN-620.

Vyakaranam, Kamesh; **Barbour, Josiah B.**; Michl, Josef. Li^+-Catalyzed Radical Polymerization of Simple Terminal Alkenes. Journal of the American Chemical Society (2006), 128(17), 5610-5611.

Barbour, Josiah B.; Karty, Joel M. Resonance and field/inductive substituent effects on the gas-phase acidities of para-substituted phenols: a direct approach employing density functional theory. Journal of Physical Organic Chemistry (2005), 18(3), 210-216.

Barbour, Josiah B.; Karty, Joel M. Resonance Energies of the Allyl Cation and Allyl Anion: Contribution by Resonance and Inductive Effects toward the Acidity and Hydride Abstraction Enthalpy of Propene. Journal of Organic Chemistry (2004), 69(3), 648-654.

Barbour, Josiah B.; Karty, Joel M. Resonance energies of the allyl ions. Abstracts, 55th Southeast Regional Meeting of the American Chemical Society, Atlanta, GA, November 16-19, 2003 (2003), 1095.

Sarita L. Pickett

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Education

University of New Hampshire School of Law, Concord, NH
Franklin Pierce Center for Intellectual Property
Juris Doctor anticipated in 2013, GPA 3.29/4.00

- Phi Alpha Delta; Diversity Action Coalition; Legislative Action Committee; 2010-Current
- SOSO Treasurer; 2010-Current

Andrews University, Berrien Springs, MI
Bachelor of Science in ACSC Biochemistry 2006, GPA 3.19/4.00

- Tait Family Scholarship for Integrity
- Andrews Partnership Scholarship for Excelling in Scholastics

Relevant Experience

University of New Hampshire Law International Technology Transfer Institute, 2011 - Current
Co-Director, Concord, NH

University of New Hampshire Law Civil Clinic, 2011 - Current
Consumer Clinic Legal Intern, Concord, NH

- Collaborating in legal research, client conferences, and mediations
- Conducting client intake, interviews, conflict checks, and legal research

University of New Hampshire School of Law, Current
Patent Research Faculty Assistant, 2011-2012
Tutor in Property, Legal Writing, Copyrights, and Intellectual Property, 2011-2012
Teacher's Assistant, 2011 - 2012
Librarian Assistant, 2011 - Current
Legal Research Faculty Assistant, 2011-2012

Legal Assistance and Referral Center, 2011
Legal Intern, Concord, NH

Honors , Awards, and Civic Experience

- 2010: TCAC Scholarship For Leadership And Community Involvement, NAR-SAAH
- 2000 – 2010: Community Outreach Coordinator and Activist; Good Will Industries; Feed America; Good Samaritan Ministries; Benton Harbor Student Outreach & Street Ministry
- 1990 – 2000: Big Sister & Big Brother; Maranatha Missionary Trip; Neighborhood Care

L. Andrew Tseng, Ph.D.

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EDUCATION

UNIVERSITY OF NEW HAMPSHIRE SCHOOL OF LAW, Concord, NH
J.D. Candidate 2013, Class Rank: Top 10%

- *Article Editor*, IDEA: The Intellectual Property Law Review, 2011-2012
- *1L, 2L Class Governor*, Student Bar Association

UNIVERSITY OF MIAMI, Coral Gables, FL
Ph.D., Molecular and Cellular Pharmacology, 2010

- NINDS/NIH Predoctoral Training Program in CNS Injury and Repair Fellowship
- *Vice President*, Biomedical Graduate Student Association

CORNELL UNIVERSITY, Ithaca, NY
A.B., Molecular and Cell Biology, 2003

PUBLICATIONS

- *Considering the Liability of Settling, Non-settling, and Immune Tortfeasors: The New Hampshire Supreme Court Interprets Comparative Fault in Light of* Nilsson *and* DeBenedetto, NHAJ TRIAL B. NEWS (forthcoming 2012).
- *Making Intellectual Property Rights Patently Clear*, N.H. BUS. REV., Mar. 9, 2012 (with Paul C. Remus).
- Interaction of an Intracellular Pentraxin with a BTB-Kelch Protein is Associated with Ubiquitylation, Aggregation and Neuronal Apoptosis. Mol Cell Neurosci 47(4):254-64 (2011).
- Temporal and Spatial Expression of Gonadotropin Releasing Hormone (GnRH) in the Brain of Developing Zebrafish (Danio rerio). Gene Expr Patterns 4(1):65-70 (2004).

EXPERIENCE

DEVINE, MILLIMET & BRANCH, Manchester, NH
Patent, Trademark & Licensing Intern, September 2011-present

- Researched and drafted memos and articles on patent, trademark, and copyright issues.

UNIVERSITY OF NEW HAMPSHIRE SCHOOL OF LAW, Concord, NH
Research Assistant, Professor Dana Remus, May 2011-present

- Conducted research on judicial ethics and the adoption of judicial codes of conduct.

MILLER SCHOOL OF MEDICINE, THE MIAMI PROJECT TO CURE PARALYSIS, Miami, FL
Graduate Research Assistant, August 2003-August 2010

- Studied protein ubiquitylation/degradation and neuronal cytotoxicity using a wide range of molecular biology, biochemical, and cell culture techniques.
- Trained five undergraduate students: supervised research projects, thesis writing, and research presentations.

CORNELL UNIVERSITY, Ithaca, NY
Undergraduate Research Assistant

- *Department of Molecular Biology and Genetics*, May 2001-May 2003
- *Department of Entomology*, January 2000-May 2001
- *U.S. Plant, Soil and Nutrition Laboratory USDA-ARS*, August 1999-May 2000

ACTIVITIES

Experienced photographer; self-taught dinghy sailor. Led a 1300 member community photo group for three years.

CHI-WEI FENG

3 Essex Street
Concord, NH 03301
603.892.0169
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EDUCATION

University of New Hampshire School of Law, Concord, NH

Candidate for Master of Intellectual Property (M.I.P.), 2012

Course work: Patent Practice & Procedure I & II, Patent Law, Pharmaceutical Patent Law, International Technology Transfer Institute, Technology Licensing

National Taiwan University, Taipei, Taiwan, R.O.C.

Bachelor of Science in Bioscience and Technology, 2009

Course Work: Molecular Biology and Lab, Biochemistry and Lab, Microbiology and Lab, Proteomics, Systems Biology, Biotech Patent, Intro to Biochip Technologies

PROFESSIONAL EXPERIENCE

International Technology Transfer Institute, University of New Hampshire School of Law Jan. 2012 – May 2012

Student

- Analyze the patent status of sporozoite vaccines against malaria and the methods of vaccination thereof.
- Conduct patent searching through Thomson Innovation™ and TotalPatent™.

National Center for Genetic Engineering and Biotechnology, NSTDA, Thailand Jun. 2008 – Sep. 2008

Overseas Trainee

- Investigated the possible role of Lambda Red Recombinase for enhancing double homologous recombination efficiency in *Plasmodium falciparum.*
- Employed experimental techniques in molecular biology including transformation, polymerase chain reaction, microarray, and etc.

Institute of Chemistry, Academia Sinica, Taiwan Oct. 2007– May. 2008

Trainee

- Conducted research on the optimal pH environment for the binding capacity of magnetic nano-particles to the enzyme of RNase B.
- Learned lab skills in protein chemistry including mass spectrometry and SDS-PAGE for characterization of given protein.

OTHER EXPERIENCE

Military Police School Sep. 2009 – Jul. 2010

Army Military Police Command, Taiwan

Training Officer, 2Lt.

LANGUAGE & SKILLS

Software Skills: Thomson Innovation, TotalPatent, and Innography.

Language: Fluent in Chinese, Skilled in Chinese-English Inter-translation.

Aarushi Gupta
38 Merrimack Street,
Concord, NH 03301
Email: aarushigupta.bt@gmail.com
Cell phone: 603-892-6878

Education

University of New Hampshire School of Law (formerly Franklin Pierce Law Center)

- Master in Intellectual Property (Degree anticipated in May '12)
- Courses include patent law, patent practice and procedure I & II, International Technology Transfer Institute, fundamentals of intellectual property, and world trade & world IP law
- Undertaken an independent research study on the America Invents Act – its compliance with TRIPS, its impact on biopiracy, and harmonization with worldwide patent practices

Amity University

- Bachelor of Technology, Biotechnology (Class of 2011)
- Class Representative, 2007-08
- Courses include biochemistry, microbiology, molecular biology, genetics, cell biology, bioinformatics, and principles of drug designing

Experience & Accomplishments

International Technology Transfer Institute (ITTI) – Technology Transfer Research Assistant (August 2011 – Present)

- Worked with respected **Dr. Stanley Kowalski,** on patent landscape reports on the diagnostics and treatment of Chagass disease, and malaria vaccines for the sporozoite stage
- Performing intensive technology-oriented patent searching and analysis on sophisticated platforms such as Thomson Innovation, TotalPatent and Innography
- Researching on technology transfer case studies, technology licensing patterns in the Ag-Bio industry, and public-private partnership (PPP) models in the transfer of innovation amongst entities in around the world

Indian Institute of Patent & Trademark Attorney (IIPTA) - Patent Analyst Intern (March 2011 – July 2011)

- Prepared a patent landscape report in the field of telomerase vaccines against ageing and cancer
- Performed intensive technology-focused patent searching on Espacenet online patent database and performed analytics such as competitive intelligence, white gap analysis and technology trends

National Research Centre on Plant Biotechnology (NRCPB) - Intern (May 2010 – July 2010)

- Performed the genetic transformation of *Triticum aestivum* (Common wheat) using biolistic (Gene) gun method, and verifying the results using GUS Assay
- Performed an independent task of patent searching for the purposes of research at NRCPB - using the USPTO online patent database to create an inexhaustive list of plant gene patents

National Bureau of Plant Genetic Resources (NBPGR) - Intern (May 2009 – July 2009)

- Performed the detection of *Bean common mosaic virus (BCMV)* in *Phaseolus Vulgaris (*French bean) using various physical, chemical and serological techniques such as Enzyme-Linked Immunosorbent Assay (ELISA), Dot-Immunobinding Assay (DIBA), Growing-On Test and Infectivity Test in a Quarantined Class-4 Containment Facility
- Used electron microscope to view *BCMV* rods by performing Leaf-Dip Assay (LDA)

Associations

Member of Intellectual Property Section, New Hampshire Bar Association
Member of South-Asian Law Students Association, UNH School of Law

Certifications & Technical Skills

Six Sigma Business Management Certification – Green Belt, May 2009
Patent Searching Certificate by UNH School of Law, January 2012

Patent Search Expertise: Thomson Innovation, TotalPatent, Innography, Espacenet, USPTO, PatentScope and Indian patent database (IPIndia.nic.in)

Interests

Hobbies: Singing, Dance, Badminton, and Travelling
Languages: English (fluent), Hindi (native), French (basic)

Amy L. Mocko

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Permanent Address:
119 Chartley Ct.
Dayton, OH 45440

Education:

University of New Hampshire School of Law, Concord, NH
(Formerly Franklin Pierce Law Center)
Juris Doctor Candidate, 2013
Legal Writing Teaching Assistant, Student Mentor, member: Licensing Executives Society, Student Bar Association
GPA 3.2/4.0

The Ohio State University, Columbus, OH
Bachelor of Science, Microbiology, June 2010
GPA 3.4 / 4.0

Experience:

UNH School of Law International Technology Transfer Institute Clinic **Spring 2012**
Researched patents, compiled and analyzed a patent landscape, collaborated with others to compile a report based on the analysis, and strategized about report use.

Blue2Green, LLC, Derry, NH
Intern **May 2011-October 2011**
Researched potential sites, created a company-wide database, researched applicable laws and State and Federal regulations, and acted as liaison between state agencies and partners.

Speedway SuperAmerica Corporate Offices, Enon, OH
Intern **Summers 2008-2009**
Researched environmental sites, provided support and documentation on projects, coordinated contract activities, arranged and performed site inspections with consultants.

The Ohio Environmental Council, Columbus, OH
Intern **October 2008- June 2009**
Researched environmental legislation, wrote case briefs, presented projects to supervising attorney, and coordinated meetings between attorneys and legislators.

Interests:

Designing and creating visual art projects, including cloth and paper materials, reading, hiking and playing the piano

SRIHARSHA VASIREDDY

90 Rumford St., Concord
New Hampshire, 03301, USA.

Contact:+603-204-1127 Sriharsha.Vasireddy@law.unh.edu
sriharshavasireddy@gmail.com

LICENSES:

Registered Pharmacist in India, with registration no. 057176/A1
Eligible to sit for the US Patent Bar Exam

EDUCATION:

University of New Hampshire School of Law, Concord, New Hampshire
Franklin Pierce Center for Intellectual Property
LLM in Intellectual Property expected, May 2012

IP Courses: Patent Law; Advanced Patent Litigation; Patent Practice & Prosecution I & II; International Technology Transfer Institute Clinic; Patent Searching; Fundamentals of Intellectual Property and Pharmaceutical Patent Law (Summer 2012).

NALSAR University of Law, Hyderabad, India
Post-Graduate Diploma in Patent Law, Hyderabad, India, May 2010

- Graduated with "A" Grade

Osmania University, Hyderabad, India
LLB (JD Equivalent), May 2011

- Ranked First in Class and Graduated with Distinction

Bachelors in Pharmacy, May 2011

- Graduated with Distinction

PROFESSIONAL EXPERIENCE:

International Technology Transfer Institute Clinic (Franklin Pierce Center for Intellectual Property)
Member, Jan 2012 – Present
Created a patent landscape for malaria vaccines by identifying and analyzing relevant US and PCT patents and publications; Developed searching strategies for Thomson Innovation, Lexis TotalPatent, Delphion and Innography.

Lowe Hauptman Ham & Brenner LLP, Alexandria VA
Winter Intern, Dec 2011 – Jan 2012
Drafted responses to office actions for pharma and other technologies; analyzed US intellectual property law cases; performed legal research.

Law Office of Ashok Ram Kumar (Advocate at AP High Court), Hyderabad, India
Intern, Jan 2011 – May 2011
Drafted and analyzed Indian intellectual property law cases; Performed legal research.

I-Win Intellectual Property Services, Hyderabad, India
Intern, May 2010 – Dec 2010

- Searched patents by using databases like Thomson Innovation, USPTO, IPO, EPO, WIPO, Delphion, Lexis TotalPatent and Google Patents.
- Conducted Invalidation Searches and Freedom to Operate (FTO) Analysis for Pharma and Bio-Technology Patents.
- Drafted Pharma and Biotech Patents.