



Sector Research Report

Diagnostics

As technology evolves, molecular and diagnostic (Dx) tests are becoming more convenient, quicker, cheaper and more available closer to or at the point of care (POC). The convergence between understanding the genome, developing biomarkers for certain diseases and technology is already accelerating the growth of (and interest in) this space. The ability to treat a patient faster and more effectively will cut out so much excess cost in the system. Drug companies are already teaming up with Dx companies to develop tests that look for biomarkers that the biopharma companies' drug targets. So instead of a patient having to try several drug regimens before they find the right drug, they can do the test and then start with the right treatment and improve the outcome for the patient. This approach can be used across all therapeutic areas: CNS, cardiovascular, oncology, etc.

OneMedResearch reports on the **Emerging Trends in Diagnostics** will look at the major areas in this sector and insights as to how best to identify the most promising investment opportunities.

- **Part I: Patent protection for biomarker discovery processes** (July 12th, 2012)
- Part II: Genome sequencing
- Part III: Cancer diagnostics
- Part IV: Proteomics
- Part V: Personalized medicine in psychiatric treatment

Diagnostics Editorial Team:

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About OneMedResearch:

OneMedResearch delivers information on investment opportunities to serious investors in healthcare and life sciences. The team produces monthly research reports exploring the emerging growth companies developing disruptive technology in life sciences. In addition, OneMedResearch produces investor guides and directories to various life sciences sectors, updated quarterly.

Investor Guides aggregate critical information, contacts and resources in one place, thereby delivering a time-saving, risk-reducing tool for anyone with a significant investment in the sector.

- A near comprehensive list of companies and short descriptions of both public and private companies, to include contact information important to deal-makers.
- Interviews with thought leaders, company executives, and investors
- Directory of resources including major investors, associations, research institutions, conferences.
- Market analysis from leading industry researchers and publications, including developments, technology advances, economics and political impact

Accompanying this printed, abridged version of the Investor Guide is an electronic version, which provides hyperlinks to interviews, news stories, and database profiles scattered throughout the guide.

To view the electronic Investor Guide to Diagnostics, visit www.onemedplace.com/investor-guide-diagnostics.pdf

Investors can also subscribe to the full investor guide, updated quarterly. The full electronic investor guide subscription will include:

- Quarterly updates of interviews and market analysis
- Expanded companies profiles with executive contact information
- Directory of investors and additional resources

To learn more about the full Investor Guide subscription, visit www.onemedplace.com.



20/20 Gene Systems

Rockville, MD.

Developmental Stage
Cancer Diagnostics

Jonathan Cohen, CEO

20/20 Gene Systems, Inc. is a protein biomarker-based diagnostics company. Its proprietary diagnostic technologies are designed for early disease detection and personalized medicine, as well as for biodefense, cancer and autoimmune disease applications. The company's patented technology analyzes multiple biomarkers in tumors to predict patient response to one more targeted therapies. 20/20 uses its proprietary multiplex immunohistochemistry platform, which allows simultaneous detection of 10+ biomarkers in a single tissue section. The company is developing PredicTOR™, a tissue-based in-vitro diagnostic assay test to predict patient response to drugs that target the PI3K/AKT/mTOR signal transduction pathway in cancer. 20/20 is also developing a blood test for early detection of lung cancer.

[Private]



Epigenomics AG

Berlin, Germany

Commercialization Stage
Cancer Diagnostics

Geert Walther Nygaard, CEO

Epigenomics AG is a molecular diagnostics company committed to improving early detection and treatment of cancer and other complex diseases. The company's lead product, Epi proColon®, is a Septin9 biomarker blood-based test for the early detection of colorectal cancer. Epi proColon has been marketed in Europe and the Middle East since October 2009, and is currently in development for the US. Epigenomics has also licensed its Septin9 biomarker colorectal cancer and methylation technology to a number of clinical laboratories in North America. Epigenomics is also developing Epi proLung BL Reflex Assay to identify the mSHOX2 biomarker in patients' bronchial fluid, which can determine the presence of malignant lung disease and facilitate a quick and reliable diagnosis. On June 12th, 2012, the company announced it had submitted the third module in its PMA filing with the FDA for Epi proColon.

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PCAsso

North Brunswick, NJ.

Start-up Stage
Retinal Disease Diagnostics

Samir Tari, Founder

PCAsso Diagnostics LLC is a privately owned, research and development diagnostics company founded in 2008. In 2009, the company signed an exclusive worldwide license with Columbia University to develop and market PolyChromatic Angiography products, a novel imaging technology that will provide quantitative information on blood-retinal barrier dysfunction, which can lead to vision loss in retinal diseases such as diabetic retinopathy, neovascular age-related macular degeneration and uveitis. The granular information provided by this technology will help ophthalmologists better grade the disease severity and tailor treatment accordingly, thus preventing both under-treatment and over-treatment. The company is seeking collaboration, in-licensing and out-licensing opportunities.

[Private]



Alverix Diagnostics

San Jose, CA.

Commercialization Stage
Point-of-Care Testing

Richard Tarbox, President, CEO

Alverix provides multiple platforms for diagnostic Point-of-Care testing. The company produces Dx Pro, a full-featured, high-precision diagnostic instrument for use in physician's office labs, ERs/ICUs, retail clinics and ambulatory care facilities. The platform can process a wide range of detection modes and test methods (reflectance, fluorescence, electrochemical, and molecular), as well as single analyte or multiplex test panels. The company also produces Dx Mini, which can be used in home environments and requires no training or maintenance. Alverix platforms can be configured for: Immunoassay infectious disease, hormones, cancer markers; biochemistry for enzymes, metabolites, lipids; electrochemistry for diabetes, clotting efficiency factors; molecular detection of DNA, RNA, genetic targets; and cytology for cellular targets.

[Private]



Bionosis

Vancouver, Canada.

Development Stage
In-Vitro Diagnostics

Pasha Ferdowsi, Co-Founder

Bionosis is an in-vitro diagnostics company developing SOFIA ("Surround Optical Fiber Immunoassay"), an immunoassay technology with numerous applications, ranging from clinical diagnostics, to the monitoring of food quality, pharmaceuticals, cosmetics, and water, among others. SOFIA holds multiple US and international patents with an expanding portfolio of new inventions resulting from ongoing development. SOFIA's most commercially competitive uses address: areas of clinical diagnostics that presently lack a sufficiently sensitive test; areas of clinical diagnostics that require a test capable of detecting disease at earlier stages of progression; uses for novel assay development incorporating diagnostic markers outside the detection limits of current technologies; and uses as a companion diagnostic to ensure the efficacy and safety of new drugs.

[Private]

Diagnostics Company Directory

The following is a list and brief description of companies around the globe operating in diagnostics, and their location.

Public companies can be found in bold.

2B BlackBio S.L | Madrid, Spain | Diagnostics products for oncology, pharmacogenetics and other therapeutic areas
454 Life Sciences Corporation | Brandford, CT | Research-focused healthcare with strengths in pharmaceuticals and diagnostics
Abbott Diagnostics | Lake Forest, IL | Global leader in in vitro diagnostics, providing instrument systems and tests
Abbott Molecular | North Chicago, IL | Provides molecular diagnostics and the analysis of DNA, RNA, and proteins at the molecular level
Abnova Corporation | Heidelberg, Germany | Producing antibodies on a large scale for academic and industrial communities
Abpro Labs | Lexington, MA | Biotechnology firm dedicated to biological research by providing tools to researchers worldwide
Accelrys | San Diego, CA | Informatics software for computation simulation, management and mining of scientific data
Accumetrics | San Diego, CA | Develops VerifyNow System for the assessment of platelet functions
Acrometrix | Benicia, CA | Division of Life Technologies, producing infectious disease testing, transplant virus testing, blood donor screening
Activiomics | London, England | Develops technologies that use mass spectrometry to interpret the activity of cellular signaling pathways
Acupath Laboratories | Plainview, New York | Offers pathology, molecular, and cytogenetic analysis
AdnaGen AG | Langenhagen, Germany | Develops test systems for laboratories
Advanced Biological Laboratories | Luxembourg | DeepChek® and ViroScore® Suite clinical genotyping solutions approved for use in Europe
Advanced Cell Diagnostics | Hayward, CA | Develops cell- and tissue-based diagnostic tests for personalized medicine, for molecular pathology
Advandx | Woburn, MA | Develops molecular diagnostic tests to help prevent infectious diseases
Affymetrix, Inc | Santa Clara, CA | Provides genomic analysis tools and reagents for understanding diseases
Agendia | Amsterdam, Netherlands | Supports oncologists in designing individualized treatment plans
Allegro Diagnostics | Boston, MA | Molecular diagnostics developed to diagnose and manage lung cancer
Almac Diagnostics | Craigavon, United Kingdom | Provides comprehensive services to healthcare industry
AltheaDx | San Diego, CA | Provides PCR-based services
Ambry Genetics | Aliso Viejo, CA | Providing knowledgeable client services and high quality research and development
Amorfix Life Sciences Ltd | Mississauga, OR | Develops therapeutic products and diagnostic devices targeting misfolded protein diseases
Analytical Biological Services | Wilmington, DE | Provides custom bioreagents for biological research
Analyticon Discovery GmbH | Potsdam, Germany | Develops compound libraries consisting of natural product and synthetic small molecules
Aperio Technologies, Inc | Vista, CA | Provides systems and services for digital pathology
Aragen Bioscience | Morgan Hill, CA | Offers a complete range of high-quality, custom R&D services
Arbor Vita | Fremont, CA | Biopharmaceutical company developing novel drugs
Arrayit Corporation | Sunnyvale, CA | Produces raw manufacturing materials and microarray platforms
Astute Medical | San Diego, CA | Identifies protein biomarkers that can serve for novel in vitro diagnostic tests to improve diagnostics
Asuragen | Austin, Texas | Fully integrated RNA-based therapeutic and diagnostics company with a focus on microRNA
Augurex Life Sciences Corp | Vancouver, Canada | Biomarkers to assist in their diagnosis optimize therapy selection and patient management
Aurigene Discovery Technologies | Bangalore, India | Drug discovery biotechnology company focusing on oncology and inflammatory diseases
Autogenomics | Vista, CA | Provide integrated solutions for genomic and proteomic analysis
AVEO Pharmaceuticals, Inc | Cambridge, MA | Develops novel targeted therapies to impact the lives of patients with cancer
Axela | Toronto, Canada | Provide various tools that enhance analysis of proteins, DNA, and RNA
Axxin | Richmond, Australia | Provides platforms and diagnostic products for biomedical applications
Baypoint Biosystems, Inc | Houston, TX | Develops companion diagnostics based on patient stratification and pharmacodynamics
Beckman Coulter Inc | Fullerton, CA | Develops biomedical testing instrument systems, tests, and supplies
Becton, Dickinson and Company | Franklin Lakes, NJ | Medical and laboratory supplies, devices and diagnostic products
BG Medicine | Waltham, MA | Life sciences company focused on development of novel diagnostic tests based on biomarkers
Binding Site Ltd | San Diego, CA | Develops immunodiagnostic assays for autoimmune disease, multiple, myeloma, and the immune system
Biocartis NV | Mechelen, Belgium | Provides novel molecular diagnostics and immunodiagnosics solutions with assay menus
Biodesix | Boulder, CO | Molecular diagnostic company dedicated to personalizing medicine
BioFortis | Columbia, MD | Software company focused on addressing the challenges in today's data-intensive environments
BioGenex Laboratories | Fremont, CA | Provides total solution for the complete automation of cell and tissue testing
Bioimagine | Sunnyvale, CA | Acquired by Roche; developing tools to analyze data
Biologix Diagnostics, LLC | Lenexa, KS | Helps market diagnosis-related technologies during their early stages of development

Biomarker Factory | Durham, NC | Provides funding for research projects in translational medicine in diagnostics

BioMarker Strategies | Baltimore, MA | Tissue based cancer diagnostics company

Biomedical Diagnostics | Ann Arbor, MI | Provides risk assessment of breast cancer

BioMérieux | Marcy l'Etoile, France | Develops reagents and automated instruments for medical analysis

Biomoda | Albuquerque, NM | Focused on the development and commercialization of diagnostic tests for the early detection of cancer

BioMosaics | Burlington, VT | Specializes in the research and development of proprietary technologies for biomarkers

Bioneer | Daedeok-gu, Korea | Biotechnology Company developing molecular biology products and technologies

Bio-Reference Laboratories | Elmwood Park, NJ | Provides clinical laboratory testing services

Biosearch Technologies | Novato, CA | Designs and manufactures fluorogenic probes and reagents for DNA synthesis

BioServe | Beltsville, MD | Provides researchers with access to human DNA, tissue and serum samples

Biosystems International SAS (BSI) | Evry Cedex, France | Blood-based diagnostics for early cancer detection and innovative antibody microarrays

Biotage AB | Uppsala, Sweden | Provides complete solutions, knowledge, and experience in the areas of genetic analysis and medicinal chemistry

BioTeam | Middleton, MA | Delivers objective, technology agnostic solutions to the life science researchers

BioTheranostics | San Diego, CA | (Formerly AviraDx) | Develops tests to support physicians in the treatment of patients with cancer

BioTrove | Woburn, MA | Focused on advancing life science and drug discovery research through micro- and nano-scale technology platforms

BioView | Nes Ziona, Italy | Develops equipment for medical institutions, commercial laboratories and universities

Cambridge Research & Instrumentation | Hopkinton, MA | Develops biomedical imaging systems

Cangen Biotechnologies | Baltimore, MD | Develops diagnostic tests for early detection of cancer

Caprion Proteomics | Montreal, Quebec | Industrialized proteomics for clinical and pre-clinical testing

CardioDx | Palo Alto, California | Develops clinically validated molecular diagnostics for heart disease

Castle Biosciences Inc | Friendswood, TX | Cancer institutions to in-license proprietary technologies and complete development and validation

Celera Diagnostics | Alameda, CA | Molecular diagnostics for infectious disease testing and genetic conditions

Celerus Diagnostics | Carpinteria, CA | Develop technological solutions to enhance diagnosis of anatomic pathology laboratories

Cell Biosciences (Now Protein Simple) | Santa Clara, CA | Power protein research to get a better understanding in the role of proteins in disease

CeMines, Inc | Evergreen, CO | Molecular biotechnology for early diagnosis, treatment and prevention of cancer

Cepheid | Sunnyvale, CA | Integrated diagnostic systems for automated and accelerated biological testing

ChemBridge | San Diego, CA | Advanced discovery chemistry products and contract research services

Chemical Computing Group | Montreal, Canada | Provides applications in drug discovery to pharmaceutical, biotech and academic researchers

China Medical Technologies | Beijing, China | Supplies customers with medical devices and supplies

Cisbio Bioassays | Bagnols Sur Ceze Cedex, France | Provides creative technological solutions through in vitro diagnostics and drug discovery

Clinical Genomics Pty Ltd | North Ryde, Australia | Develop better healthcare products for detecting and preventing disease

Clinical Reference Labs | Lenexa, KS | Offers testing services in various areas including molecular diagnostics, and bioanalytics

Collaborative Drug Discovery | Burlingame, CA | Different paradigm for cloud-based collaborative drug discovery

Compendia Bioscience | Ann Arbor, MI | Developing online information systems for facilitating oncology drug development

Compugen | Tel Aviv, Israel | A genomics-based drug and diagnostic discovery company offering consulting services

Corgenix Medical | Broomfield, CO | Specialized diagnostic test kits for vascular diseases and immunological disorders

Correlogic Systems | Rockville, MD | Develops technologies to identify hidden protein patterns

Covance | Princeton, NJ | Pharmaceutical research, development, and manufacturing services

Crescendo Bioscience | San Carlos, CA | Developing a broad range of diagnostic tools to provide greater insight to rheumatoid arthritis

Critical Diagnostics | New York, NY | Healthcare company developing cardiac diagnostic tools

Crown Bio | Santa Clara, CA | Provides unique translational platforms and cost effective drug discovery solutions

CS-Keys | Indianapolis, IN | Develops cancer-specific biomarkers through proteomics

Cureline, Inc | San Francisco, CA | Human biospecimen CRO specializing in human tissue research projects

Curidium Medica Limited | London, England | Personalized medicine technology for psychiatric disorders

CvergenX | Tampa, FL | Biotechnology company delivering personalized radiation therapy to cancer patients

Cylex | Columbia, MD | Develops in vitro diagnostic products for the assessment of immunity

Cytocell | Cambridge, UK | Screening solutions for detection of human genetic diseases

CytoCore | Chicago, Illinois | Develops screening systems to assist in the early detection of cancer

Dako Denmark A/S | Glostrup, Denmark | Specialized diagnostic systems founded on immunology and protein chemistry

deCODE Genetics | Reykjavik, Iceland | Drugs and DNA-based diagnostics based upon inherited causes of common diseases

DermaGenoma, Inc | Irvine, California | Molecular dermatology company developing new prescription based therapies for skin conditions

DiaGenic | Oslo, Norway | Develops patient-friendly diagnostic tests for the early detection of major diseases

Diagnocure | Quebec, Canada | Develops and provides diagnostic tests for cancer detection and management

Diagnoplex | Switzerland | Develops non-invasive cancer screening tests

Diagnostic Biosystems | Pleasanton, CA | Providing innovative anatomic pathology reagents to improve the practice of pathology

DNA Direct | San Francisco, CA | Genetic pre and post testing guidance and decision support solutions company

Docro | Seymour, CT | Provides services to support the development of in vitro diagnostic tests

DxS Ltd | Manchester, United Kingdom | Pharmacogenetic services with support drug discovery and drug development

DxTerity Diagnostics | Compton, CA | Develops technology to increase the usage of genomic testing in routine medical care

EDP Biotech Corporation | Knoxville, TN | Development and sale of early onset diagnostic tests

Enamine LLC | Ukraine | Providing Life Science industries with a wide spectrum of smart chemistry solution

Epistem Plc | Manchester, United Kingdom | Contract research for pre-clinical services to the biotechnology and pharmaceutical industries

Eragen Bioscience | Madison, Wisconsin | Acquired by Luminex Genetic testing for infectious diseases, genetics, and cancer

e-Therapeutics | United Kingdom | Develop new treatments for disease by applying network pharmacology

Euroimmun AG | Luebeck, Germany | Produces a wide range of reagents for medical laboratory diagnostics

Eutropics | Cambridge, MA | Pharmaceuticals | Develops more effective and less toxic cancer therapies

Everist Genomics | Ann Arbor, MI | Personalized medical company, unique diagnostics, prognostics, and therapeutic selection technologies

EXACT Sciences | Madison, WI | Molecular diagnostics company focused on colorectal cancer

Exiqon A/S | Copenhagen, Denmark | Technology for enhancing assays and for immobilization of biological macromolecules

ExonHit Therapeutics | Gaithersburg, MD | RNA-based diagnostic tests and small molecule therapeutics to fight Alzheimer's disease and cancer

Exosome Diagnostics | New York, NY | Exosome-based diagnostics in oncology and endocrinology

Expression Pathology Inc | Gaithersburg, MD | Develops products that enable thorough analysis of protein in human tissue

Ezose Sciences | Pine Brook, NJ | Offers a new solution that is compatible with biological samples

Falcon Genomics, Inc | Pittsburgh, PA | Develops tools for the personalized analysis of tumor cells

FASgen Diagnostics, LLC | Baltimore, MD | Develops small molecule therapeutics and diagnostics

Fluxion Biosciences | San Francisco, CA | Develops analytical instruments for functional cell-based analysis

Foligo Therapeutics, Inc | Rockville, MD | Improve treatment options for ovarian cancer patients through molecular medicines and diagnostics

Folio Biosciences | Powell, OH | Provides biospecimen and histology services for the scientific research community

FortBio | Menlo Park, CA | Develops simple, accessible bio-molecule detects and analysis solutions

Foundation Medicine | Cambridge, MA | Brings comprehensive genomic analysis to routine cancer care

Fujirebio Diagnostics | Malvern, PA | Develops in vitro diagnostic products using nucleic acid based technology

Gastrocor | Uniondale, NY | Focus on the diagnosis of colorectal cancer and other conditions affecting the gastrointestinal tract

Gene Express Inc | Wilmington, NC | Platform technology for multi-gene expression measurement

Genelex Corporation | Seattle, WA | Provides comprehensive DNA testing services that enhance the health and safety of society

GeneNews Limited | Toronto, Canada | Developing blood-based molecular diagnostics tests for various diseases

Genera Biosystems Limited | Victoria, Australia | Develops multiplexed molecular diagnostic tests

Genetix Applied Imaging | Sunnyvale, CA | Develops products that support basic research, pharmaceutical and biotherapeutic development

Genomind, LLC | Chalfpoint, PA | Supports the development of personalized medicine for neuropsychiatric disorders

Genoptix | Carlsbad, California | Services that help in diagnosis, treatment decisions, and monitoring of hematopoietic diseases

GenoVive LLC | New Orleans, LA | Develops a diet program customized to a patients DNA

Gen-Probe Inc | San Diego, CA | Develops cost-effective nucleic acid probe-based products

GMS Biotech | Inverness, IL | Develops microarrays and other similar devices for the analysis of many gene sites in parallel

Health Discovery Corporation | Savannah, Georgia | Develops and evaluates new drugs and medical therapies

HistoRx | New Haven, CT | Provides analysis of biomarkers to generate information on new therapeutics

HTG Molecular Diagnostics | Tuscon, AZ | Develop technologies to accelerate discoveries to improve patient care

Ikonisys, Inc | New Haven, CT | Automated detection of rare cells through digital microscopy and fluorescent-light based analysis

illumina | San Diego, CA | Develops tools for large-scale analysis of genetic variation and function

Immucor, Inc | Atlanta, GA | In vitro diagnostics company specializing in the area of pre-transfusion diagnostics

Ingenuity Systems | Redwood City, CA | Software to model, analyze, and understand complex biological systems

Innogenetics NV | Gent, Belgium | Therapeutic vaccines to replace ineffective or harmful treatments

Integrated Diagnostics | Seattle, WA | Develop molecular diagnostics that use proteomics and genomics to detect disease earlier

Intelligent Pharma | Barcelona, Spain | Develops new computational technologies for drug discovery

InterGenetics Inc | Oklahoma City, OK | Leading to the first broad genetic predictive test for breast cancer

Interleukin Genetics | Waltham, MA | Genetic tests to gauge the effects of inflammatory response on health and disease

InteRNA Technologies B.V | Nijmegen, Netherlands | Develops miRNA-based therapeutics to improve cancer therapy effectiveness

Intrinsic Bioprobes | Tempe, AZ | Use mass spectrometry based technologies to improve the diagnosis of disease

Invirion Diagnostics, LLC | Oak Brook, IL | Genomics company that monitors viral diseases and provides diagnostics

Invivoscribe Technologies | San Diego, CA | Tools for molecular diagnostics, hematopathology, and complementary DNA synthesis

Ipsogen SA | Marseille, France | Molecular tools for patient risk stratification and predicting patient response to treatment

Iris BioTechnologies Inc | Marktredwitz, Germany | Focused on establishing new and enduring medical treatment standards

IRIS International | Chatsworth, CA | Develops in vitro diagnostic urinalysis systems, sample collection, and processing

Iverson Genetic Diagnostics | Bothell, WA | Develops genetic tests for comprehensive disease detection and informed treatment

Kalexsyn | Kalamazoo, MI | Provides contract medicinal chemistry services for early phases of drug discovery

Kreatech Holding BV | Amsterdam, Netherlands | Develops tools for the labeling and detection of DNA, RNA, and Proteins

Lab21 Healthcare | Greenville, SC | Support healthcare industries with technically advanced products and services

Laboratory Corporation of America Holdings | Burlington, NC | Develops tools for routine testing, patient diagnosis, and treatment of disease

LC Sciences | Houston, TX | Genomics and proteomics company offering innovative and quality products and services

Life Technologies | Grand Island, NY | Global life sciences company with an extensive product range for lab use

Linkage Biosciences | San Francisco, CA | Develops products that improve and expedite complex genetic testing

Luminex Corporation | Austin, TX | Biological testing-technologies with applications throughout the life-sciences

MabCure Inc | New York, NY | Develops novel diagnostics for the early detection of cancer

MacroArray Technologies, LLC | Villanova, PA | Novel products that improve patient outcomes by linking diagnostic and therapeutic medicine

MagArray Inc | Sunnyvale, CA | Commercializes the magneto-nano sensor technology and an assay platform supplier

Martell Biosystems, Inc | Minneapolis, MN | Develops novel tests for the early diagnosis of cancer

Med BioGene, Inc (MBI) | Vancouver, Canada | Develops genomic-based clinical laboratory diagnostic tests

Medical Prognosis Institute | Hershholm, Denmark | Develops tools for the diagnosis and prognosis of cancer

Metabolon, Inc | Durham, NC | Technology and methodologies that detect and quantify the small molecules present in biological specimens

Metanomics Health | Berlin, Germany | Metabolic network analysis applied to nutritional research

Miraculins Inc | Winnipeg, Canada | Diagnostics for cancers of the digestive, genital, and urinary systems

Monogram Biosciences | South San Francisco, CA | Develops products to guide and improve treatment of viral diseases

MTM Laboratories AG | Westborough, Massachusetts | Diagnostics for early detection of cervical cancer

Myriad Genetics | Salt Lake City, UT | Develops genomic and proteomic drug and diagnostic discovery

Nanosphere Inc | Northbrook, IL | Nanotechnology-based life sciences company

Neogenix Oncology Inc | Great Neck, NY | Developing therapeutic and diagnostic products for the early detection of cancer

NextGen Sciences | Huntingdon, United Kingdom | Protein research solutions for the drug discovery process

NorDiag ASA | Bergen, Norway | Early diagnosis or screening of colorectal cancer

Novartis Molecular Diagnostics | Basel, Switzerland | Solutions for preventive screening and the prediction of health outcomes

Nuvera Biosciences | Woburn, MA | Develops novel molecular diagnostics for cancer care

Olink AB | Uppsala, Sweden | Develops novel technologies for analysis of proteins and nucleic acids

Oncimmune LLC | De Soto, KS | Focused on advancing early cancer detection using autoantibody assay technology

OncoMethylome Sciences S.A | Durham, NC | Gene methylation tests that detect cancer at an early stage

OncoVista Innovative Therapies | San Antonio, TX | Development-stage pharmaceutical company dedicated to providing treatments to cancer

On-Q-ity | Waltham, MA | Personalized medicine diagnostics for oncology patients

OPKO Health | Miami, FL | Development of pharmaceuticals and instruments for the diagnosis and treatment of ophthalmologic disorders

Orion Genomics | Saint Louis, MI | Oncology diagnostic products for cancer screenings and therapy selection

Oxford BioTherapeutics | Abingdon, United Kingdom | Develops of targeted antibody-based medicines for oncology

Oxford Gene Technology | Yanton, United Kingdom | Provides innovative clinical genetics and diagnostic solutions to advance molecular medicine

Pathogenica | Boston, MA | Develops commercial applications of pathogen sequencing through DNA sequencing technologies

Pathwork Diagnostics | Redwood City, CA | Develops innovative, high-value molecular diagnostics for oncology

PerkinElmer Inc | Waltham, MA | Provides scientific instruments, consumables and services

Personalis | Menlo Park, CA | Applies genome analysis for clinical medicine

Phadia AB | Uppsala, Sweden | Clinical diagnosis and monitoring of allergy, asthma, and autoimmune diseases

Photocure ASA | Oslo, Norway | Photodynamic technologies for skin cancer, other skin disease, and internal cancer

Population Diagnostics | Melville, NY | Applies human genetics to develop DNA-based diagnostics and personalized medicine tests

Power 3 Medical Products, Inc | The Woodlands, TX | Disease detection through analysis of proteins

Precision Therapeutics | Pittsburgh, PA | Develops treatment support tools to assist physicians and benefit cancer patients

Prediction Sciences | La Jolla, CA | Develops high-value molecular diagnostics and assays for detection, prognosis and treatment

Predictive Biosciences | Lexington, MA | Develops tests for diagnosing and monitoring cancer

Progenika BioPharma | Derio, Spain | Identify genes and proteins as diagnostic and therapeutic tools

PrognosDx Health, Inc | Palo Alto, CA | Focused on improving the treatment of cancer and other diseases through epigenetic technology

Prometheus Laboratories Inc | San Diego, CA | Treating gastrointestinal tract disorder and autoimmune diseases

Provista Life Sciences LLC | Phoenix, AZ | Development of diagnostics for early detection of cancer and central nervous system diseases

Psynomics | La Jolla, CA | Offers DNA-based diagnostic and therapeutic tests to help patients suffering from mental illness

Psynova Neurotech Limited | Cambridge, United Kingdom | Biomarkers for Neuropsychiatric and other mental illnesses

Qiagen NV | Valencia, CA | Provides sample and assay technologies

QLIDA Diagnostics Inc | Philadelphia, PA | Diagnostic tests for life-threatening diseases

Quest Diagnostics | Madison, NJ | Leading provider of diagnostic testing, information, and services

Response Genetics, Inc | Los Angeles, CA | Pharmacogenomic cancer diagnostic technology

Roche Molecular Diagnostics | Basel, Switzerland | Diagnostic company with broad product and service offerings

Rosetta Genomics | Rehovot, Israel | Molecular diagnostics company advancing minimally invasive molecular tests

Rubicon Genomics, Inc | Ann Arbor, MI | Pre-analytical processes to improve performance of analytical platforms for research and clinical testing

Rules-Based Medicine, Inc (Myriad RBM) | Austin, TX | Provides comprehensive protein biomarker services

Saladax Biomedical, Inc (SBI) | Bethlehem, PA | Develops chemotherapy management assays for anti-cancer drugs

Seegene | Rockville, MD | Specializes in oligo technologies

Sekisui Diagnostics (American Diagnostics) | Framingham, MA | Medical diagnostic products related to the diagnosis and research of disorders

Sequenom Inc | San Diego, CA | Disease gene discovery program and extensive DNA sample repository

Siemens Healthcare Diagnostics | Tarrytown, NY | Offers diagnostics solutions that assist in the diagnosis of disease

Sienna Cancer Diagnostics | Melbourne, Australia | Focused on increasing the value of novel test for the early diagnosis of cancer

Signature Genomic Laboratories, LLC | Spokane, WA | Provides microarray-based chromosome analysis

Singulex Inc | Hayward, CA | Instrumentation and assay systems for nucleic acid and protein detection

Sirius Genomics | Vancouver, Canada | Use patient genetics to develop DNA-based companion diagnostic and pharmacogenetic tests

Skyline Diagnostics B.V | Rotterdam, Netherlands | Develops microarray technology in collaboration with academic and industrial partners

Soar BioDynamics, Ltd | San Francisco, CA | Develop technologies to screen for prostate cancer

SomaLogic | Boulder, CO | Develops protein analysis tools and reagents for the life science community

Soricimed BioPharma Inc | Toronto, Canada | Develops globally applicable cancer and pain management platforms

Source MDx (Out of Business) | Boulder, CO | Develops molecular diagnostic assays and tests for cancer and other inflammatory diseases

Spartan Bioscience | Ottawa, Canada | Develops DNA analyzers for on-demand applications

Strategic Diagnostics Inc | Newark, DE | Antibodies and immunoreagents for a broad range of applications

SureGene, LLC | Louisville, KY | Utilizes genetic technology to find the genetic basis for psychiatric diseases and drug response

Synergz Bioscience Ltd | Evanston, IL | Provides genomic-based risk stratification research for respiratory medicine

Targeted Molecular Diagnostics, LLC | Westmont, IL | Diagnostics laboratory focusing on oncology and serves the drug development process

TcLand Expression | Nantes, France | Develops personalized companion diagnostics

Theranostics Health (TH) | Rockville, MD | Provides research services to drug development companies

Transgenomic | Omaha, NE | Provides products and services for automated high sensitivity genetic variation and mutation analysis

TrimGen Corporation | Sparks Glencoe, MD | Focused on nucleic acid-based molecular diagnosis

TrovaGene, Inc | San Diego, CA | Provides non-invasive molecular diagnosis of diseases

Ventana Medical Systems | Tucson, Arizona | Develops instruments that automate tissue preparation and slide staining

Veridex, LLC | Raritan, NJ | Provides physicians with high-value in vitro diagnostic oncology products

Vermillion Inc | Fremont, CA | Develops diagnostic tests for oncology, hermatology, cardiology and women's health

ViennaLab Diagnostics GmbH | Vienna, Austria | Offers a range of diagnostic tests based on reverse hybridization

Virco BVBA | Mechelen, Belgium | Diagnostic services for the management of HIV infection

Vitatex Inc | Stony Brook, NY | Commercializes proprietary rare cell-enrichment research and diagnostic products

WaferGen Biosystems, Inc | Fremont, CA | Genomic analysis solutions for the pharmaceutical and life science industries

Wako Diagnostics | Richmond, VA | Promotes diagnostic reagents and offers test kits for unique analytes and routine testing

Xceed Molecular (formerly MetriGenix Corporation) | Toronto, Canada | Develops molecular and genetic testing technology

XDx | Brisbane, California | Molecular diagnostics to translate immune status into clinically actionable information

ZetiQ Technologies Ltd | Tel Aviv, Israel | Develops cancer diagnostic tools to target the high market value of cancer diagnostic

Zila | Phoenix, AZ | Products focused on oral care and improved health

Companies operating in personal genomics

23andMe | Mountain View, CA | Develops new ways of accelerating research and provides personalized genetic services

Accelerated Medical Diagnostics, LLC | Davis, CA | Develops technology to provide direct measurement of in vivo cellular responses

Amoy Diagnostics Co. Ltd | Xiamen, China | Provides molecular diagnostic products and services to healthcare institutions

ApoCell, Inc | Houston, TX | Develop personalized medicine through biomarker technologies which provide better understanding

Atossa Genetics | Seattle, Washington | Healthcare company focused on the development of novel cellular and molecular diagnostics

Biocept | San Diego, CA | Laboratory services company specializing in oncology tests

BioCurex | Richmond, Canada | Biotechnology company that develops products for early cancer diagnosis

Biofortuna Ltd. | Wirral, UK | Freeze-dried expertise and cryo-preserved to stabilize all reagents required for PCR

Bostwick Laboratories | Glen Allen, VA | Provides prompt interpretation of outpatient biopsies

Cancer Genetics | Rutherford, NJ | Provides product and services that enable cancer diagnostics and personalized treatments

CancerGuide Diagnostics | Durham, NC | Develops novel molecular diagnostic assays to assist oncologists

Caris Life Sciences | Irving, TX | Develops innovative technology for personalized healthcare

Chronix Biomedical | San Jose, CA | Provides diagnosis and management of chronic diseases and cancer

CombiMatrix Molecular Diagnostics | Mukilteo, WA | DNA microarrays for pharmaceutical, biotech, and agrochemical purposes

DiaTech Oncology | Brentwood, TN | Develop resources that promote individualized therapy and improve drug sensitivity testing of cancer cells

Evotec AG | Hamburg, Germany | Focused on rapidly progressing innovative product approaches

Genetic Technologies | Grover, MO | Focused on testing and evaluation of forensic evidence as related to human identification

GenMark Diagnostics | Carlsbad, California | Provides multiplexed molecular tests to aid in diagnosis and therapy

Genomas | Hartford, CT | Biomedical company advancing DNA-Guided Medicine and personalized healthcare

Inostics GmbH | Hamburg, Germany | Develop diagnostic tools improve cancer drug development and patient management

Insight Genetics | Nashville, TN | Provides molecular diagnostic solutions that enable personalized cancer care and improve patient outcomes

IntegraGen SA | Evry, France | Using molecular genetics and medical biology to develop genome analysis products

Knome, Inc | Cambridge, MA | Interpret of human whole genomes, informatics and tools for geneticists, researchers, and patients

Med BioGene | Vancouver, Canada | Develops genomic-based clinical laboratory diagnostic tests

Metamark Genetics | Cambridge, MA | Improve survival for cancer patients by empowering personalized treatment decisions

Mira Dx | New Haven, CT | Works with patients to assess genetic risks and find most effective treatment for cancer

MolecularMD Corp | Portland Oregon | Provides molecular testing services to support novel targeted cancer therapies

Nanostring Technologies | Seattle, WA | Provides life science tools for translational research and develops molecular diagnostics

Navigenics | Foster City, California | Offers personalized, genetics-based consumer health and wellness services

NewGene | Newcastle, United Kingdom | Develops molecular diagnostics using sequencing and genotyping technologies

NobleGen Biosciences | Concord, MA | Develops DNA sequencing instruments for personalized medicine

Nodality | San Francisco, CA | Focused on improving drug development for therapeutics and improving patient care

OvaGene Oncology | Irvine, CA | Develops novel gene-based assays for the improvement cancer care and gynecologic cancer patients

Pacific Edge Biotechnology Ltd. (PEB) | Dunedin, New Zealand | Biomedical company specializing in diagnosis for cancer

Pathway Genomics | San Diego, CA | Provides physicians with comprehensive genotyping reports, including propensity for certain diseases

Pharmigene | Palo Alto, CA | Develop diagnostic tests for personalized evaluation and health

Pinpoint Genomics, Inc | Mountain View, CA | Provide clinicians and cancer patients with molecular diagnostic tools for cancer treatment

Radient Pharmaceuticals | Tustin, CA | Develops and delivers in vitro diagnostic cancer tests Saladax Biomedical | already profiled

ScreenCell | Paris, France | Focused on providing easy and rapid access to circulating rare cells

Signal Genetics | New York, NY | Provides detailed diagnostic results to assist cancer patients and physicians

Signature Diagnostics AG | Potsdam, Germany | Prognostic gene signatures to predict outcomes and drug response in cancer patients



Alverix Diagnostics
San Jose, CA.

Commercialization Stage
Point-of-Care Testing

Richard Tarbox, President, CEO

Alverix provides multiple platforms for diagnostic Point-of-Care testing. The company produces Dx Pro, a full-featured, high-precision diagnostic instrument for use in physician's office labs, ERs/ICUs, retail clinics and ambulatory care facilities. The platform can process a wide range of detection modes and test methods (reflectance, fluorescence, electrochemical, and molecular), as well as single analyte or multiplex test panels. The company also produces Dx Mini, which can be used in home environments and requires no training or maintenance. Alverix platforms can be configured for: Immunoassay infectious disease, hormones, cancer markers; biochemistry for enzymes, metabolites, lipids; electrochemistry for diabetes, clotting efficiency factors; molecular detection of DNA, RNA, genetic targets; and cytology for cellular targets.

[Private]



BioMotion Suite
North Salem, NY.

Commercialization Stage
Data-Driven Care

Michael Montgomery, CEO

BioMotion Suite, Inc develops a new generation of remote monitoring solutions for patients with movement disorders. The company's technology will enable doctors to objectively monitor how patients are responding to medications, providing a 3D view of the course of care. The company's lead product is a specialized solution for Parkinson's disease, which measures patients' motor symptoms, providing doctors with actionable data to improve treatment. The platform incorporates wearable sensors to measure symptoms, enabling physicians to assess therapy in patients with limited mobility. The system accumulates objective and real-time outcome measures. The company was founded in 2010.

[Private]



Complete Genomics
Mountain View, CA.

Commercialization Stage
Genome Sequencing

Clifford Reid, Co-Founder, CEO

Listen to the [OneMedRadio](#) interview with Clifford Reid

Complete Genomics is a life sciences company that provides whole human genome sequencing and analysis as a simple outsourced service to researchers. Complete Genomics provides assembled and annotated genomic data as well as product management and full-service bioinformatics support. The company has optimized its sequencing platform for human DNA to achieve industry-leading accuracy levels of 99.9998%, and ensures project success by providing end-to-end project management and bioinformatics support. The company provides standard sequencing, cancer sequencing, and reanalysis services. The low reagent usage and high imaging efficiency of Complete Genomics' sequencing platform enable sequencing of whole human genomes at a fraction of the cost of alternative approaches.

[NASDAQ: GNOM 66M]



VisionGate
Phoenix, AZ.

Developmental Stage
Cancer Diagnostics

Alan Nelson, Founder, CEO

VisionGate, Inc. has developed a non-invasive test for the early detection of lung cancer, using its automated 3D cell-imaging platform, the Cell-CT(R), which generates high-resolution 3D biosignatures from intact cells using a sputum sample. The Cell-CT automated system harnesses the power of cutting-edge optics and computational technology that have the capability to capture images very rapidly, rendering scanned objects into 3D digital images. The company's LuCED test is initially being launched for adjunctive use with low dose x-ray computed tomography (CT) screening for the early detection of lung cancer in high-risk patients, when curative therapy is still feasible. The Cell-CT platform is also applicable to the diagnosis of a wide range of other disorders, and VisionGate's recent success in automating the system make it feasible for use in routine clinical medicine.

[Private]

Resource Directory

The following is a list of resources active in diagnostics. In this list we have identified: foundations and associations; research institutions; events; and publications. On this page is an example of the expanded resource profile found in the full guide.

Foundations/Associations

Adriana Jenkins Foundation for Personalized Medicine
American Society of Human Genetics (ASHG)
Association for Molecular Pathology (AMP)
Association of Medical Diagnostics Manufacturers
Autism Research Foundation
Avon Foundation Breast Center
Bill & Melinda Gates Foundation
Bonnie J Addario Lung Cancer Foundation
College of American Pathologists
Conant Foundation
Fairbanks Institute for Healthy Communities
FasterCures
Foundation for Innovative New Diagnostics
Foundation for the National Institutes of Health
Foundation Medicine Cancer Diagnostics
Genome British Columbia
IDA Foundation
Jeff George Foundation
Lung Cancer Foundation of America
Lustgarten Foundation
Michael J Fox Foundation
Multiple Myeloma Research Foundation
National Breast Cancer Foundation
National Foundation for Autism Research
National Foundation for Cancer Research
National Pharmaceutical Council
New York Academy of Sciences
Personalized Medicine Coalition
Prevent Cancer Foundation
Progeria Research Foundation
Quest Diagnostics Foundation
Seattle Cancer Care Alliance
Society of Diagnostic Medical Sonography
Susan G Komen for the Cure
The Critical Path Institute
The Dana Foundation
The Dr. John T. Macdonald Foundation
The Kavli Foundation
United States & Canadian Academy of Pathology



**American Society
Of Human Genetics**
Bethesda, MD.
(301) 634-7300

Professional membership organization for human genetics specialists worldwide. Nearly 8,000 members include: researchers, academics, clinicians, laboratory practice professionals, genetic counselors, nurses and others who have a special interest in the field of human genetics. Additional resources include annual meetings and the production of a respected journal. ASHG also advocates for genetic research and provides financial support.

Mary-Claire King, President
*****@ashg.org

Joann Boughman, Executive Vice President
*****@ashg.org

Resource Directory (Continued)

Research Institutions

Academy of Molecular Imaging
American Association for Cancer Research
American Institute for Medical & Biological Engineering
Australian Institute for Bioengineering and Nanotechnology
Autism Research Institute
Baylor College of Medicine Department of Molecular and Human Genetics
Breast Cancer Research Foundation
Cardiovascular Genetic Research, University of Texas
Catholic Health Initiative's Center for Translational Research
Centers for Disease Control and Prevention
Cepmed
Cincinnati Children's Hospital Imaging Research Center
Cleveland Clinic Genomic Medicine Institute
Columbus Regional Hospital Lung Institute
Coriell Institute for Medical Research
CREATE Health
Fairbanks Institute for Healthy Communities
FasterCures
Fred Hutchinson Cancer Research Center
Genome British Columbia
Genomics Institute of the Novartis Research Foundation
Institute for Systems Biology
Institute for Systems Biology
Institute for Translational Oncology Research (ITOR)
Institute for Translational Oncology Research (ITOR)
Institute of Genomics and Integrative Biology
Institute of Medicine
J Craig Venter Institute
Marshfield Clinic
MD Anderson Department of Experimental Diagnostic Imaging
MSKCC Prostate Cancer Diagnostic Center
National Human Genome Research Institute
National Institute of Mental Health
Prostate Cancer Research Institute
Reproductive Genetics Institute
Stanford Cancer Institute Nanotechnology Diagnostics
The Broad Institute of MIT and Harvard
The Brown Foundation Institute of Molecular Medicine for the Prevention of Human Diseases, University of Texas
The Critical Path Institute
The Institute of Prenatal Diagnostics and Reproductive Genetics
The Jackson Laboratory
The Systems Biology Institute
UCSF Institute for Human Genetics
University of Cincinnati Metabolic Disease Institute
University of Washington Center for Genomics and Public Health

Publications/Journals

Carnegie Magazine
Discoveries Magazine
Future Medicine Ltd
The Journal of Molecular Diagnostics
The Journal of Clinical and Diagnostic Research
The Canadian Journal of Diagnostics
Imaging and Diagnostics Magazine
Informa Healthcare
MDDI
Clinical Medicine and Diagnostics
European Journal of Clinic and Diagnostics

Events

Personalized Medicine World Conference
UPCP Personalized Medicine Conference
The Burrill Personalized Medicine Meeting
National Press Club State of Personalized Medicine
Biomarkers World Europe
San Francisco State University Personalized Medicine Conference
BIO International Convention
International Pharmaco-EEG Society Annual Meeting
Mayo Clinic Individualizing Medicine Conference

OneMedSentinel Clippings – Diagnostics

[OneMedRadio](#) interviews Dr. Eric Topol, “Rockstar of Science”

In this interview, Dr. Eric Topol, author of the book “The Creative Destruction of Medicine,” discusses the state of the healthcare system and what technological innovations are arising to combat the inefficiencies and challenges of the healthcare complex. Dr. Topol, an advocate for the digital revolution in medicine, looks at these tools within the backdrop of legislative rulings.

[OneMedRadio](#) discusses gene therapy and diagnostics with Dr. Andrew Senyei of Enterprise Partners Venture Capital.

In this interview, OneMedRadio sits down with a respected investor in pharmaceuticals, biopharmaceuticals, diagnostics, medical devices, and other tangential sectors. Dr. Senyei holds 20 patents in healthcare related products, including a biochemical test that predicts preterm delivery.

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“Dr. Shi of EdgeTech Law: Genome Sequencing Could Soon Enter Mainstream”

In this part of our special interview series, Dr. Qin Shi of Edgetech Law discusses the emerging areas of significant unmet need in life science, and what investment opportunities may arise. Dr. Shi offers musings on emerging markets, genome sequencing and the JOBS Act, and gives advice to prospective investors.

Brett Johnson: What is your advice to a prospective investor in diagnostics?

Dr. Qin Shi: Look for the winners – compared to drugs, diagnostics has shorter run ways to revenue and can be great investment. Many factors can bear on whether you have a winner – new, disruptive technology, unique platform or business model, smart IP position, local market advantage, etc...are all relevant considerations.

BJ: What are some of the most promising emerging markets? What particular technologies do you have your eye on?

QS: I think there is consensus that among the BRIC countries, China, despite its issues, presents great opportunity. Excess liquidity there in recent years makes China a potential alternative source for capital – in addition to being a source for cost-effective R&D services and manufacturing, and a market to target. Of particular relevance, the central government’s 12th five-year plan has designated the pharmaceutical and biopharmaceutical industry as a “strategic” industry – which means this is an area “ear-marked” for growth in China. You can definitely expect, as we are seeing, significant resources and policy favors in this area. In terms of technologies, oncology is certainly on the top of our list for China.

We also focus on new diagnostics, devices, and platform technologies that can sustain a long product line. Clinical assets for some of the other chronic indications are also part of our focus. I should note that depending on specific matters, for deals or partnerships with China, in some cases we work on behalf of the US, European, or Japanese companies to out-license products or technology, while in other cases we work on behalf of China-based entities to in-license quality assets. Of course, besides licensing, those transactions may have multiple and different dimensions, including partnership, JV, acquisitions, and equity participation among other things.

Brett Johnson: You previously worked in the genomics area at the time when the human genome was first sequenced. Do you see that genome sequencing will eventually be commodified for the general public, aka: hit the \$1000/test mark?

Dr. Qin Shi: Still today I have hanging in my office the original, large human genome map based on Celera’s genome sequence published in the February, 2000 issue of Science magazine. That was a very interesting time; and we have come a long, long way. My colleagues in the NIH and FDA tell me that \$1000/test is in the near horizon.

My guess is that, if we use the downward trajectory of the cost of microprocessors in recent decades – while their speed goes up – as a cross reference, we will be seeing the cost of sequencing coming down. More relevant, as we have competition in the market among some of the best companies in the space, the cost is going to go down further. Genome sequencing can indeed be heading towards commodity tests in wellness labs around the world.

BJ: What are regulatory bodies saying about genome sequencing?

QS: That would be a different question. In fact, you may be touching on a complex area of regulatory policy where changes are expected. For example, in the field of direct-to-consumer genetic testing, if it goes beyond recreation and wellness – such as searching for ancestry or choosing suitable supplements – and becomes what’s called direct-to-consumer medical or diagnostics genetic testing, a series of federal and state laws will become applicable. Most notably this includes the Clinical Laboratory Improvement Amendments of 1988, which regulates clinical labs where tests are run, and patient protection and privacy laws at the state level.

Additionally, the claims are subject to the oversight by the FTC for consumer protection. Moreover, the FDA has the authority to regulate some of those tests depending on how they are administered – such as Laboratory Developed Tests (LDTs) or In Vitro Diagnostic Multivariate Index Assay (IVDMIA). And yet, there is lobbying for new legislation to regulate DTC companies. As the market matures, so will we hopefully see the regulatory framework clear up in this area.

BJ: Talk about the JOBS Act for a bit. Will healthcare companies and diagnostics companies in particular, find any use for crowdfunding?

QS: It may be a bit too early to tell. It may not be until 2013 when the SEC starts to issue corresponding rules on crowdfunding. Theoretically, this expands on the traditional angel model, and provides alternative sources for funding to start-ups. However, there are many pieces to how this would actually work, and ensuring regulatory compliance will have some additional cost. Again, it’s a bit too early to tell whether this paradigm will be a success and will fuel the growth of diagnostics and other healthcare companies.

BJ: Speaking of JOBS, why do you seek experienced lawyers/advisors previously in science and engineering? Why do they find success at Edgetech Law?

QS: We believe it is important to work with like-minded people who share the same passion. Those who have had varied experiences in life, including in science and engineering, or business and law, have an edge to excel in what we focus on – which is to bring value to our client’s technology ventures and to help make things happen.

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“Patent Infringement Special Report: The Most Pressing Cases”

The healthcare industry is experiencing the aftershocks of several landmark cases that may redefine the definition of intellectual property, and as such these decisions may change the strategy of emerging companies with unique technology.

On March 20th, 2012, the US Supreme Court ruled 9-0 in favor of the Mayo Clinic in its appeal against Prometheus Laboratories over infringement of two patents related to a diagnostic test. The Mayo Clinic, a former client of Prometheus, developed its own version of a test based on drug metabolites in the blood.

The lawsuit originated in 2004 after the Mayo Clinic developed its own version of the blood test, which is used to determine the optimal drug dosages for patients with autoimmune diseases such as Crohn’s disease. The test involves administering a drug called thiopurine to patients and then determining the levels of thiopurine metabolites in the patient’s red blood cells.

The Mayo Clinic claimed they did not have to honor the Prometheus patents because the company cannot own a monopoly on the metabolites created by a drug. The Supreme Court agreed; in the ruling, Justice Stephen Breyer wrote: “We conclude that the patent claims at issue here effectively claim the underlying laws of nature themselves. The claims are consequently invalid.”

In a New York Times story, Prometheus said that the decision against it “will, in our view, encourage imitation, not innovation.”

Bernard Greenspan, Director of Intellectual Property for Prometheus Laboratories, said that current patent law places the burden of stopping infringement squarely on the shoulders of the patent holder. Monitoring and distinguishing both non-infringing and infringing actions “will only add costs and redirect resources from new developments,” he said in a recent Genetic Engineering and Biotechnology News story. It would be difficult for labs to conduct confirming tests without infringing on the patents of primary test developers, he said of this ruling, a counter-intuitive detriment to further medical research.

“The chilling effect on research and development of new and innovative tests created by a carve-out to a non-licensed party to avoid infringement will be far-reaching,” Greenspan said. “Established companies, university technology transfer offices, and job creation by startup ventures will be faced with the proposition that they will lose proprietary benefits of patents. Any steps taken to weaken those rights, while having a presupposed short-term gain in access to current technology, will result in long-term reduction of investments needed to commercialize future innovations thus creating a decrease in access to future technologies.”

Still, there is a different crux at the core of the recent Mayo ruling. Ultimately, are exclusive patents more conducive to scientific progress? Is granting a corporation the opportunity to reap profit after investing millions of dollars in R&D – and, theoretically, simultaneously creating incentive for other companies to follow suit – the only way to ensure drug development?

Shares of Myriad Genetics, Inc. (NASDAQ: MYGN) fell 10 percent in the wake of the Mayo ruling. The diagnostics cancer company is currently a defendant in a federal patent case brought by the Association for Medical Pathology.

Myriad seeks to protect seven patents supporting its BRCAAnalysis test, which looks for genetic mutations that indicate an increased risk of inherited breast cancer. The BRCA1 and BRCA2 genes, which were isolated by Myriad Genetics and the University of Utah, are both closely associated with the risk of developing breast and ovarian cancer. Myriad manufactures the only test currently available to identify the two genes.

On March 26, the Supreme Court remanded this case to the Federal Circuit Court of Appeals, a specialized court that hears patent cases. The issue at hand is whether the Mayo decision yields a legal precedent that gene isolation is a law of nature, as DNA itself is indeed a law of nature. In similar patent cases outside of healthcare, the courts tend to support the practice of mining natural phenomena as unique. Patently-O, a leading intellectual property blog, notes that the Mayo decision could refute this ‘uniqueness’ in healthcare and particularly gene isolation:

Following Mayo, the court could logically find that the information in the DNA represents a law of nature, that the DNA itself is a natural phenomenon, that the isolation of the DNA simply employs an isolation process already well known and expected at the time of the invention, and ultimately that the isolated DNA is unpatentable because it effectively claims a law of nature or natural phenomenon.

Though Prometheus patented a process while Myriad claims a composition of matter, the authors note the composition was only arrived at by the “already well-known process of isolating human DNA.”

In July 2011, the Federal Circuit Court of Appeals ruled 2-to-1 in favor of Myriad, stating that the two genes could be patented because they did not occur in isolation in nature. This reversed a 2010 New York District Court decision that Myriad could not patent the genes.

The history of the Myriad case dates back to 2009, when the AMP, the American Civil Liberties Union and the Public Patent Foundation filed a lawsuit against the US Patent and Trademark Office and Myriad. They argued that Myriad created a monopoly with its patent, since the company possesses the only test available for the BRCA1 and BRCA2 genes. Additionally, they argued that the company also restricts other researchers’ access to the genes.

Opinions of the Myriad case are divided, GEN reports. Richard Marsh, Myriad EVP, General Counsel and Secretary, noted that Myriad invested \$500 million over 17 years before breaking even on research, development and commercialization of its tests.

“Myriad wouldn’t have been able to make this capital investment without the promise of exclusive patent rights,” he said. “The risk and reward inherent in the ability to obtain exclusive license rights in the patent system is the driving force behind investment in genetic tests and hence their development and commercialization to the general public.”

However, Daniel J. Nevriy, Ph.D., founder of the Nevriy Patent Law Group, argued that the scientific practice Myriad claimed as unique did not noticeably deviate from the methods previously determined to be unpatentable law of nature.

“Myriad’s rejected mutation analysis patent merely required comparison of a mutation sequence with a control sequence, with no additional step such as assaying or isolating the gene and determining the sequence,” Nevriy said in the GEN story. “There’s no transformative step in the way that there is a transformative step in Prometheus’ claims of determining or administering. In Myriad, the claim is purely mental.”

Critics of Myriad included Misha Angrist, Assistant Professor of the practice at Duke Institute for Genomic Sciences & Policy. Angrist faulted Myriad for not making its mutation data open to independent verification and scientific scrutiny. He cited the nonparticipation in the international collaborative mutaDATABASE and lack of contribution to the NIH-funded Breast Cancer Information Core since 2004.

“The implication is that if it were not for Myriad there would be no analytically valid, clinically valid, and useful BRCA testing for American women,” Angrist testified. “This contention is simply, excuse my French, bullshit in Babylon.”

To view the electronic Investor Guide to Diagnostics, visit:

www.onemedplace.com/investor-guide-diagnostics.pdf

To learn more about the full Investor Guide subscription, which provides access to quarterly updates of interviews and directories, visit www.onemedplace.com.