

North American Frost & Sullivan Award for Excellence in Technology Innovation of the Year

2007

FROST & SULLIVAN

North American Proteomics for Biomarker Discovery
Excellence in Technology of the Year Award

AWARD DESCRIPTION

Frost & Sullivan's Excellence in Technology of the Year Award is bestowed upon a company that has pioneered the development and introduction of an innovative technology into the market; a technology that has either impacted or has the potential to impact several market sectors. This award recognizes a company's successful technology development that is expected to bring significant contributions to the industry in terms of adoption, change, and competitive posture. It also recognizes the company's overall technical excellence and its commitment toward technology innovation.

RESEARCH METHODOLOGIES

To choose the award recipient, Frost & Sullivan's analyst team tracks technology innovation in key hi-tech markets. The selection process includes primary participant interviews and extensive primary and secondary research via the bottom-up approach. The analyst team shortlists candidates on the basis of a set of qualitative and quantitative measurements. The analysts also consider the pace of technology innovation, and the potential relevance or significance of the technology to the overall industry. The ultimate award recipient is chosen after a thorough evaluation of this research.

MEASUREMENT CRITERIA

In addition to the methodology described above, there are specific criteria used to determine the final rankings. The recipient of this award has excelled based on one or more of the following criteria:

- Number of new technologies developed or introduced
- Significance of a technology/technologies in the industry
- Competitive advantage of technology/technologies vis-à-vis competing technologies
- Ease of adoption of new technology/technologies
- Potential of technology/technologies to become an industry standard
- General impact of technology in terms of shifting R&D focus patents, scientific publications, papers in peer reviewed journals.

THE FROST & SULLIVAN 2007 NORTH AMERICAN EXCELLENCE IN TECHNOLOGY OF THE YEAR AWARD IN THE FIELD OF PROTEOMICS FOR BIOMARKER DISCOVERY GOES TO CAPRION PROTEOMICS, FOR ITS DEVELOPMENT OF THE CELL CARTA PROTEOMICS TECHNOLOGY PLATFORM THAT IS ABLE TO EFFICIENTLY DETECT AND PROFILE THE DIFFERENTIAL EXPRESSION OF PROTEINS IN SOLID TISSUES, PLASMA, AND OTHER ACCESSIBLE FLUIDS. THIS PLATFORM HOLDS IMMENSE POTENTIAL FOR THE DISCOVERY OF PROTEIN BIOMARKERS USED IN PRECLINICAL AND CLINICAL COMPOUND DEVELOPMENT, AS WELL AS THE DISCOVERY OF NOVEL THERAPEUTIC DRUG TARGETS.

HUMAN PROTEOME INFORMATION IS BEING APPLIED TO THE DISCOVERY AND EVALUATION OF DRUG TARGETS, DRUG CANDIDATES AND BIOMARKERS. PROTEOMIC TECHNOLOGY PLATFORMS ARE CONSTANTLY EVOLVING AND VARY SIGNIFICANTLY IN TERMS OF DESIGN, WHICH INFLUENCES SPEED, COMPLEXITY, COST, AND IMPORTANTLY, IN TERMS OF THE VALUE OF THE DATA RETURNED. COMPLEMENTARY TO ADVANCES IN GENOMICS AND SYSTEMS BIOLOGY, PROTEOMICS PROMISES TO MAKE A SIGNIFICANT CONTRIBUTION IN IDENTIFYING BIOMARKERS AND SPEEDING UP THE DRUG DEVELOPMENT PROCESS.

DISCOVERIES AND INNOVATIONS OFTEN STEM FROM LIMITATIONS IN CURRENT TECHNOLOGIES. PROTEOMICS TECHNOLOGIES HAVE

DELIVERED MANY PUTATIVE BIOMARKERS TO THE MARKET, BUT SEVERAL ARE YET TO MOVE FROM THE DISCOVERY AND DEVELOPMENT PHASE TO THE VALIDATION AND APPLICATION PHASE. THIS BOTTLENECK CAN BE PRIMARILY ATTRIBUTED TO THE COMPLEXITY AND VARIABILITY OF THE HUMAN PROTEOME, IN ADDITION TO THE NEED FOR ROBUST PROTEOMIC TECHNOLOGY PLATFORMS THAT CAN CARRY OUT LARGE BIOMARKER STUDIES WITH SUFFICIENTLY HIGH SENSITIVITY AND RELIABILITY. THEN THERE IS ALSO NEED FOR APPROPRIATE METHODS TO IDENTIFY BIOMARKERS AMONG THE LOW ABUNDANCE PLASMA PROTEINS.

TO ADDRESS SUCH CHALLENGES IN TERMS OF PROTEOMICS, CAPRION PROTEOMICS DEVELOPED CELL CARTA. THIS PROTEOMICS PLATFORM CAN BE USED TO IDENTIFY PROTEINS IN SOLID TISSUES, PLASMA, AND OTHER ACCESSIBLE FLUIDS, AND TO DETERMINE THEIR ROLES IN VARIOUS DISEASES BY FACILITATING THE COMPARISON OF NORMAL AND DISEASED TISSUES. THE PLATFORM IS ALSO CAPABLE OF DISCOVERING LOW ABUNDANCE CIRCULATING BIOMARKERS.

CAPRION HAS FOLLOWED PRINCIPALLY TWO APPROACHES. ONE APPROACH HAS BEEN TO COMPARE CLINICAL OR PRECLINICAL PLASMA SAMPLES FOLLOWING DEPLETION OF HIGH ABUNDANCE PROTEINS, DIGESTION TO PEPTIDES, FRACTIONATION, AND CHROMATOGRAPHY-MASS SPECTROMETRY. PEPTIDE IONS ARE

MATCHED ACROSS SAMPLE SETS OF ANY SIZE AND THOSE IONS SHOWING SIGNIFICANT DIFFERENTIAL INTENSITY ARE TARGETED FOR FRAGMENTATION, SEQUENCE ANALYSIS, AND PARENT PROTEIN IDENTIFICATION. PROTEINS ASSOCIATED WITH DRUG RESPONSE OR DISEASE CAN THEN BE CONFIRMED WITH ANTIBODY ANALYSIS OF THE ORIGINAL SAMPLE SET AND VALIDATED IN A LARGER COHORT.

ANOTHER APPROACH HAS ALSO BEEN IMPLEMENTED WHEREIN ACCESS TO AFFECTED TISSUE IS POSSIBLE, SUCH AS FROM SURGICAL RESECTION OF CANCERS OR ADIPOSE TISSUE OR FROM CIRCULATING PERIPHERAL BLOOD MONONUCLEAR CELLS, AS WELL AS FROM ANIMAL MODELS. PROTEINS ARE ISOLATED AND IDENTIFIED FROM THE SECRETORY PATHWAY WHERE THEY ARE MUCH MORE CONCENTRATED THAN IN THE BLOOD. THEIR DIFFERENTIAL EXPRESSION IN THE BLOOD IS THEN CONFIRMED USING A MORE SENSITIVE TARGETED ANTIBODY ASSAY.

CAPRION'S CELL CARTA PROTEOMICS PLATFORM HAS ADVANCED FUNCTIONALITY, WHICH ENABLES IT TO PERFORM SIMULTANEOUS TRACKING AND MEASUREMENT OF ALMOST 50,000 IONS ACROSS VERY LARGE DATA SETS. IT ACCOMPLISHES THIS BY UTILIZING LABEL-FREE MASS SPECTROMETRY IN CONJUNCTION WITH A SUITE OF PROPRIETARY SOFTWARE, WHICH IS OVER AND ABOVE AN EXTREMELY CONTROLLED PROCESS TO GUARANTEE RELIABILITY OF THE DATA PRODUCED. THE PLATFORM IS GEARED TOWARD EARLY CLINICAL DEVELOPMENT (DRUG EFFICACY AND TOXICITY) BUT IT CAN BE USED IN LATE PRECLINICAL STUDIES (COMPOUND NOMINATION PROCESS) AS WELL.

SUCH A TYPE OF PROTEOMICS PLATFORM COULD BE USED IN DRUG DISCOVERY FOR TWO MAJOR APPLICATIONS—CLINICAL BIOMARKER DISCOVERY AND ONCOLOGY TARGET IDENTIFICATION. FOR THE FIRST TIME, CAPRION HAS COMPREHENSIBLY AND EXHAUSTIVELY MAPPED THE BARRIER BETWEEN THE OUTSIDE OF THE CELL AND INSIDE OF THE CELL, THEREBY IDENTIFYING CRITICAL PROTEINS THAT CHANGE DURING CANCERS AND SUBSEQUENTLY TARGETING THEM.

CAPRION CARRIES OUT BIOMARKER DISCOVERY PRIMARILY FOR ITS PARTNERS, IN TERMS OF DISEASE OR DRUG EFFICACY, WHILE ITS IN-HOUSE DISCOVERY EFFORT FOCUSES ON ALZHEIMER'S DISEASE AND CANCER DIAGNOSTICS. WHILE THE MARKERS IDENTIFIED FOR BOTH DISEASES ARE CURRENTLY UNDERGOING VALIDATION, CAPRION HAS ESTABLISHED ACTIVE BIOMARKER PROGRAMS WITH COMPANIES LIKE PFIZER, CENTOCOR, JANSSEN, DAIICHI-SANKYO, AND VERTEX, AND HAS COMPLETED PROJECTS FOR MANY OTHERS.

THE CELL CARTA PLATFORM ALSO FINDS APPLICATIONS IN DEVELOPING CELL-SURFACE TARGETS FOR TARGETED CANCER THERAPY. TO DATE, THE ONCOLOGY PROGRAM HAS

SUCCESSFULLY IDENTIFIED CELL-SURFACE TARGETS IN THREE MAJOR CANCER INDICATIONS: COLON, LUNG, AND PROSTATE CANCERS. TO ENHANCE THE PENETRATION AND AVAILABILITY OF ITS TECHNOLOGIES, CAPRION HAS FORMED STRATEGIC TARGET-LICENSING AGREEMENTS WITH COMPANIES SUCH AS BIOGEN IDEC, ABBOTT LABORATORIES, ICOS CORPORATION, AND CENTOCOR. THE PARTNERS MAKE AND TEST ANTIBODIES AGAINST THE TARGETS AND PLAN TO DEVELOP THE BEST CANDIDATES AS THERAPEUTICS.

ON THE FRONT END, CAPRION IS COLLABORATING WITH A NUMBER OF UNIVERSITY HOSPITALS SUCH AS MCGILL UNIVERSITY IN MONTREAL AS WELL AS THE UNIVERSITY OF MONTREAL TO SOURCE SAMPLES (PLASMA, ONCOLOGY); THIS, IN ADDITION TO ITS ORGANELLAR ISOLATION PROTOCOLS FURTHER DISTINGUISH ITS CAPABILITIES IN TERMS OF BOTH BIOMARKER AND CELL-SURFACE TARGET DISCOVERY. THE COMPANY HAS APPLIED FOR PATENT PROTECTION ON MUCH OF ITS BIOINFORMATICS SOFTWARE AS WELL AS ON OTHER ASPECTS OF THE PLATFORM.

IN ITS QUEST FOR EXCELLENCE IN PROTEOMICS, THE COMPANY IS CONSTANTLY WORKING TO IMPROVE THE ABILITY TO FIND VERY LOW ABUNDANCE BIOMARKERS IN BLOOD. IT IS FOCUSING ON IDENTIFYING SECRETED PROTEINS IN THE GOLGI OF TISSUES OUTSIDE OF ONCOLOGY, BEGINNING WITH A STUDY COMPARING THE PROTEINS SECRETED FROM VISCERAL FAT COMPARED WITH SUBCUTANEOUS FAT. IT IS ALSO FURTHERING ITS RESEARCH EFFORTS FOR THE VALIDATION OF PROTEIN MARKERS.

CLEARLY CAPRION POSSESSES EXCEPTIONAL EXPERTISE IN CELL BIOLOGY AND HAS LEVERAGED IT FOR THE DEVELOPMENT OF THE UNIQUE CELL CARTA PLATFORM. SUCH A PLATFORM HOLDS POTENTIAL FOR COMPREHENSIVE PROTEOMIC COMPARISONS OF NORMAL AND DISEASED CELLS. THE STUDY WITH PROSTATE CANCER IDENTIFIED MOST OF THE KNOWN SECRETED PROTEINS SUCH AS PSA, MIF, ACPP, AND KLK2, AS WELL AS MANY NOVEL PROTEINS, WHICH ARE IN THE PROCESS OF VALIDATION. THE COMPANY NOW HAS A CONTRACT WITH A MAJOR PHARMACEUTICAL COMPANY IN THE AREA OF SECRETED PROTEINS.

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