published as WO 2004/016155 A3 on 26 Feb 2004 (DHHS Reference No. E–248–2001/0–PCT–02).

Licensing Contact: Michael Shmilovich; (301) 435–5019; *shmilovm@mail.nih.gov.*

Available for licensing and commercial development is a multifocal apparatus for delivering an agent or for gathering information about a biological tissue, such as optical spectroscopy for tissue characterization (nuclear chromatic density). The apparatus includes a needle or catheter having a lumen extending longitudinally at least partially through it and a deployment port within the distal portion of the catheter. A plurality of extendable-retractable needles are housed within the catheter lumen, when deployed, extend through the deployment port. The needles may be solid or hollow and may deliver an agent to the tissue, include a mechanism for gathering information about the tissue, or both. Optical spectroscopy in a needle-based system provides in vivo tissue characterization without removal of tissue for microscopic analysis, which may be helpful during surgery or image guided therapies to localize cancerous tissue.

Figure 1 is a schematic diagram of one embodiment of the apparatus in use. The distal end of the apparatus is shown within a neoplasm and the needles are in a deployed state.

Figure 2 is an enlarged, longitudinal section through the distal end of an embodiment of the apparatus, showing several extendable-retractable needles in a non-deployed, or retracted, state.

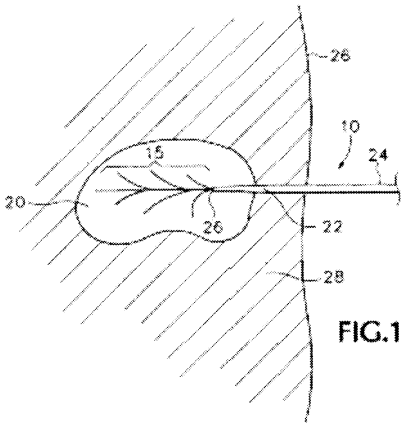

FIG.1

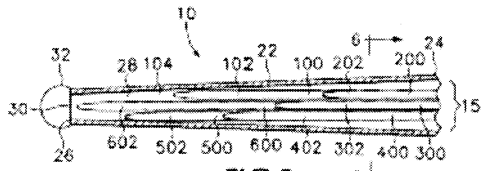

FIG.2

In addition to licensing, the technology is available for further development through collaborative research with the inventors via a Cooperative Research and Development Agreement (CRADA).

Dated: February 1, 2005.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 05–2365 Filed 2–7–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Monoclonal Antibody 90.12 Recognizes a Novel B Cell Surface Antigen Upregulated on Both Activated and Apoptotic Lymphocytes

Marjorie A. Shapiro *et al.* (FDA).

DHHS Reference No. E–195–2004/0—Research Tool.

Licensing Contact: Cristina Thalhammer-Reyero; 301/435-4507; *thalhamc@mail.nih.gov.*

Monoclonal antibody 90.12 recognizes a molecule expressed on the surface of a subset of B lymphocytes and on all types of blood cells. This antigen is increased upon stimulation of B and T lymphocytes as well as on cells undergoing programmed cell death. Amino acid sequencing of the beginning of the protein suggests that it is a member of the S100 family of calcium binding proteins. The antibody is further described in ''Characterization of a B cell surface antigen with homology to the S100 protein MRP8'' by Shapiro MA, Fitzsimmons SP, Clark KJ, Biochem Biophys Res Commun. 1999 Sep 16;263(1):17–22 and ''A novel activation induced lymphocyte surface antigen, 90.12, is also expressed on apoptotic cells'' by Clark KJ, Monser M, Stein KE, Shapiro MA, Scand J Immunol. 2000 Feb;51(2):155–63.

Methods for Analyzing High Dimensional Data for Classifying, Diagnosing, Prognosticating, and/or Predicting Diseases and Other Biological States

Javed Khan and Paul S. Meltzer (NHGRI), *et al.*

U.S. Patent Application No. 10/133,937 filed 25 Apr 2002 (DHHS Reference No. E–324–2001/0–US–01).

Licensing Contact: Cristina Thalhammer-Reyero; 301/435–4507; *thalhamc@mail.nih.gov.*

This invention relates to a method of using supervised pattern recognition methods to classifying, diagnosing, predicting, or prognosticating various diseases. The method includes

obtaining high dimensional experimental data, such as gene expression profiling data, filtering the data, reducing the dimensionality of the data through use of one or more methods, training a supervised pattern recognition method, ranking individual data points from the data, choosing multiple data points from the data based on the relative ranking, and using the multiple data points to determine if an unknown set of experimental data indicates a diseased condition, a predilection for a diseased condition, or a prognosis about a diseased condition.

Artificial neural networks (ANNs) are computer-based algorithms capable of pattern recognition particularly suited to making diagnoses. ANNs do not require explicit encoding of process knowledge in a set of rules and can be trained from examples to recognize and categorize complex patterns. ANNs learn more efficiently when the data to be input into the neural network is preprocessed. Various ANN approaches to the analysis of data have seen extensive application to biomedical problems, including those in the areas of diagnosis and drug development. Unsupervised neural networks are also extensively used for the analysis of DNA microarray data.

The technology is further described in J. Khan *et al.*, ''Classification and diagnostic prediction of cancers using gene expression profiling and artificial neural networks,'' Nature Medicine, 7(6):673–679, June 2001.

Selections of Genes

Javed Khan and Paul S. Meltzer (NHGRI), *et al.*

U.S. Patent Application No. 10/159,563 filed 31 May 2002 (DHHS Reference No. E–324–2001/1–US–01).

Licensing Contact: Cristina Thalhammer-Reyero; 301/435–4507; *thalhamc@mail.nih.gov.*

The invention provides selections of genes expressed in a cancer cell that function to characterize such cancer, and methods of using the same for diagnosis and for targeting the therapy of selected cancers. In particular, methods are provided to classify cancers belonging to distinct diagnostic categories, which often present diagnostic dilemmas in clinical practice, such as the small round blue cell tumors (SRBCTs) of childhood, including neuroblastoma (NB), rhabdomyosarcoma RMS), Burkitt's lymphoma (BL), and the Ewing family of tumors (EWS). More specifically, the invention is an application of Artificial Neural Networks (ANNs) for the diagnostic classification of cancers based on gene expression profiling data derived from cDNA microarrays. The ANNs were trained using as models. The ANNs then correctly classified all samples tested and identified the genes most relevant to the classification. Their study demonstrated the potential applications of these methods for tumor diagnosis and for the identification of candidate targets for therapy. The uniqueness of this method is taking gene expression data generated by microarrays, minimizing the genes from the original 1000s to less than 100, identifying which genes are the most relevant to a classification, which gives an immediate clue to the actual biological processes involved, not just surrogate markers which have no bearing on the biology.

The technology is further described in J. Khan *et al.*, ''Classification and diagnostic prediction of cancers using gene expression profiling and artificial neural networks,'' Nature Medicine 7(6): 673–679, June 2001.

Dated: February 1, 2005.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 05–2366 Filed 2–7–05; 8:45 am]

BILLING CODE 4140–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

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Methods for Prophylaxis and Treatment of HER–2/neu Tumors

John C Morris, Jay A. Berzofsky, Yoshio Sakai, Jong-Myun Park, Masake Terabe (all of NCI).

Serial Nos. PCT/US2003/034362 filed 29 Oct 2003 (DHHS Reference No. E–025–2003/1–PCT–1) and 60/422,395 filed 30 Oct 2002 (DHHS Reference No. E–025–2003/0–US–01).

Licensing Contact: Susan S. Rucker; (301) 435–4478; *ruckersu@mail.nih.gov.*

This application relates to methods for cancer prophylaxis and treatment. More particularly, the application relates to methods for the treatment and prophylaxis of cancers caused by the activity of the HER–2/neu/erbB–2 gene employing immunotherapy. Such cancers include breast cancers, cancers of the female genital tract and some cancers of the gastrointestinal tract.

The methods claimed involve the use of a HER–2/neu vaccine employing recombinant non-replicating adenovirus expressing a HER–2/neu/erbB–2 gene. In a preferred embodiment the vaccine comprises a recombinant non-replicating adenoviral vector encoding a HER–2/neu/erbB–2 gene that is expressed as a truncated HER–2/neu/erbB–2 protein. Antigen presenting cells, such as dendritic cells infected with the recombinant adenoviral vector, process and present the truncated HER–2/neu/erbB–2 protein, thereby stimulating an immune response. Preferred HER–2/neu/erbB–2 proteins contain regions of the extracellular domain and the transmembrane domain of the intact HER–2/neu/erbB–2 gene product and do not contain any tyrosine kinase domains.

This work has been published in part in Sakai, Y, *et al.* Cancer Research 64(21): 8022 (Nov 1 2004) and as WO 2004/041065 (May 21 2004).

Antibodies and Polypeptides to AAMP–1 for Use in Diagnosis and Therapy of AAMP–1–Expressing Cancers

Lance Liotta *et al.* (NCI).

U.S. Patent No. 6,274,134 issued 14 Aug 2001 (DHHS Reference No. E–084–1991/1–US–01); Australian Patent No. 684806 issued 23 Apr 1998 (DHHS Reference No. E–084–1991/1–AU–05).

Licensing Contact: Thomas Clouse; (301) 435–4076; *clousetp@mail.nih.gov.*

Angio-associated migratory cell protein (AAMP–1) was first isolated from a human melanoma cell line as a motility-associated cell protein. AAMP–1 contains two immunoglobin domains,