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Mohammed Dakna[a], Zengyou He[b], Wei Chuan Yu[b], Harald Mischak[a], Walter Kolch[c]

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[c] The Beatson Institute for Cancer Research & Sir Henry Wellcome Functional Genomics Facility, University of Glasgow, Glasgow, UK

Received 9 July 2008; Accepted 28 October 2008. Available online 6 November 2008.

Abstract

The search for biomarkers in biological fluids that can be used for disease diagnosis and prognosis using mass spectrometry has emerged to become a state-of-the-art methodology for clinical proteomics. Poor cross platform comparison of the findings, however, makes the need for comparison studies probably as urgent as the need for new ones. It is now increasingly recognized that standardized statistical and bioinformatics approaches during data processing are of utmost importance for such comparisons. This paper reviews two of the currently most promising methods, namely LC–MS and CE-MS techniques, and software tools used to analyze the huge amount of data they generate. We further review the statistical issues of feature selection and sample classification.

Keywords: LC–MS; CE-MS; Biomarkers; Clinical proteomics; Statistical data analysis

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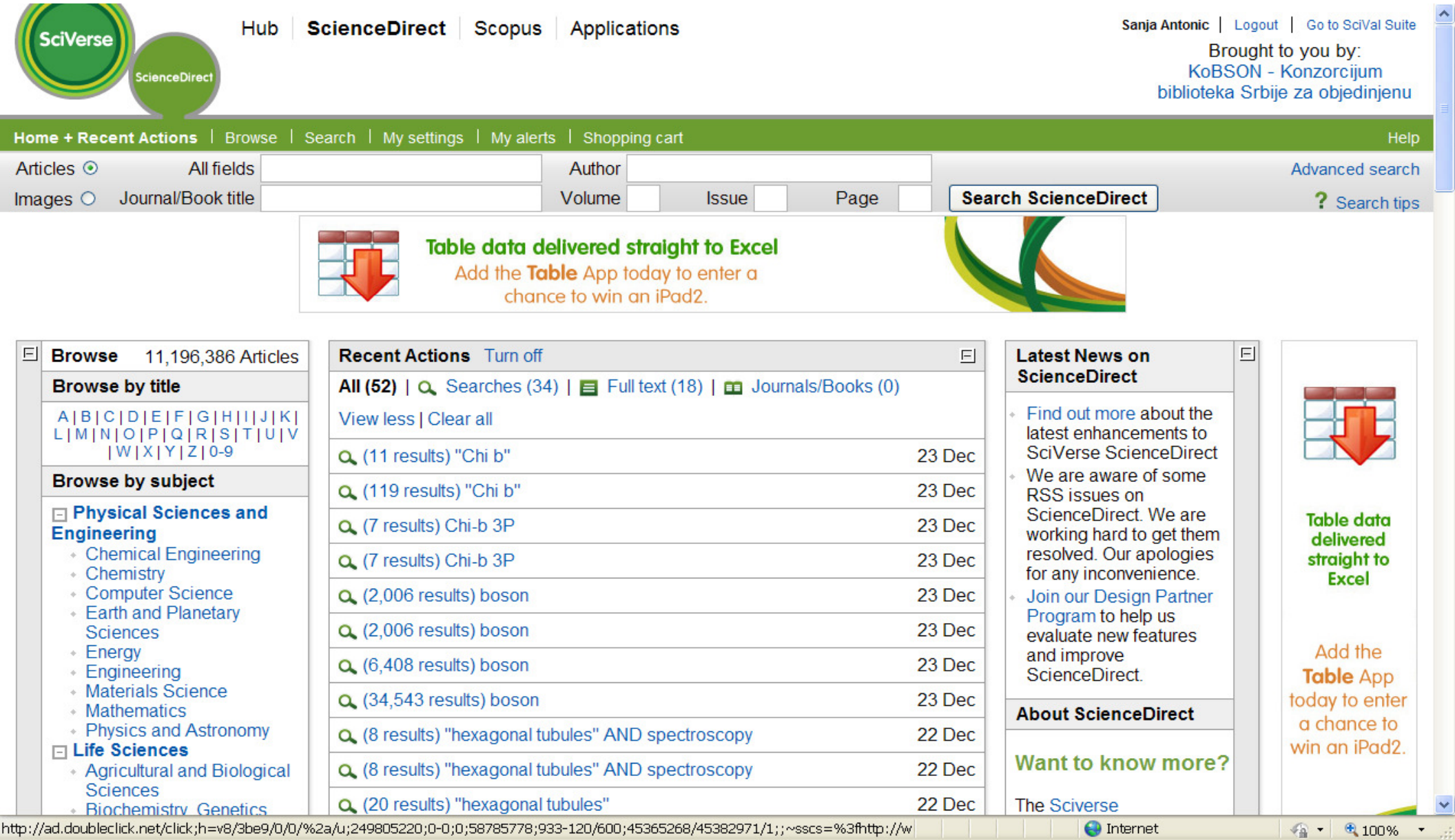

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▶ We applied the metabolomics approach to assess the mechanisms of melamine-induced nephrolithiasis in young children. ▶ Using the nephrolithiasis patients with no history of melamine exposure to filter out biomarkers unique to the melamine-induced nephrolithiasis group. ▶ Examining hypoxanthine and proline significantly distinguishing the controls/melamine exposure groups. ▶ The predictive model showed the good performance to identify the markers.

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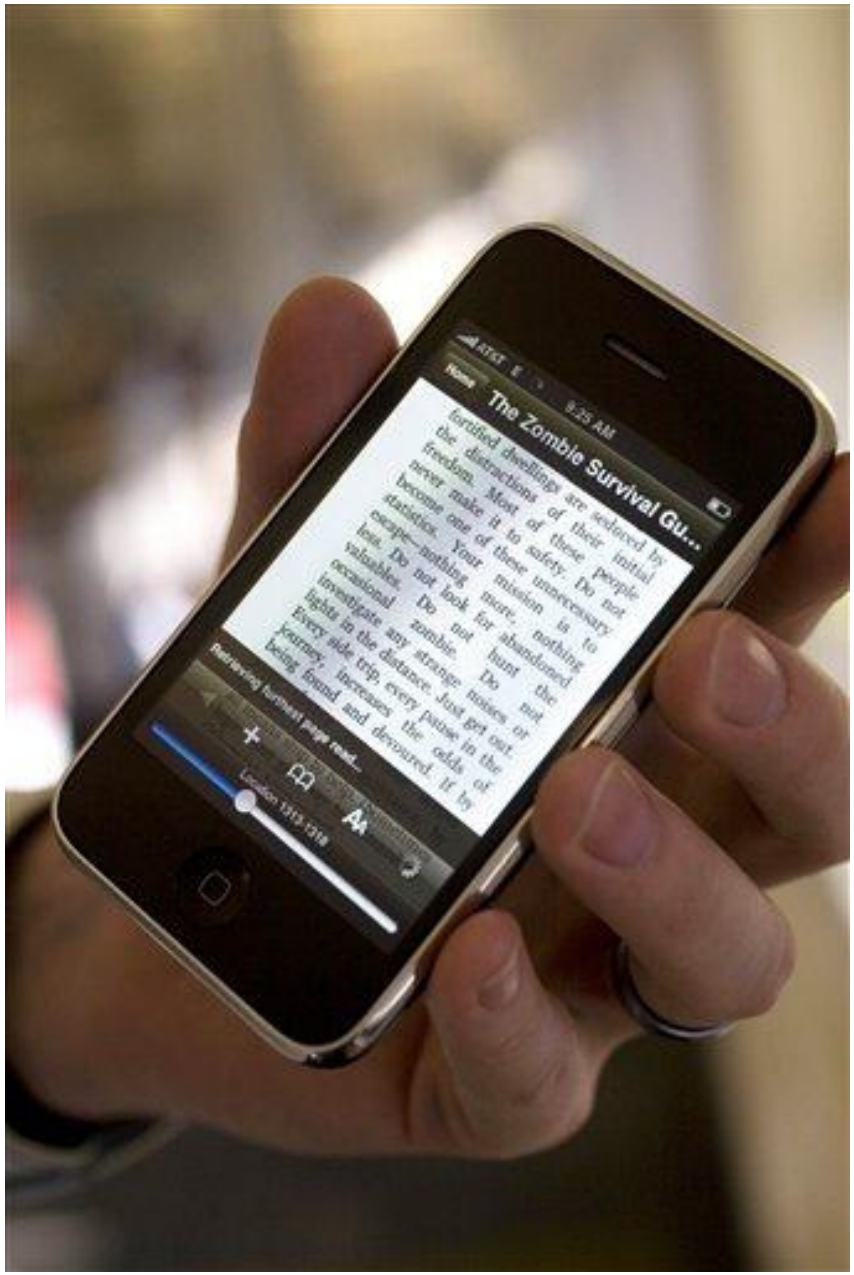

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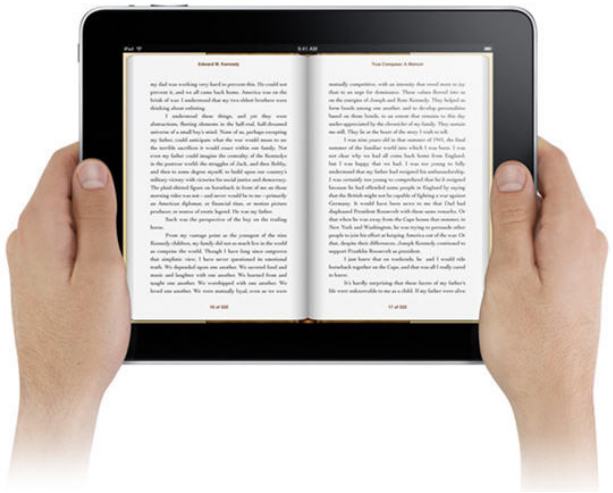

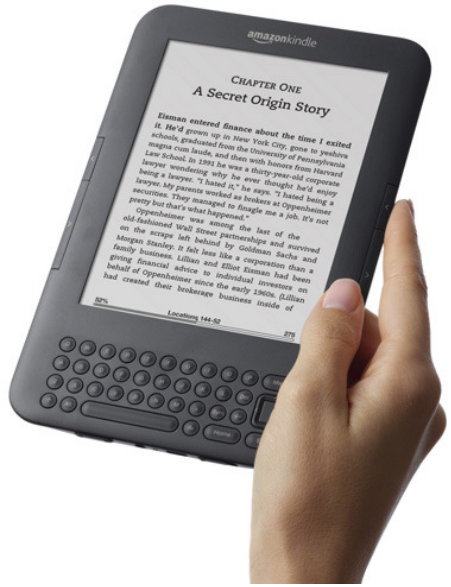

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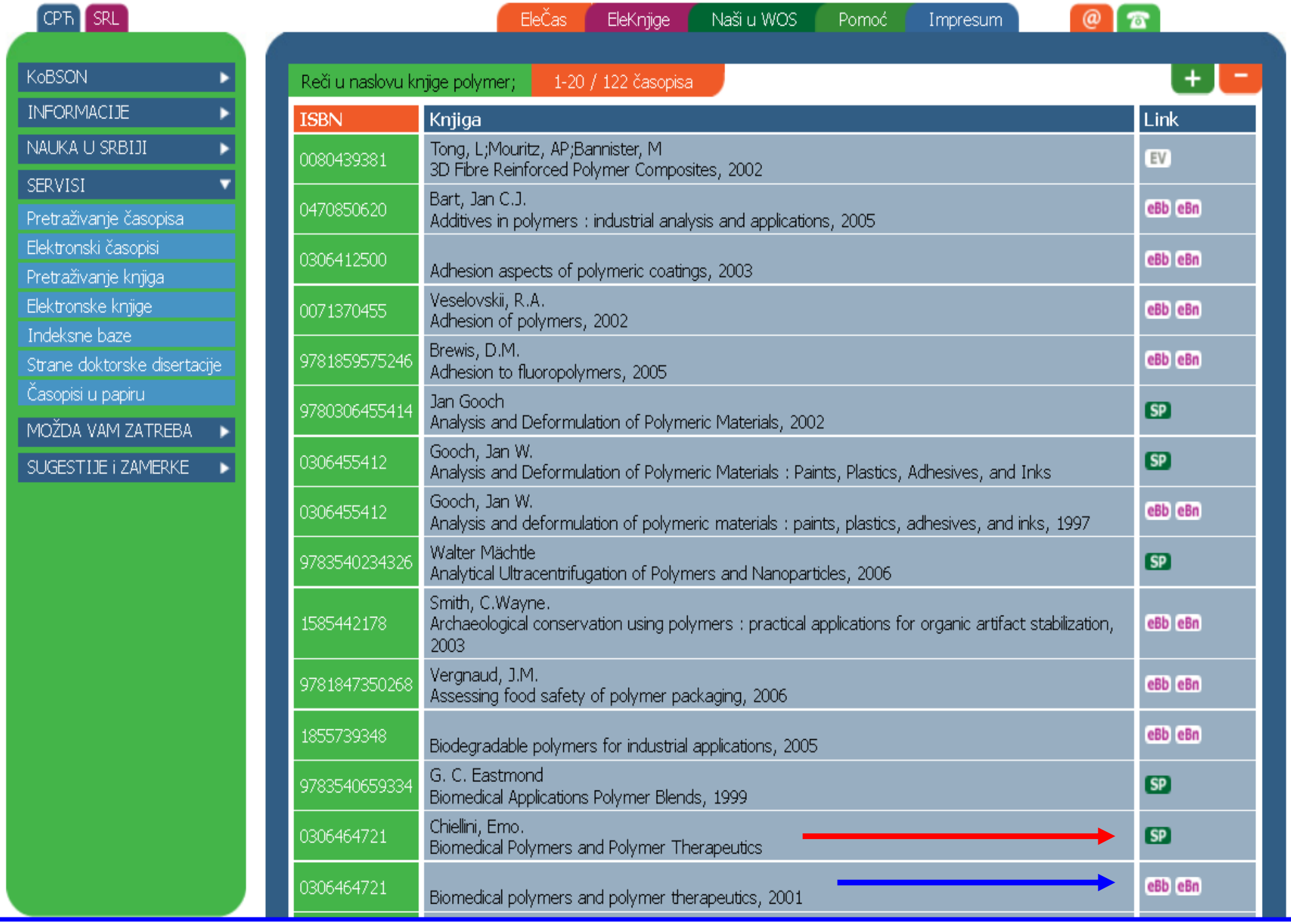
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Application to Cancer Chemotherapy of 33-36

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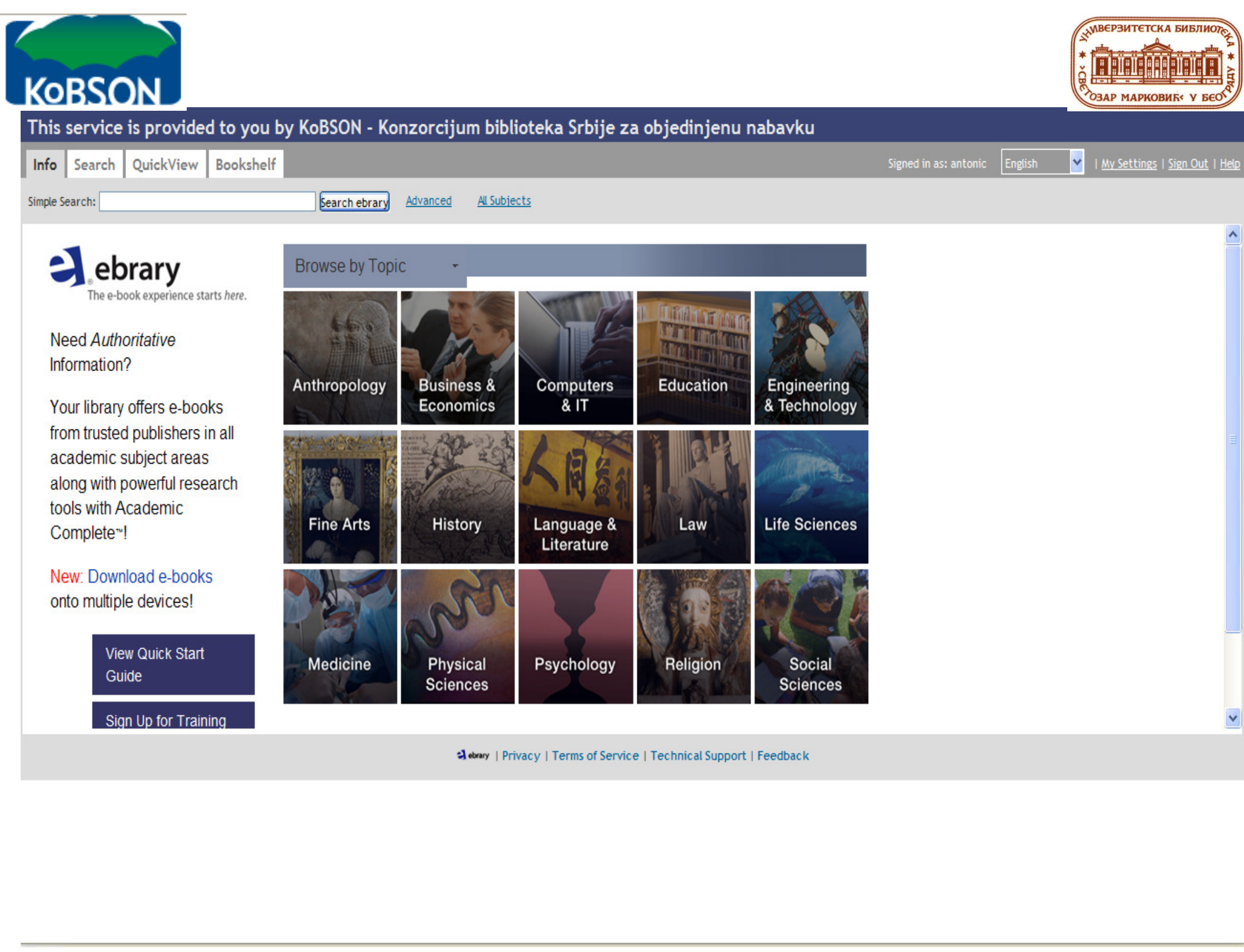
Philip R. Dash and Leonard W. Seymour
CRC Institute for Cancer Studies, University of Birmingham, B15 2TA, U.K.

1. INTRODUCTION

The concept of gene therapy as a treatment for human disease is almost as old as molecular biology itself. One of the first proposals for the use of genes in the treatment of human diseases was made by Tatum in his 1958 Nobel Prize acceptance speech, while the term gene therapy was coined by Szybalski in the early 1960s[1]. However, it wasn't until the early 1990s that the science of gene therapy had progressed enough to enter clinical trials[2].

The idea underlying gene therapy is that human disease might be treated by the transfer of genetic material into specific cells of a patient in order either to replace a defective gene or to introduce a new function to the cell[3,4]. The potential of gene therapy to treat a wide range of diseases has led to very rapid advances in the science of gene transfer and in understanding the molecular basis of many diseases. Despite this, and a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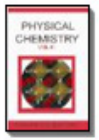

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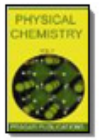

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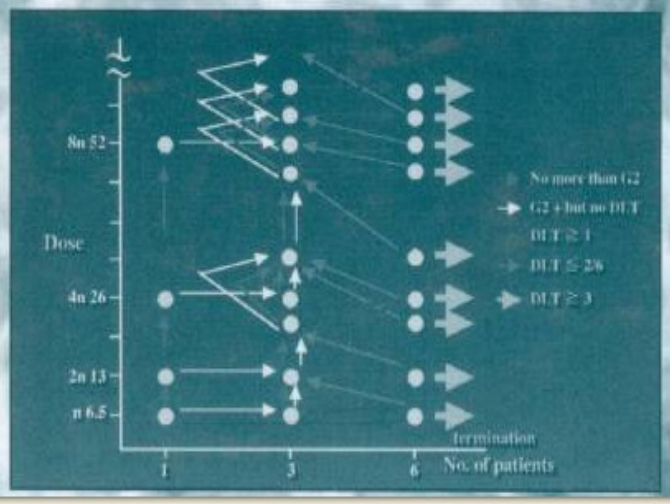

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Chiellini, Emo

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Contents

2. POTENTIAL DISEASE TARGETS FOR GENE THERAPY

2.1 Gene therapy of inherited genetic diseases

The replacement of inherited defective genes is, perhaps, the most obvious use of gene therapy. The aim of replacement gene therapy is to replace a missing or defective gene that is responsible for the disease in order to restore normal function. The ultimate aim is the permanent correction of the disorder, possibly by integration of the gene into stem cells. A major limitation to this type of treatment is the problem of gaining access to the relevant tissues. For this reason, the early gene replacement strategies have focused on readily accessible tissue such as muscle, lung, blood and bone marrow[3].

Blood cells and bone marrow are associated with a number of relatively

NTIAL DISEASE TARGETS FOR GENE APY

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Blood cells and bone marrow are associated with a number of relatively common genetic diseases and as such are a major target for gene therapy. Gene transfer into lymphocytes or haemopoetic stem cells potentially allows the treatment of a variety of diseases including immune deficiency disorders such as adenosine deaminase deficiency (ADA-SCID); storage disorders such as Gaucher's disease and haemoglobinopathies such as sickle cell anaemia and the thalassemias. The only clinical trials involving gene transfer into lymphocytes have been concerned with the correction of ADA-SCID, a very rare immune deficiency syndrome, and most work has concentrated on transfer of genes into stem cells[1].

Cystic fibrosis is the most common inherited genetic disease in Europe and the United States. A mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene results in the production of an abnormal protein that does not properly control the flow of chloride ions across membranes. The major clinical manifestation of this disease is in the airway epithelia, resulting in chronic inflammation with subsequent damage to the lung tissue. The average life expectancy of patients with CF is around 30

Gene therapy has the potential to be used in the treatment of almost any disease with a genetic component. There are a number of cardiovascular diseases that are under investigation for possible treatment with gene therapy. For example, familial hypercholesterolaemia might be treated by transferring the gene encoding for the low density lipoprotein receptor into hepatocytes in order to reduce the level of serum cholesterol[10-12]. Other strategies for the gene therapy of cardiovascular disease include inhibiting smooth muscle cell proliferation, that might lead to stenosis, following balloon angioplasty[13,14] and stimulation of vascular growth to overcome ischaemia[10].

Other diseases that have been investigated for possible treatment with gene therapy include AIDS[1,15], neurodegenerative diseases such as Alzheimer's and Parkinson's[16], traumatic nerve injury[17] and autoimmune diseases[1,18].

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of the gene therapy clinical trials'.

There are numerous approaches to using gene therapy to treat cancer, and some of these are outlined below.

Immunotherapy. The immunotherapy approach to cancer gene therapy is one in which the immunogenicity of tumours is increased by causing the local production of immunomodulatory agents such as cytokines (interleukin-2 or granulocyte macrophage colony stimulating factor for example) or by increasing the level of MHC antigen expression[7]. Increasing the immunogenicity of tumours may then lead to an antitumour response. Because immunity is a systemic reaction, this immune reaction could potentially eliminate all the tumour cells in the body, including sites of metastatic deposit.

Gene Directed Enzyme Pro-drug Therapy (GDEPT). The introduction of genes that encode enzymes capable of converting pro-drugs to cytotoxic drugs is the basis of the GDEPT approach to cancer gene therapy. A relatively harmless pro-drug can be administered to a patient following the transfection of some tumour cells with genes encoding enzymes that will activate the pro-drug *in situ* to form a cytotoxic drug that will kill the tumour cell. This approach may be considered as using gene therapy to improve upon conventional chemotherapy. The local expression of an activating enzyme ensures that the peripheral toxicity often associated with chemotherapy is reduced. The use of a relatively harmless pro-drug ensures that high doses can be administered to the patient, resulting in high

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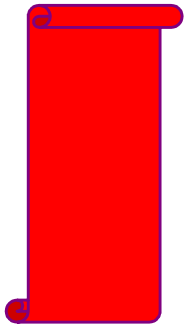

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Contents | Notes | Highlights

Notes	Page
ciljne bolesti	362
ostala oboljenja	364

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InfoTools | Page 362 of 470

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