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## Headline

**Zorana Zrnić-Vukojević,** Head of the Chemistry and Chemical Technology Department, Intellectual Property Office of the Republic of Serbia

# International Year of Chemistry

"An object only seems to have colour, it only seems to be sweet or bitter: in essence, however, the only existing things are atoms and empty space" – Democritus

At the initiative of UNESCO and IUPAC, the United Nations declared 2011 the International Year of Chemistry with the slogan "Chemistry – our life, our future", the purpose being to present the achievements of chemistry and its contribution to the well-being of humanity on a global level, by organising a series of events to attract the attention of young people and to stimulate their interest in chemistry.

Chemistry has rightly been referred to as the central fundamental science, as it is essential for the understanding of the material nature of the world surrounding us. It studies the composition and characteristics of substances, the changes these substances undergo and the laws governing such changes. It contributes to our understanding of the origin of substances, living beings and life processes, which are controlled by chemical reactions, with the knowledge of molecular transformations forming the basis for developing innovative solutions in the production of food, drugs, fuel and materials, etc.

Large investments by chemical companies in the area of research, as well as the time required for developing new products and new technologies, contribute to the increasing significance of patent protection granted for inventions in the field of chemistry, particularly pharmacy and biotechnology. Inventions in the field of chemistry are extremely diverse, and patent applications in this field are often complex, involving several inventions mutually related by a single inventive step. Generally, inventions in the field of chemistry may be divided into three categories: product, product use and procedure. A chemical product is usually only a compound, mixture (composition), formulation or preparation, etc. In addition to new chemical compounds synthesised in laboratories, patent protection may also be granted for compounds existing in nature, but which have been isolated in their pure state for the first time. The specificity of inventions in the field of chemistry lies in the fact that the use of a chemical compound is not obvious from its structure or physical-chemical characteristics. As a result, each patent application in this field must include a narrative description of the use of the invention. Patents may also be granted for inventions involving a new medicinal use of well-known drugs. All processes and procedures meeting the general requirements for patentability may acquire patent protection. This excludes surgical and diagnostic procedures and medical treatment procedures applied directly to humans and animals, which are not patentable. However, patents may possibly be granted for products and compounds used in such procedures.

Concurrently with the development of new fields of chemistry and technology, changes have also been introduced in the area of patent protection for inventions to provide patent holders with greater and more efficient protection.

"The nation and the state that manages to surpass other nations in the chemical science will take the lead in the future in respect of its wealth and general education" Sir William Ramsay, Nobel Prize Winner in Chemistry, 1904. ■

## Interview

**Zoran Vujčić,** Associate Professor Faculty of Chemistry of the University of Belgrade

# Best technological innovation 2010

НАЈБОЉА ТЕХНОЛОШКА иНОВАЦИЈА

The joint team TOP 014 (Zoran Vujčić, associate professor at the Faculty of Chemistry, Miroslava Vujčić D.Sc. from Belgrade, Petar Krunić D.Sc. and Gorica Stevanović from IRC Krušik, Valjevo) were the winners of the 2010 Best Technological Innovation Competition, with their innovation in the field of biotechnology. The team developed a new biocatalyst for the production of inverted syrup. The innovation concerns IHMI (immobilised chemically modified invertase). Inverted sweeteners in the food industry are obtained (both in Serbia and globally) through different chemical (acid) processes and, less frequently, through biochemical processes. The quality of IHMI, invented by Prof. Zoran Vujčić, has been reaffirmed by his research group's scientific publications in leading international magazines. It is a simple combination of materials and methods for obtaining the enzyme (biocatalyst), for its chemical modification and immobilisation, and for use in the production of inverted sugar in a column reactor. The output achieved is 24 times the volume of IHMI per day. One kilogram of IHMI yields a minimum of 1 000 litres (1 320 kg) of inverted syrup. The quality of the whole process, including its optimisation and application, has been proven in a pilot plant.

The sweetener (a sugar produced by inversion) is often called "artificial honey" and is used in the food and pharmaceutical industries, especially in the baked goods and fruit-juice industries as a substitute for honey and for sweetening infant food. Inverted sugar is a substitute for consumer sugar as it is 1.4 times sweeter, thus the quantity of sweetener required for fruit juices or baked goods is reduced by up to 40%, which is reflected in the production price. The use of inverted sugar results in a dietary product with a reduced energy value and improved organoleptic characteristics. It is healthier given the absence of the toxic compound, hydroxymethylfurfural, present in the acid process, and it does not require expensive corrosion-resistant equipment. It contains no surplus salt, which results from acid neutralisation in the acid process, thus making it more suitable as a sweetener for infant food. The process is up to 30% cheaper than the acid process.

The IHMI process can also be used for producing inverted sugars with different degrees of inversion (0 to 100%), depending on the specific requirements of the baked-goods industry. As opposed to the acid process, in which inversion generally never exceeds 70% and cannot be stopped after reaching the desired degree, this process can be easily automated with the possibility of increasing the capacities as required. ■

**Prof. Bojana Obradović,** Sc.D., Vice Dean
Faculty of Technology and Metallurgy of the University of Belgrade

# Workshop "From Idea to Licence" – identifying new perspectives for students and professors at the Faculty of Technology and Metallurgy

From 7 to 10 March 2011, Christopher Moody and Elena Andonova from "ISIS Innovation", a technology transfer centre at Oxford University, organised the second week of the course "From Idea to Licence" at the Intellectual Property Office. Participants included a significant number of faculty members and PhD students at the Faculty of Technology and Metallurgy, University of Belgrade. The Faculty of Technology and Metallurgy is actively conducting fundamental and applied scientific research within numerous national and international scientific projects. The research also attracts a considerable number of PhD students who participate in the projects, achieving significant results in terms of both the number and quality of scientific publications. However, until now, PhD students lacked the opportunity to learn about the possibilities and means of marketing their innovative ideas and discoveries, particularly through establishing spin-out companies. The course "From Idea to Licence" specifically addressed these issues in a systematic and realistic manner, describing the main phases involved in marketing inventions, from intellectual property protection, assessment of marketing potential, marketing methods, approaching potential clients and presentation of inventions through to licence deals and launching spin-out companies. The unique quality of the course lies in the use of real examples of innovations, licences and spin-outs, followed by interactive discussions, which familiarised students with the whole process of technology transfer. In addition, faculty staff and students benefited from an introduction to the Education and Information Centre of the Intellectual Property Office and to the Centre for Technology Transfer of the University of Belgrade. Consequently, students began reflecting on their scientific results with a different attitude, considering all necessary steps for marketing their inventions. Thus, the overall impression was overwhelmingly positive, especially with regard to students' awareness of new perspectives on career development after completing their PhD studies. ■

Jasmina Stojkovska and Željka Jovanović, PhD students at the Faculty of Technology and Metallurgy and participants in the course "From Idea to Licence", with the protected invention NanoAktiv – antimicrobial alginate microbeads with silver nanoparticles for potential pharmaceutical applications

**Slavica Cvetojević,** Senior Patent Researcher
Hemofarm A.D.

# Patent protection in the area of pharmaceutics

Pharmaceutical products are specific in terms of their intended use, and their availability is of particular significance for every state. Development of new drugs involves large investments, long-term trials and high risks. The pharmaceutical industry depends entirely on patents and thus has been divided into innovative and generic pharmaceuticals.

Up until 1 January 1993, our country provided no patent protection for medicines. The drug-synthesis procedure was subject to protection, but the drug itself (the active substance) was not patentable. Under TRIPS, state signatories are now obliged to provide for the protection of drugs (the active substance)

Patent applications for active substances are usually filed immediately upon identifying the compound and obtaining the results of the first pre-clinical trials pointing to potential therapeutic indications. Delaying the filing of a patent application creates a risk that someone else working in that area may make the same invention and file a patent application first. This stage is followed by clinical trials, the most expensive and risky phase in drug development, extending over a period of at least 6 years. The safety and efficiency data collected during clinical trials are then examined by regulatory authorities in the individual countries for the purpose of deciding whether to approve the drug for sale.

The subject-matter of the supplementary protection certificate (SPC) is not an invention as in the case of patents. Instead it is a concrete product manufactured on the basis of a patented invention, which is then released for sale subject to a specific approval granted by the competent authority.

In order to increase the development of drugs intended for children, the EU has introduced pediatric exclusivity providing for an additional 6-month term of protection following the expiry of the SPC. In order to obtain pediatric exclusivity, the pharmaceutical company concerned must meet a set of stringent regulations in order to be granted approval for the sale of a pharmaceutical for children.

Exclusive protection of confidential data provides supplementary protection for the original drug. It determines the period of time during which a generic manufacturer cannot file a request for a licence to sell the drug. This period is determined by reference to the data and the results of clinical and pre clinical trials previously carried out by the manufacturer during development of the original drug. In accordance with the Regulation on the Procedure and Requirements for Obtaining a Licence for the Sale of Drugs, dated 1 January 2010, a generic drug licence may be obtained only after the expiry of 10 years from the date of receiving the first licence for the reference drug.

In order to ensure protection against their competitors and to safeguard their monopolies, innovative companies usually file new applications for the same drug. Thus, patent protection may also be provided for different salts, polymorphs and hydrate structures, upgraded processes, new compositions and formulations, optical isomers, active metabolites, prodrugs, new indications, combined therapies and medicinal aids for drug-administration methods. ■

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# Technology stories

Patents protect technical inventions that are novel, inventive and industrially applicable. In the chemistry fields, the invention is often a chemical product with innovative properties and its use. Patents are also granted for a process or apparatus related to the chemical product.

The technology stories presented here demonstrate the function of patents as an essential element in providing the patentee with a competitive advantage.

## Liquid gold

Desalination is on the increase as demand for healthy drinking water grows: in 2010, there were 15 180 desalination plants worldwide, with a total capacity of 65.2 million cubic metres per day. The process is used in 150 countries, and approximately 300 million people around the world rely on desalinated water for some or all of their daily needs.

## Organic light-emitting diodes

The future of light is taking shape in chemistry labs. LEDs are already used in many areas of our everyday life; they are in street lighting, torches and car headlamps, and they make up the decorative lighting on buildings such as the new Formula 1 motordrome in Abu Dhabi. Unlike incandescent light bulbs, which give off 95% of their energy in the form of heat and only 5% as light, LEDs offer far greater efficiency and longer life.

## Adopting orphans

Orphan drugs only treat a small proportion of rare illnesses but their importance is vast. The term "orphan drug" was originally coined because of pharmaceutical companies' marginal interest in the sector, largely due to the prohibitive cost of investing in novel pharmaceutical agents intended for a small number of patients.

http://www.epo.org/news-issues/issues/chemistry/technologies.html ■

**Sanja Bogdanović,** M.Sc., Pharm., Spec.

# Original and generic drugs

Due to the prevailing prejudice that generic drugs are produced in inferior conditions and that they are of a poorer quality, many patients are often faced with the dilemma of whether such drugs, given their significantly lower prices, are as efficient and safe as the original drugs.

In fact, generic drugs are essentially similar to the original drugs, having the same quantitative and qualitative composition in terms of the active substance, having the same pharmaceutical dosage form and being biologically equivalent to the original drugs.

Innovative companies invest large funds in drug research and development. The time required from the moment a new substance is invented to the moment of its approval for marketing is between 10 and 15 years on average, with the procedure costing between 800 and 900 million US dollars. In order to be able to recover the funds invested and to invest the profit in new research work, innovative companies devote particular attention to obtaining patents for their inventions. In accordance with TRIPS, generic companies are not allowed to produce generic copies. However, after expiry of the patent, generic companies can market drugs that are therapeutically equivalent to the original drugs with the same quality, safety and efficiency. Generic drugs, however, have a lower price in relation to the original drugs (20-90% due to smaller investments in expensive research), thus prompting innovative companies to also reduce their prices for competitive reasons.

Generic drugs have to meet strict quality requirements in relation to the original drug in order for their producers to be able to obtain a licence from the European Medicines Agency to market the drug. Generic companies produce drugs, in accordance with the standards of good manufacturing practices (GMP), in plants that have been tested and approved by competent medical inspectorates. Following the granting of marketing approval, medical authorities continue to monitor drug quality. The European Generic Medicines Association (EGA) encourages the highest standards in the production of medicinal substances and medicinal preparations.

The pharmaceutical market research company IMS estimates that generic companies will continue to develop at an increasing rate, with production growth of 11.4% per year until 2013, while the growth of innovative companies is estimated to be 1.8% annually in the same period. Innovative companies, on the other hand, emphasise that the quality of generic drugs cannot be compared to that of original drugs. There is a huge difference, they claim, in the fact that generic drugs involve only bioequivalence studies, while original drugs are based on evidence of clinical efficiency, documented by more than 800 studies covering more than 400 000 patients.

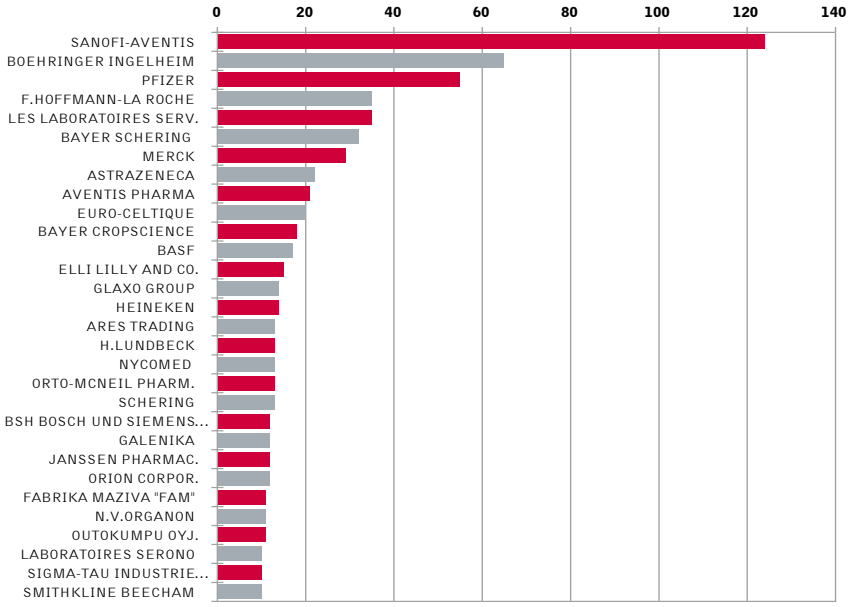
At a time when medical systems even in rich European countries are faced with budget deficits, generic drugs form a key component of the sustainability of medical protection. As stated by the EGA, they now account for virtually half of the pharmaceutical market in the EU, with around 18% of total funds being allocated to generic drugs. According to their data, the use of generic drugs results in savings of more than EUR 25 billion each year for both patients and medical systems in the EU. ■

Daniela Zlatić-Šutić, Senior Advisor
Intellectual Property Office of the Republic of Serbia

# Patent holders in Serbia in the period 2006-2010

In order to show the importance of patenting in the field of chemistry and chemical technology, an overview of the first 30 patent holders in Serbia over the last 5 years is provided in the figure. Despite the global trend of increasing patents in the field of ICT, most patents in Serbia are in the field of chemistry and chemical technology, particularly in pharmacy and phytopharmacy. Due to relatively large investments in research and development in companies involved in this field, management of IPR has gained strategic importance in the countries in which these companies operate. That is why, among the first 30 patent holders, there are only 2 domestic companies and only 3 companies whose activities are not directly related to chemistry and chemical technology. ■

**First 30 patent holders in the Republic of Serbia in the period from 2006-2010.**




## News

Nikola Radovanović, Advisor
Intellectual Property Office

### Promotion of innovation and cluster development

From 23 to 24 February, the Intellectual Property Office was the venue for a workshop organised by the latter, together with SECEP and ICIP. The workshop was designed for managers of organisations providing support for company operation, focusing on the topic of promotion of innovation and development of clusters.

The purpose of this two-day workshop was to present guidelines for supporting the development of clusters, and subsequently to exchange experiences and knowledge. A presentation was given on the IMP3rove innovation management methodology and the precise steps to be taken were identified with regard to training and assisting those institutions providing support for company operation. ■

### Lectures on intellectual property at the faculties

Throughout March, experts at the Education Information Centre held two workshops intended for faculties. The workshop discussing the basics of intellectual property rights was held at the Faculty of Mining and Geology in Belgrade, while the workshop "Patent protection for new technical solutions and patent database search" was held at the Faculty of Mechanical Engineering in Niš. ■

### The second part of the workshop "From Idea to Licence"

This week, the Intellectual Property Office was the venue of the second part of the workshop "From Idea to Licence". As a follow up to the workshop held in the last week of January, the second part also discussed the topics of intellectual property and technology transfer, with a special focus on the significant issues of confidentiality and marketing of inventions. The workshop "From Idea to Licence" was designed for professors and the academic community of the University of Belgrade. ■

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Education and Information Centre

The Intellectual Property Office of the Republic of Serbia