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RECENT DEVELOPMENTS AND CHALLENGES IN THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

TOPICAL ISSUES OF INTELLECTUAL PROPERTY RIGHTS PROTECTION AND GENERIC PHARMACEUTICAL COMPANIES

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INTRODUCTION

I am particularly pleased with the invitation extended to me to take part in the work of this Conference.

I accept this invitation as an invitation to the most successfully developing pharmaceutical company in Bulgaria during the last couple of years in its capacity of a representative of the global pharmaceutical industry and especially one of its branches dubbed brand generic companies. The generic pharmaceutical companies are an important element of drug manufacturing and their business activity has significant social and economic dimensions.

On the threshold of the third millennium humanity has become aware of a new reality: the exceptional importance of intellectual property for the social and economic development of countries in the age of globalization. In the sphere of the real economy, pharmaceutical industry included, industrial property and its protection is the key to the successful development not only of individual companies, but for the welfare of society at large. The time is coming when the strongest will be those who possess intellectual property and have made the respective efforts for its legal protection.

Industrial property in the area of pharmaceuticals is marked by characteristics and specificity of its own. This industrial property is of a decisive significance not only for the companies manufacturing original drugs, but for the generic companies as well. The legal protection of this property and its economic potential are especially important prerequisites for securing the competitiveness and market success of drug manufacturers. At the same time this is the way in which funds and possibilities can be secured for research and drug development and a reasonable balance can be found between the interests of competitors.

On the basis of this understanding, I would like to focus your attention on two groups of issues of particular importance for the pharmaceutical industry.

The first group includes problems characteristics for drug manufacturing only. These are the issues concerning the so-called pipe-line protection of substances; the additional protection of substances and medicinal products; the patenting of methods of treatment, second and subsequent treatment included; and the clinical tests during the time of patent protection. For all of you, leading patent specialists, the specificity of these issues is well-known, but here I would like to share with you the view point of generic drug manufacturers.

The Patent Act effective in the Republic of Bulgaria since 1993 provides for the legal protection by means of patents of products obtained in a chemical or microbiological way and of medicinal, cosmetic, and nutritional substances or flavours, obtained by a chemical or another method, including the products of genetic engineering, following an application by the patent holder or the applicant on the condition that:

1. The products has not been sold on the territory of the Republic of Bulgaria prior the date on which the patent application is filed with the Patent Office;

2. No author's certificate has been issued by the Republic of Bulgaria related to an object identical with the object for which a patent application is being filed;

3. The applicant or the patent holder has a sizable business activity in the country of origin of the innovation.

This kind of legal protection has been introduced in a similar way in other countries such as the Czech Republic, Rumania, Hungary, Poland, etc. This system of legal protetion placed the Bulgarian pharmaceutical industry in a complicated social, economic, and legal environment without providing for an adequate period of transition. As a result, Bulgarian society experienced serious economic and social consequences such as higher prices of imported drugs, lack of locally produced counterparts of drugs; lack of drugs because of their high prices and due to effective patents issued in compliance with the order mentioned above; restriction of the business activity of the local pharmaceutical companies as a result of which the internal budget revenues diminished and employment in the country declined on the whole.

We should learn the lessons taught by the pipe-line protection mechanisms and effects observed in the post-implemntation period with a view to the inevitable introduction of additional protection of medicinal and plant protection products. The national and international legislation in this respect should be examined carefully with a view to the most appropriate timing for the introduction of this type of protection. The choice of a mechanism for the introduction of additional protection should take into account the peculiarities of the national legal systems and the level to which they have been harmonized and unified with the international legal acts. It would be unjustified to arrive at a more favorable effect for the holders of rights who have availed themselves of the pipe-line protection legal system. On the other hand, what should be taken into consideration is the extent to which the functioning of the regulatory authorities in the sphere of drug manufacturing and sales has been legally provided for, and the degree of its harmonization with international legal standards, which also has a bearing upon the timing and choice of mechanisms for the introduction of additional protection. A reliable international information system should be set up whereby the national Patent Offices issuing additional protection certificates could make appropriate and legitimate decisions as to the duration of the period in which such protection will be effective.

The Bulgarian legislation provides for the issuance of patents for second and subsequent application of substances in medicine. This can be said to be a felicitous experience that should be shared and further developed.

It is natural to raise issue about clinical tests in the period of patent protection. The legal provisions in this respect are of a great significance for the pharmaceutical industry and society at large. The clarity and categorical nature of these legal provisions are a true merit for any national legal system and should be stimulated as a process and supported by leading fora of specialists in this field such as this one. It is commendable for clinical tests to be permitted in the period of patent protection and such legal provisions meet both the public interest and the basic principles of the intellectual property system as well.

The second group of issues concerns all entities holding rights to intellectual property objects. In our capacity of business entities we think that international treaties such as the Treaty on Patent Cooperation, the European Patent Convention and the Euro-Asian Patent System, the Agreements on the International Registration of Trade Marks - the Madrid Agreement, its Protocol, the Regulation for Issuing Community Marks, and a number of others contribute to the effective and reliable protection of intellectual property. Balkanpharma and the Industrial Property Alliance in the field of pharmaceuticals, chemistry

and biology, whose member Balkanpharma is, were active participants in the process of Bulgaria's accession to the Protocol of the Madrid Agreement on international trade mark registration. At the same time, I would like to draw your attention to the mechanism for automatic dissemination of EU trade marks on the territories of the newly acceded EU member countries, and to the difficulties encountered in its application, related to the already active national trade marks and such that have been acquired through international procedures.

The availability of reliable patent information through a rapid and efficient access to the Internet is of particular importance when correct and effective management decisions have to be made. It is necessary that this information be complete and exhaustive, including sources from all countries. This would facilitate the development of both industry and R&D, and on the other hand it would further develop the system of intellectual property protection.

The Republic of Bulgaria has a century-long traditional knowledge experience in the field of making medicines and the treatment of diseases, namely herb collection, herb potion making, and natural disease treatment with herbs. But this traditional knowledge in the age of industrialization and the development of contemporary society finds it increasing more difficult to overcome the barriers of time and reach the new generations, regardless of the fact that our modem times are marked by the powerful development of information technologies and the formation of the global information society. This is the reason why I warmly support the ideas of the WIPO Director General, Dr. K. Idris, in the field of traditional knowledge protection and greet all attempts and endeavors geared to developing this system.

At the end of my presentation I would like to convey to you my wishes for the fruitful work of this Conference. The team of Balkanpharma is ready to cooperate with you and discuss all issues related to the system of intellectual property protection and its future development.

I also avail of the opportunity to thank Prof. Borissov - Chairman of the National Intellectual Property Association in Bulgaria - for the splendid atmosphere and organization in which this world forum is taking place.

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