MUDr. Vladimír Pacholík

of Eli Lilly, Chairman of the AmCham Health Care Committee/LAWG

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Answers That Matter.

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Reflecting on the main topic of this issue of Connection, AmCham invited MUDr. Vladimír Pacholík, Chair of the AmCham Health Care Committee/LAWG to share his views on innovation and IPR protection from the perspective of the pharmaceutical industry.

What are the main priorities of the AmCham Health Care Committee under your leadership?

To create and maintain a standard entrepreneurial environment for the business development of companies focused primarily on research and development. Every health care system in the world is struggling with its financing and governments and customers are looking for ways of saving. This is fully justifiable provided everybody gets a fair chance to compete. The AmCham Health Care Committee has proven to be crucial for protection of the R&D industry in the previous 2 - 3 years. By protection, I do not mean the creation of unfair trade barriers for others; on the contrary, AmCham has been supporting competition and a healthy business environment. But there are different interests at stake and IPR protection is one of key ones.

Producers of original innovative medicines are dedicated to discovering, developing, and launching new medicines to match the relentless needs of patients around the world. They invest huge amounts of money and it is a risky business. An environment that helps them to feed back resources needed for further development is therefore absolutely crucial. There would be no generic manufacturing without the original R&D industry.

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As this issue of our Connection magazine is focused on Intellectual Property Rights protection and innovation, can you explain why this topic is of such importance for the pharmaceutical companies? How much does it cost to develop an original drug?

It really does cost well over $1.2 billion to develop new medicines. The fact is, drug discovery is a risky, expensive process. For each promising molecule that makes it, many do not. For every 5,000 compounds tested in the laboratory, only one will get to the market. What other industry would bet its future on 5,000-to-1 odds? The drugs that succeed must not only recoup their own costs but also fund research and development to ease the suffering of future generations. It's a little known fact that drug makers invest more in R&D as a percentage of sales than any other industry. Top companies invest up to 20 per cent of sales on research and development.

On one the hand, the development of an effective and safe drug is very expensive and time demanding, on the other hand, health care authorities, customers and providers in most countries support, as early and as easily as possible, the introduction of generics. In your opinion, is Slovakia on the right track in terms of finding the balance between the research-based and generic industry? Where do you see the biggest challenges?

In the past there were attempts by certain producers and lobbying groups in Slovakia to weaken the position of the original companies that were focused on research and development. It is tempting to speed up the initial registration process to get cheap generics to the marketplace as soon as possible. But everything has its time. The Medicines Act (140/1998 Z.z) was amended last year to ensure that patent infringing drugs would not be allowed onto the market. This step took place after fierce discussion. The US government acknowledged this positive development in the protection of intellectual property rights by removing Slovakia from the Special 301 Watch List and ensured that Slovakia was not considered during the 2007 review.

The most recent amendment (270/2007 Z.z) was approved by Parliament in July of this year. It allowed a compromise between generic manufacturers and the patent holders by registering generic drugs in advance of patent expiration, while ensuring that the generic version of the drug did not come onto the market before the patent expired.

However, the recent provision in the Ministry of Health's draft amendment proposed the elimination part 8 of Article 22 of the Medicine Act (140/1998 Z.z). For the time being this provision draft has been withdrawn again, but the vehemence and frequency of proposals aimed at undermining patent rights

protection suggest that this is an ongoing battle in which the IPR can be threatened.

Another example: The Ministry of Health prepared an amendment of the 577/2004 Z.z. Act on Health Care which has already passed through the first reading in the Parliament. In my opinion, section 5 of §12 does not allow equal access to the market place - generic producers get advantage over original ones. Generics can be registered and reimbursed in times when the patent of the original drug is still in place.

The government facilitates and encourages the situation when the generic producer gets both registration and reimbursement and if they dare to infringe the valid patent, they market their drug and the original producer takes a lengthy and hopeless battle at the trade court. This approach creates a permanent threat to the R&D industry.

Patents are an important part of America's history and Americans have always taken pride in being a nation of innovators and investors. Given your experience from working in a US company, what would you highlight as the main benefits of investing into R&D? What can Slovakia learn from the US example in this respect?

The U.S. is the last true free market in the world. In countries with government-controlled prices, companies that do not abide by government-set prices face serious issues to market their products. Over time, these price controls can have a disastrous effect on innovation. Up until the 1970s, European firms developed the majority of new medicines sold globally. But by the 1990s, the U.S. was developing more new medicines than all of Europe. In 2003, of the world's top 10 selling drugs, 8 originated in the U.S. Slowly but surely, there is an increased realization across parts of the world, including Europe, that price controls stifle innovation. Over the last 40 years, the use of medicines has cut the number of hospital admissions for major diseases in half. Yet the focus of many governments is the cost of care for the next budget cycle. This leads to artificial constraints on the price and volume of medicines sold. While such practices hold down costs in the short run, often over time they increase the likelihood of patients needing more surgery, hospitalization, and long-term care at a much greater cost.

We cannot find cures if we do not innovate, and we can only innovate if the climate is right. Healthy patients are our mission. But we must also be profitable, or we will cease to exist. Ours is a very high-risk business, and people put their money, time and talents into it with the prospect of a return that is commensurate with the risk. Government leaders must remain mindful of the need for a research-based pharmaceutical industry. There are costs involved—it doesn't come free. But they also need to be aware of the value of pharmaceutical innovation, both to human health and to the overall cost reductions that stem from the preventative nature of prescription drugs.

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The pharmaceutical industry is extensively regulated by the state. However, there are certain issues, such as the Codes of Ethics, which are left to the self-regulation of companies. The European Federation of Pharmaceutical Industries and Associations supervises the adherence to ethical principles in promotional activities and the marketing practices of companies at the European level. How does this work within Slovakia?

In Slovakia there are three pharmaceutical associations: SAFS- Representing the original producers focused on R&D, GENAS- The association of manufacturers of genetics, and ADL- Representing wholesalers and distributors. SAFS is a member of the EFPIA and follows and implements all regulations on promotional activities and marketing practices imposed at the European level, besides being fully compliant with Slovak laws and regulations set by the ŠUKL, the regulatory agency. The EFPIA regularly reviews some topics and issues guidelines and provisions that are obligatory for its members.

SAFS has been at the forefront of initiatives focused on compliance with these rules and initiated 3 amendments of the so called Ethical Code of the pharmaceutical industry that is mandatory for all members. It is necessary to stress that all 3 associations established a common Industrial Ethical Committee where all players, as well as representatives of the medical community, are present. The IEC is a platform for the mediation and solving of problems among industry members. It has obviously has no ambition to become a universal watch dog for practices in the industry, but it helps to clarify issues and complaints arising amongst competitors.

Not all the companies on the Slovak market are members of SAFS, and some of them might not comply with the strict ethical rules. Can this present a competitive disadvantage for companies with high ethical standards?

First of all it is necessary to say that compliance with ethical rules has been improving over the last couple of years. But not everybody understands these rules in the same way. I cannot speak for all competitors but I see that the majority of American based companies associated in AmCham apply the strictest possible rules. A reputation once lost is hardly possible to regain. And cheating is not just about reputation. Besides local laws, the American companies are also subject to the Foreign Corrupt Practices Act. Every employee knows the company is listed on Wall Street and that a potential scandal in one country spreads like fire. In some cases the FCPA imposes stricter regulations than those codified by local laws.

Back to your question, there are differences in understanding of good promotion practices among companies and some may be tempted to go to the edge or to behave in a grey zone that is not explicitly regulated. This, in my opinion, is shortsighted and can create only a short-term advantage. The industry has suffered in public opinion because of breaking the rules. The medical community, patients and payers will appreciate fair behavior. Those who play by the rules will be rewarded because of being trustworthy.

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