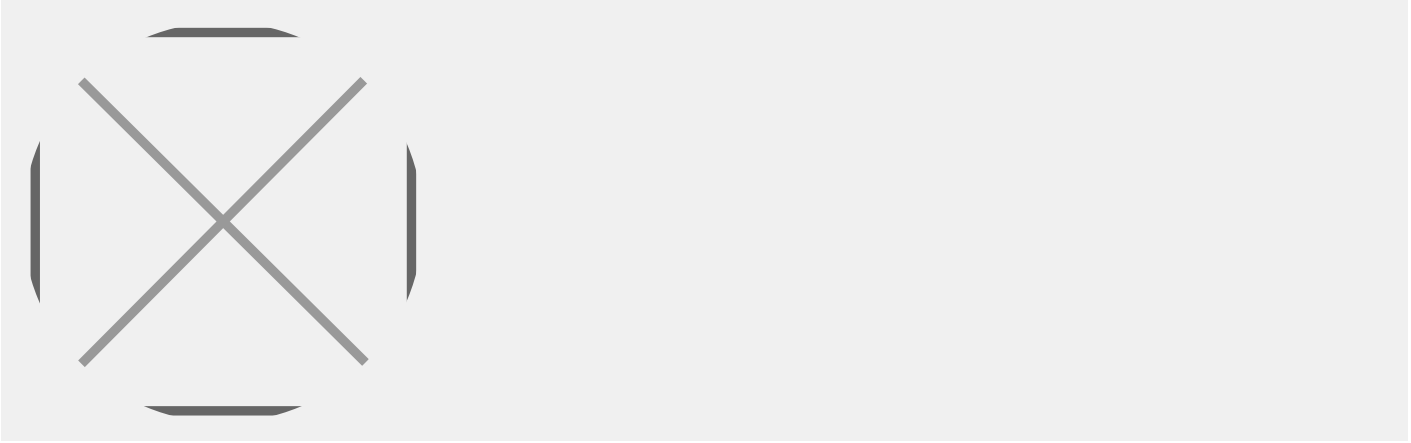
Interview with Paul Melling, Founding Partner, Baker & McKenzie Russia



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Baker & McKenzie differentiates itself from competitors by offering an industry-focused practice. Has this model continued to give this company a leading edge in Russia, and, overall, what is your assessment of this firm's positioning on the Russian market today?

I would say yes, this has differentiated us from competitors. Knowledge of the industry is paramount in developing work for pharmaceutical companies. In fact, it is important in developing work in any industry. As lawyers, we try to really understand what organizations' commercial pressures are, so that we are able to give them more commercially useful and commercially oriented legal advice.

There are particular issues that affect the healthcare sector specifically that do not necessarily affect other industries. Furthermore, there are some peculiarities of the healthcare sector that make legal issues a high priority for pharmaceutical- and healthcare-related organizations—it is the nature of their business.

For those reasons, we try to stay close to the industry. You cannot truly understand the industry unless you understand the regulatory environment. Therefore we have a strong regulatory basis as the foundation for our practice.

Moreover, we try to involve ourselves more with our clients' business. We are very active in the pharmaceutical trade association, for example, and I sit on the board. My colleagues here participate in the committees of that association.

In terms of positioning, sometimes you are not entirely objective as to where you yourself stand in the market, but I think we act for the majority of the research-based multinational pharmaceutical companies and the majority of the medical device companies that do business in Russia. I am not saying we do all the work for all these companies or that we are the only law firm these companies use; they will use a variety of firms for different things. But generally speaking, it would be easier for me to tell you the names of the companies that we do not act for than the ones we do! Because of that, we are probably regarded in the industry as one of the leading firms in the market.

Let's look at the positioning of the pharma companies you advise. You told Focus Reports in a past interview that those pharma investors who remained in the market in the post-crisis period of 1998—in fact, not only remained, but invested aggressively—have been the most successful. What are the ramifications of this trajectory today, and do you believe it is the impetus for the very unusual pharma market leadership mix we see in Russia in comparison with global rankings?

That is an interesting question, and I think the short answer is "yes." We can take the example of Nycomed. Globally, Nycomed is quite a way down the list of the top 20 or 30 pharmaceutical companies; but here in Russia, the company is very highly positioned. There are numerous reasons for Nycomed's success, but one of the pivotal components is its commitment to the Russian market through bad times and good. Companies that have always been very positive about Russia, that have always invested in Russia, and that have expanded in Russia even in trying times, have done very well. I think that is one of the reasons why the listing of top ten companies in this market, relative to the listing of top ten companies in Europe or the U.S., is quite different.

It is a bit of a truism, but it is still true all the same, that Russians tend to remember those who did not falter during adverse economic periods. They also tend to run from those that did. Hence, a company is in a stronger position if it can prove a long-term commitment to this market.

Do you believe the leadership mix will harmonize with global rankings, or will Russia continue to have an unusual scenario?

I think it is probably going to normalize, because the pharmaceutical industry now is very much on the radar screen of the Kremlin and of the Russian government. For most of the 15-17 years that I have been practicing in this area, it has not been on the radar, but now it is. There is money being pumped into the pharmaceutical market, and there is a genuine intent to try to build a strong domestic Russian industry.

We see not only encouragement, but also really a mandate, that companies start to invest in manufacturing here and develop local facilities. As this drive develops, and the big multi-nationals start to commit more effort and resources to this market, I think you will probably see the rankings

level out.

Let us look at some of the specifics of the market. One of the reasons you provided for the fact that the financial crisis of 1998 had a particularly strong affect on the pharmaceutical industry was that companies relied too heavily on distributors, offering them deep lines of credit. They were left in quite an unfavorable situation when, during the crisis, many distributors defaulted. We see that distributors continue to play a much stronger role in Russia than they do globally. Does this model continue to put pharma companies at risk?

To a certain extent, I believe that it does—but the nature of the risk has changed. The relationship between pharmaceutical companies and distributors is a very different one now than it was in 1998. In 1998, it was a very 'arms-length' relationship. Now, if you talk to most pharmaceutical companies, they will tell you that their association with their major distributors is almost like a partnership. Not in the legal sense, but in the commercial sense—in that they are working far closer together.

First of all, pharmaceutical companies have gotten to know their distributors a lot better. They need to, because of the focus on compliance now. Due to the emphasis placed by Western companies on ethical practices, they cannot just appoint any distributor who walks through the door and says, "I want to be your distributor." In 1997, if someone had walked through the door and said, "I want to be your distributor in Southern Russia" the only question would have been "Can you pay us?" If the answer was yes, then they were appointed. That is no longer the case.

There is a lot more cooperation between pharmaceutical companies and distributors in terms of training, for example—pharma companies particularly ensure that their distributors have a strong knowledge of compliance issues. There is a lot more due diligence done on distributors before they are appointed. Again, this leads to a far closer relationship with distributor organizations.

Credit, of course, is monitored a lot more carefully. But there is still an exposure, in that pharmaceutical companies are still dependent on distributors to get their products out there.

This dependence is why pharma companies continue to be at risk, to a certain extent. There is a very narrow group of distributors—five or six major enterprises—that control a disproportionate amount of the market. If you do not have a relationship with those distributors, then you have a problem, because they are the only distributors with the infrastructure to cover the entire territory. Because of that, you cannot afford to upset them—or at least you have to be very careful.

As you began to mention, as pharmaceutical companies develop a stronger presence here, they bring with them their global compliance standards. How do you view the relationship between these compliance standards and an environment still largely affected by questionable ethical practices? Does the environment cause companies to loosen their

standards, or are strict global principles changing this environment?

First of all, multinational companies cannot afford to let the way business is done here affect their approach to the market and their ethical practices. They cannot afford to "go native," as you might say. Therein lays the challenge. Their problem is that they have to build an ethical business culture within their companies, even though their companies are operating in a culture that is not highly ethical.

I always have to qualify that remark because it is not so much that Russians are bad people or they are all criminals. It is simply that anybody who has lived here through the demise of the Soviet Union and the early years of the Russian Federation would understand why Russian business culture is what it is. In those days, the only way to survive was to look for the shortcut and look to wheeling-and-dealing under the radar.

If you took a snapshot of the average Russian company in 1996, 85 percent of its business would have been "black" and maybe only 15 percent of it would have been "white." Now it is the other way around— probably 85-90 percent "white" and only 10 percent "black." However, if you were in a business environment back in the 1990s where most of the business was in the black economy—and in the black economy you do not need laws, you do not need contracts, you do not need rules—in order to be successful, you needed to adjust to the environment. A lot of successful businessmen have grown their businesses through that period and if they did not, then their mother and fathers did, or their uncles and aunts did.

Hence, that culture is very deeply embedded. So the challenge for a big multinational company like a Pfizer or a Johnson & Johnson is how they can do business with reference to their internal standards, and the Western legislative standards they must adhere to as Western companies.

How is it possible to do business in that way, in this environment, which generally has a very different culture?

It takes a lot of time and effort in training, and building strong corporate values—but I think there is good news as well. First of all, let us give some credit where credit is due: the Russian government has done much to attack corruption, particularly in the Medvedev years. When Prime Minister Putin was President, he always seemed to view discussions about corruption in Russia as "Russia bashing," and got very defensive. I believe that President Medvedev, on the other hand, genuinely understands that this is one of the major barriers to attracting significant foreign investment in Russia; not only corruption as such, but the perception of corruption in this market.

You may be familiar with Transparency International and their Perceived Corruption Index from 1 to 178. Russia is the only one of the four BRIC countries that is ranked lower than 100; the others are all up in the 60s and 70s. Moreover, Russia is the only one that is actually falling. Its ranking was

previously in the 140s, but last year it was in the 150s: 154 I think. The worst is Somalia at 178, and because a lot of countries are tied for position, Somalia is only about 10 or 12 places below Russia. So 10 or 12 places below Russia is a country where there is no de facto government!

Russians get very upset about this notion. They think it is a very inaccurate portrayal of where Russia is at the moment. However, the problem is, while I believe it is an inaccurate portrayal of real corruption here, it is a very accurate portrayal of the perception of corruption.

That perception needs to be attacked. Mr. Medvedev understands that this is a major issue and he has taken a number of steps. Most recently, he has signed up for the OECD Anti-bribery Convention and they have increased their penalties for bribery very significantly. With measures like these, the landscape is slowly improving.

Do you not think it is true that these battles are only being fought at the very highest levels, rather than at the lowest levels; the everyday officials companies are dealing with?

I would not say so. If you increase the fine levied upon a company for bribery, as the president has done recently—the maximum fine is now a minimum of 100 times the amount of the bribe—that is not dealing with just the high level activity at the top. If you introduce for the first time a prohibition against bribing foreign officials, which has never before existed, I think you are moving in the right direction.

The other thing that gives one cause for optimism is the impact that Western trends are having on Russia. I mean to say that large multinational companies cannot afford to do business the way they used to. Compliance, ethics, and etc. are no longer abstract issues—they are now truly critical.

Furthermore, Russian businessmen are smart and they can figure out that ethics is good for business. If I am a pharmaceutical distributor now, and I have my own business ethics program, and my compliance program and compliance training, and I readily will agree to train my own senior management together with the management of my big multinational clients, and I will happily sign up for strict compliance wording in my contracts, I am going to get more business than the distributor who does not.

This mentality is starting to have an impact on the market—in some ways, more of an impact than the efforts of the government itself.

That said, if you come here 20 years from now, we will probably still be talking about corruption problems and challenges in Russia, because this is such an enormous issue. But I think there is real progress being made.

One of the large headlines of the day is that the government may now restrict the interaction between pharmaceutical companies and healthcare specialists. Baker & McKenzie is

actively involved in discussions with the Russian government regarding this proposed legislation. How do you advise your clients? Do they have reason to worry that their traditional marketing routes will close?

The first thing to say about this is, if you talk to most honest pharmaceutical businessmen here, they will tell you that there is some real purpose behind this legislation. There was a problem that needed to be addressed. There have been some unfortunate practices that have built up in certain companies, in certain areas, with certain products, in terms interaction with healthcare professionals. So when Prime Minister Putin made his famous speech in October 2009 about pharmaceutical companies inviting Russian healthcare specialists to warm beaches to discuss business—this ultimately led to the draft law which is having its second reading in the Duma. There is no doubt that Mr. Putin had a point, and there were unethical practices going on that needed to be regulated.

But does the law go too far?

Indeed, we argue that it does go too far. On one hand, you have to regulate the interaction of pharmaceutical companies and healthcare professionals, to avoid abuse to protect the patient—that is clear. On the other hand, if you over-regulate then you have an issue in getting information regarding new developments in healthcare to the practicing healthcare professional.

Russia creates more obstacles than most in that regard, because at the moment, it still has a very conservative approach to the marketing of Rx pharmaceuticals on the Internet. So if you cannot get information to doctors through the Web, and you cannot get information to healthcare professionals through personal visits, and you stick all sorts of prohibitions and restrictions and obstacles around holding conferences, then how on earth do you get the information through?

Hence, there has to be a balance. Our sense of the industry is that the current draft of the legislation does not quite have that balance right. We are all for greater regulation; we understand that self-regulation does not always work and there needs to be some oversight. On the other hand, the worry is that healthcare specialists will just be terrified of having any interaction at all with any representative of the pharmaceutical industry—and that will ultimately have a negative impact on the patient.

So unless the law is redrafted, there is no solution?

It is being discussed at the moment. It had its first reading at the end of last month. It will have its second reading at the end of this month. My understanding is that it is going to be “fast-tracked” so we are going to have it enacted probably before the summer is over, I think. It has been around for a long time already, but we shall see. Ultimately, it may depend on whether Mister Putin and

President Medvedev decide to give it their personal attention or not. But it is going through a process at the moment, and through committee. There are different views being expressed. It is too early to say where the law is eventually going to come out. We are quite optimistic that there will be modifications to the legislation—which probably will not give the industry everything it is looking for, but will create a better balance.

What about IP? Russia is still an emerging economy, and both the government and a large portion of the population will seek to get drugs as cheaply as possible, putting pressure on innovators. What is your assessment of intellectual property protection in Russia, and as companies expand their presence on this market, should the IP framework concern them?

Again, it is a story of improvement over what was before, but the story still has a long way to go.

Much has changed a lot in the last 10 years. However, for pharmaceuticals, there remains a counterfeit problem. The counterfeit problem is not necessarily all Russia-created, because a lot of the counterfeits that appear in Russia come from China, or they come from central Asia. Regardless of origin, it is still an issue.

The weapons for attacking intellectual property infringement—be they counterfeits or trademark infringements, or what have you—are a lot more sophisticated now and work a lot better than they did in previous years. If you speak to our IP lawyers here when they are putting together an anti-counterfeiting campaign, you would find that they work closely with the customs authorities to stop goods at the border, and they work closely with the police because trademark infringement and intellectual property infringement is a criminal offense here. The courts have become far more sophisticated as well, and far more effective.

It is a bit like the story with compliance and business ethics. Is there a challenge here? Absolutely. Is the challenge any greater than in any other emerging markets? I do not think so. It would be difficult to convince me that intellectual property infringement is less of an issue in China than it is in Russia.

So you believe that the problem would be specifically with counterfeiting—rather than state-sanctioned early adoption of generics in violation of patents?

Russia is a generics market, and it is probably fair to say that generics players have the ear of the Russian government more so than the big research-based multinationals. I think that is probably always going to be the case, and we have had a few challenges in that regard. The big debate was over data exclusivity for many years. We finally managed to get in the new law of six-year data exclusivity period. Unfortunately, it only applies if Russia joins the WTO—which of course Russia may or may not do.

Moreover, unfortunately, the product registration procedure basically allows you to register generics without having to gain access to protected data, anyway. So data protection does not mean an awful lot. The watering down of that provision quite clearly was done by a very powerful generics lobby. This is a frustration, but it is not a killer in terms of research-based companies doing business here. I think generally speaking, the IP environment has gotten considerably better—to such an extent that companies who would never have dreamt of locally manufacturing patented products, are now contemplating it.

In 2009, the AIPM honored you for your "Outstanding Contribution to the Development of the Russian Pharmaceuticals Market." What do you believe has been the contribution of this firm to the evolution of the pharma market here?

We got that award principally because of our involvement with AIPM over the years. So when you are talking about what Baker & McKenzie's contribution is, you really have to talk about what AIPM's contribution is.

I think that the AIPM has its critics, including from within the AIPM, but I think most people will tell you that it has been an effective trade association over the years, in terms of lobbying for the interests of the pharmaceutical industry—particularly in the legal and regulatory sphere. This is where Baker & McKenzie come in. We have done a lot internally within the AIPM, in terms of working on their ethics code and their procedures for resolving marketing disputes. Further, I believe we ultimately received this award because we have long been a mainstay in this industry.

As founding partner of Baker & McKenzie in Russia, what else is left to do and what are your aspirations for the future development of this firm?

There is an enormous amount left to do! This is, without a shadow of a doubt, the most exciting time to be a lawyer working with the pharmaceutical industry in Russia there has ever been. Now, more and more companies are looking to expand here, to develop manufacturing facilities here, to make strategic acquisitions here, and etc. There is this enormous compliance challenge that continues to play a role. There is just so much happening in the industry, and it is remarkable to be a part of it.

The challenge for Baker & McKenzie is, in 15-17 years' time, to still be the leading legal firm in Russia for the industry; and hopefully to have a practice that is three, four or five times the size that it is now—because we have clients that are doing three, four and five times the business.

I am genuinely hopeful that Pharma 2020 and the strategy that the Russian government has will work, and there will be a strong local industry developed. We are already working on some interesting projects for joint R&D here in Russia between pharmaceutical companies and Russian companies, and with regard to "pharmaceutical clusters." And hopefully in 10 or 15 years' time,

there are going to be research-based Russian pharmaceutical companies we are going to be acting for and helping to take international.

What type of legacy would you like to leave as the founder, to your eventual successor?

The biggest legacy is to be able to make sure that Baker & McKenzie moves from strength to strength, led by Russian lawyers. We are in the process now of gradually transitioning to a new generation of leadership within the firm, and this new generation is all Russian. They are all homegrown, and they are all now (or will be) full partners in the firm.

What would you like your final message to be? What is your final message to the international readers of Pharmaceutical Executive?

Do not believe everything you read in Western newspapers about Russia's corrupt business environment. If it is not one of your priority markets, it should be. It demands a lot of effort, but it is well worth your labor.

Furthermore, do not believe that it is impossible to do business in Russia in a completely ethical fashion. It is entirely possible—and there are many successful companies that can serve as your example.

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