Interview with Olessia Akimtseva, Senior Associate, CMS Russia

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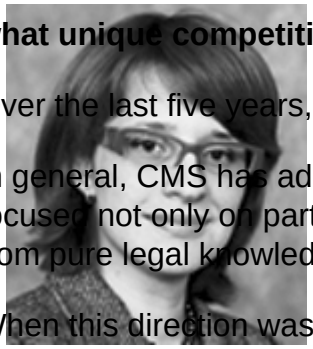

e CMSâ??s own presence in the life sciences field in Russia, and what unique competitive advantages does the firm bring to this area of practice?

Over the last five years, we have been truly active in the Russian life sciences market.

In general, CMS has adopted a so-called â??industry-orientedâ?? policy. We, as a law firm, are focused not only on particular areas of law, but also on particular industries. We believe that apart from pure legal knowledge, knowledge of industry brings significant added value to our work.

When this direction was decided upon, our partners began to hire in-house lawyers from pharmaceutical companies. Personally, I am a former in-house lawyer for Sanofi. The idea was to invite people who had background experience from the insideâ??this very much helps in better understanding a given industry.

We attempt to be more than advisors that produce very long memos! We attempt to really maintain a strong feel for our sector. This is our goal, and we spend as much time as we can in its pursuit.

We are lucky to work in a very interesting legal environment here in Russian life sciences. This is a period of massive legislative changeâ??especially the last two years. It is a good time for lawyers such as those at CMS, who are able to combine legal knowledge with an understanding of the industry.

Can you delve further into the value of your personal experience at Sanofi, and how you utilize it to advise your current clients?

I definitely gained a stronger understanding of the rules of the game. Especially now, if you work purely with disparate pieces of legislation, you could become incredibly confused. You could come to find out that given pieces of legislationâ??pricing, for exampleâ??are, to a certain extent, pushing companies out of Russia rather than attracting them. On the other hand, there are massive discussions about attracting local manufacturing and related matters, and the very complex question of what will ultimately come about from such initiatives. When you come from within a pharmaceutical company, you have a certain sense for the trends. You understand the big picture, and the general direction. Especially if we speak about large-scale governmental programs, and their effects upon Big Pharma, there is a lot of politics involvedâ??we deal with more than pure legal or economic issues. After all, pharmaceuticals are a socially sensate area.

CMS has quite a number of industry-focused divisions outside of life sciences. To what degree is the life sciences group significant to the practice at large?

Actually, this sphere is gaining more and more importance.

The 2009 financial crisis definitely affected law firms, because of its affects on traditional legal sectors like M&A and real estate. Life sciences was a sector where the need for legal services remained high despite the recession. Many firms, including ours, began to pay more attention to this area.

Today, life sciences is still of course very much alive and very much developing, and there is much to be done. The legislation, as I have mentioned, is changing at a dynamic rate. This really brings work for lawyers.

For the past two years, CMS has been the leading law firm across Europe in terms of the number of life sciences M&A deals where the organization has played an advisory role. This year, CMS acted on behalf of Takeda in the much-discussed Nycomed acquisition. Why did Takeda choose CMS for this deal, and how does its execution illustrate CMS at its best?

I am happy that you asked this question, because this is something that we truly put our full energies into.

Takeda chose CMS because of our cross-jurisdictional capabilities. We are really able to provide expedient support in many jurisdictions simultaneously, and, furthermore, to concurrently solve challenges across multiple geographies.

It was hard work for us, because we had to react quickly, and we had to work together as a global firm. Luckily, the life sciences team in CMS arranged everything in such a way that we could easily call colleagues across international borders, work together page by page, and produce a result.

The Takeda deal really came together very well. We are pleased at the outcome of our collaboration with colleagues from different offices. We regularly meet each other, and speak about mutual challenges, and this approach has paid off. We are speaking now of global integration, and having a â??one-stop shop.â??

Letâ??s look into some of the Russia-specific challenges this industry is facing. The Russian government is actively working to reduce the countryâ??s reliance on imported medicine, and the authorities have commented that multinational companies that do not localize operations in some fashion will eventually lose market position. What is your understanding of the legislative action the government will take to â??forceâ?? the localization of the industry, and how do you advise your clients to act going forward?

First of all, we continue to advise our clients to proceed with caution. In spite of the obvious trends toward localization, every decision should be very well planned and developed.

Speaking from a purely legal context, among the benefits of local manufacture today I can mention, first, 15% preference that a company can receive in the course of state tenders. The confounding element, however, is that this preference is normally approved only until the end of the respective year. You never know, therefore, what will happen next year. For example, recently, there was a bit of a strange story: the preference was approved, but then the order was somehow suspended, and became effective only at the beginning of July. Finally, we received a clear signal that the preference will be available this year also. However, it is again valid only until the end of 2011, and our clients cannot be sure what will happen in 2012.

Another benefit is certain flexibility for domestic manufacturers in terms of pricing for medicines that are on the EDL list. Those with domestic production are more at liberty to adjust these prices.

Limited tax incentives are also possible depending on local legislation of Russian regions.

A particularly significant mystery is what the status of â??local manufacturerâ?• will entail. To this effect, we have recently drafted a number of articles, memos, and etc. There are, of course, many companies that are interested in getting this status even from the stage of packaging. This is quite logical, because you cannot start with full-cycle immediatelyâ??the industry simply does not work that way. I really doubt that many companies would undertake the challenge of bringing full-cycle production here, although as far as I understand some already have. The point is, however, that speaking from a purely legislative standpoint, there is no sufficient ground to call packaging the production of a real domestic product. There are a variety of interpretations, and the big problem is that we do not have clear rules on this very sensitive issue.

Given this lack of clarity, should companies use a â??wait-and-seeâ?? approach?

We tell our clients that if they have a combination of reasons to localize, including reputational, political, and so forth, then they should proceed. However, they should certainly not base their decision on the belief that as soon as they become locals, they will receive some kind of incredible benefits. In terms of matters like reputation, there are clear effects; economically speaking, not that obviouse.

Will there be penalties if companies do not localize?

No penaltiesâ??so far. In fact, I doubt that there will be legislation structured in the form of penalties. I believe, it will be a system more based on preferences. Introducing penalties of this kind is not the best way to develop the economy, nor increase foreign direct investment.

Looking deeper into this environment, one interesting area is IP protection, where you are an expert. To what degree is there property protection here for pharma companies?

My personal opinion is that Russian legislation is quite developed. On paper, the level of protection is high. The problem, however, of Russian legislation is not its content, but rather its enforcement. Enforcement does not always uphold the written law.

For example, Russia has finally adopted a number of changes and new legal provisions in the area of data exclusivity. This is mostly caused by our obligations stemming from prospective ascension to the WTO. The provisions will be enforced only after the process is completeâ??and as is well known, Russia has entertained the idea of joining the WTO for the better part of 20 years!

For now, we at least we have the legislative framework in place for data exclusivity. There are a number of discussions regarding how it would really work. Will it truly ensure protection for companies? We will know for sure only when it is implemented.

In general, in terms of IP protection, law enforcement practice is really developing. Recently, CMS has had a number of successful patent infringement cases, where we argued for the enforcement of patents. We see some positive trends therein.

I definitely believe that on the governmental level, there is an understanding that IP protection is absolutely crucialâ??especially in all the drafts and discussions related to local manufacturing status, where there were certain bullet points on the transfer of IP. Of course, in the absence of such protection, no business would consider localizing production here.

Can you provide some examples of characteristic cases that CMS participated in in the IP field?

I of course cannot name client namesâ??however, I can give you the following example, of a case that was on the border of the pharma and chemical industries. The case regarded a particular chemical compound. There was a situation wherein the method related to compound use was protected. Within the law, it is possible to protect the compound itself, and to protect the method of its use. It is very difficult to enforce a patent when you have method protection, because it very much depends on the interpretation of the court.

This case fully depended on the flexibility of the arbiters. In spite of negative decisions in the early stages, in later stages, the court adopted a decision in our favor, and affected a rather broad interpretation of the possible ways to infringe method patent. They finally recognized an infringement of patent, and ordered the Russian manufacturer to discontinue production of the relevant product.

This was quite an important decision, because it showed, again, the evolving position of the Russian legal system toward greater IP protection. The court elected to protect these rights in a situation where they could have well chosen not to.

Do cases like this shape IP decisions going forward?

I believe so. If we have cases where courts, even in disputable situations, tend to side with the patent holder, then it really shows that they understand the importance of IP rights, and this will very likely influence future decisions. In turn, this encourages multinationals to invest in the Russian market.

Of course, there remain examples that are less positive. However, I think it is also a task for companies to create a discipline where they really fight for their patents and for their rights.

While we are on the subject, in terms of IP, another interesting issueâ??which is more crucial for medical device manufacturersâ??is parallel import. In Russia, we have a so-called â??national principleâ?? in the legislation, which is soon going to change into a â??regional principleâ?? when we join the Customs Union. Right now, parallel import is a grey area because despite the fact that it is illegal under Russian legislation, the Russian Supreme Arbitration Court has yet to produce a clear decision in this respect. There have been several controversial cases, and the situation definitely requires clarification. The FAS, for example, really support parallel importers, and their participation in state tenders. Manufacturers of products, on the other hand, really suffer from this economically, and wish to take measuresâ??especially bearing in mind that Russian legislation seemingly allows them to take measures. However, due to the controversy of law enforcement practice, many companies cannot take the decision to act, because if they lose, they will lose more than the case: they main loose reputational ground as well. This is another example of good legislation, but problems with law enforcement practices.

You are developing an interesting picture of the environment here: there seems to be a wealth of uncertainty; and even when given legislation is in place, it is not enforced. How can companies conduct business in such conditions?

Everything is perhaps not that dramatic. Lawyers tend to scare, especially in the face of changing legislation.

I think that business, as well as lawyers, need to be very active, and very reactive. Legislation is truly developing very fast. For example, after the law on Circulation of Medicines passed, changes were adopted several times, almost monthly. This is a specific situation to Russia: you will not see this in

every country.

That is why we need to be ready. There are few certainties upon which we can totally rely. We have new rules, new methodologies, approved every year. That is life. On the other hand, if we understand the trend, we are well-positioned. To illustrate, the localization of manufacturing, is a trend that is not going anywhere. In spite of some pieces of legislation that appear rather controversial in view of this trend, the overall legislative development is still going in a direction that is quite clear.

To what extent can a firm like CMS help multinationals that are used to stability and predictable legislation adapt to this environment?

This is definitely one of our key directions. Our international experience helps quite a bit. In Russia, the environment trails even certain Eastern European countries, which have already adopted certain strict regulations.

For example, there is another law to be adopted soon, on the basics of healthcare protection. This law will introduce significant limitations on marketing practices, and on companiesâ?? relations with healthcare professionals. Such limitations already exist in a number of countries, and in Eastern Europe, where the mentality and environment in comparable to Russia, we already underwent discussions regarding how business will proceed when field forces will have limited access to doctors. We can learn from the experience of our clients and colleagues in those countries.

If we look beyond the challenges in the sector, with the wealth of new partnerships appearing in this sector, the new infrastructure being built, and new legislation to tackle, it is surely an exciting time to act on behalf of pharmaceutical companies in Russia. What does CMS envision for the future of its Russian life sciences division, and how can it grow in step with the boom of the sector itself?

We are definitely expanding our life sciences practice, despite the challenge of attracting lawyers from within the industry.

We are, as you mentioned, a â??one stop shop,â?? so we have various services including tax, legislation, and so forthâ??and we are really trying to educate our colleagues from a life sciences perspective. We want our lawyers to be able to work within many aspects of the law, but to understand and feel life sciences specificsâ??because even in seemingly unrelated areas like employment, if you are a life sciences company, you have specific issues related to your personnel. Given the prospective healthcare protection law, for example, we are developing specific policies and rules for employers to explain how staff should behave and interact with healthcare specialists. This is already on the border of regulatory legislation and pure labor legislation. We need to invite and educate our labor specialists to be able to produce a tailored product for our clients.

On a personal level, what attracted you to CMS?

Possibilities. At the stage when I joined CMS, although it was a bit early in the game, the trends were obvious that legislative changes were on the horizon, and there would be much work for lawyers.

It was also very interesting for me to begin working for more than one company, and to be able to summarize the experience of different businesses, of different practices, and different strategies. These are the benefits of working as a consultantâ??you have exposure to many cases, and you can broaden your knowledge and experience base.

What is your final message to the international readers of Pharmaceutical Executive?

The legal environment in Russia sometimes seems confusing, and sometimes seems challenging. Still, it does not preclude companies from realizing all of the great opportunities that this market has to offer.

With the further development of legislation, I believe it will help, rather than prevent, the growth of industry. CMS is ready to assist in its proper implementation. With proper implementation, companies will achieve a high degree of success here.

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