

IP/Technology Transfer

Published online: 5 August 2004, doi:10.1038/bioent823

▼ Russian biotech needs better patent protection

Alla Katsnelson¹

Alla Katsnelson is a news intern for *Nature Biotechnology*.

Scientists in Russia seek overseas partners to commercialize their inventions, but the country's immature business climate often stands in the way.

On 16 July, trade representatives from the European Union and the United States criticized Russia's lax enforcement of intellectual property (IP) laws during talks on the country's membership candidacy to the World Trade Organization. Resolving the country's IP issues would be a boon to its growing biotech industry, which is poised to benefit greatly from wider collaborations with Western companies.

"Russian science has almost no money, although we have very qualified people," says Vladimir Khavinson, director of the Institute of Bioregulation and Gerontology in St. Petersburg, who has licensed several inventions to Western companies. Licensing deals with Western partners are "a way for us to finance the research," he says.

Throughout the past decade, most international licensing deals have been brokered by the International Science and Technology Center (ISTC), which was established in 1992 in Moscow as an intergovernmental nonproliferation program to redirect militarized research to peaceful ends. The ISTC acts as a partnering service between overseas companies and Russian researchers—assisting with IP questions, organizing transfers of funds and equipment, and generally conducting extensive project management. Business conducted via the ISTC is also exempt from tax and customs fees.

More recently, small biopharmaceutical development companies have begun seeking out Russian partners independent of government partnering help. "I think we're seeing an increasing amount of interest in this method of partnering," says Roop Chandwani, CEO of London-based biopharmaceutical product development company TTRBio.

The problem, however, is that Russia's business climate is still immature, which can make such partnerships challenging. "Foreign companies still have a hard time finding adequate partnership in Russia," says Sergei Simaranov, president of Moscow-based TechnoConsult, a firm that helps Russian biotech ventures commercialize their products with overseas companies.

IP protection—or lack thereof—is one major obstacle to the maturation of Russia's biotech industry. "Until the early 1990s, all patents were the property of the government, giving no incentive for the general public to protect and care for personal inventions," says Olga Rodstein, an associate attorney at Heller Ehrman White & McAuliffe in Menlo Park, California. Russian laws for IP protection were modernized in 1992 after the fall of the Soviet Union, revised again last year, and are now comparable to those in the European Union and the United States. For example, patents are valid in Russia for 20 years and are granted to the first to file, as in the EU, rather than to the first to invent, as in the US.

However, Rodstein says that IP enforcement is still weak in Russia. In large part, the difficulty stems from the absence of precedents for interpreting laws relating to patents and the free-market economy, most of which are barely a decade old. Especially outside urban centers like Moscow and St. Petersburg, judges and lawyers tend to be less experienced in dealing



ISTC

Scientists from the Engelhardt Institute for Molecular Biology in Moscow collaborated with the US Centers for Disease Control in Atlanta to develop this DNA microarray assay for clinical diagnosis of tuberculosis.

with international trade issues relating to export or arbitration, says Rodstein.

Furthermore, confusion about regulations surrounding ownership abounds. "One of the saddest things I ever saw was in the early 1990s when a ministerial delegation [from Russia] came to the UK with a thick book listing all their biotech prospects and inventions," says Ian Harvey, CEO of the London-based British Technology Group (BTG) and chair of the UK Intellectual Property Institute. By publishing these ideas in a brochure, the group had put them in the public domain, destroying their patentability, he says. "It's like if you're [trying to] help your parents but it turns out you've actually killed them instead."

According to BTG estimates, the total lifetime cost of patenting a "moderately complex" technology in ten key countries is about \$250,000. This includes attorney costs for due diligence and writing the patent, as well as licensing and maintenance fees, but does not include potential patent litigation costs. Even if an invention is registered in Russia, patenting internationally is often out of the price range of cash-strapped researchers.

In addition to poor IP protection, commercialization of Russian biotech is hindered because most scientists lack an understanding of Western business practices. Scientists who want to find an overseas partner to develop their product often do not know how to write competitive business plans or prepare their ventures to receive investment—and few resources within the country exist to help them. Khavinson adds, "We don't know the legal system [in the West] and have great difficulty in making contracts." Unfamiliarity with business culture also leads to a different conception of value, says Chandwani. "The mentality of Russian scientists is that they've invested so many years in their research that they believe the quantifiable sum of that is what they're worth. But markets don't work like that—it's more about potential."

In the long term, however, overseas collaborations can play an important role in creating an infrastructure for biotech commercialization within Russia, not only by funding innovative research but also by training scientists in the intricacies of bringing their inventions to market. "There's a lot of talk in Russia of integrating into Europe, but the mechanism of integration is not obvious," says Simaranov. "Really, though, the mechanism of integration is technology."

Web links

TechnoConsult

<http://www.technoconsult.ru/>

Russia's International Science & Technology Center

<http://www.istc.ru/>

Heller Ehrman White & McAuliffe

<http://www.hewm.com/>

British Technology Group

<http://www.btgplc.com/>

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