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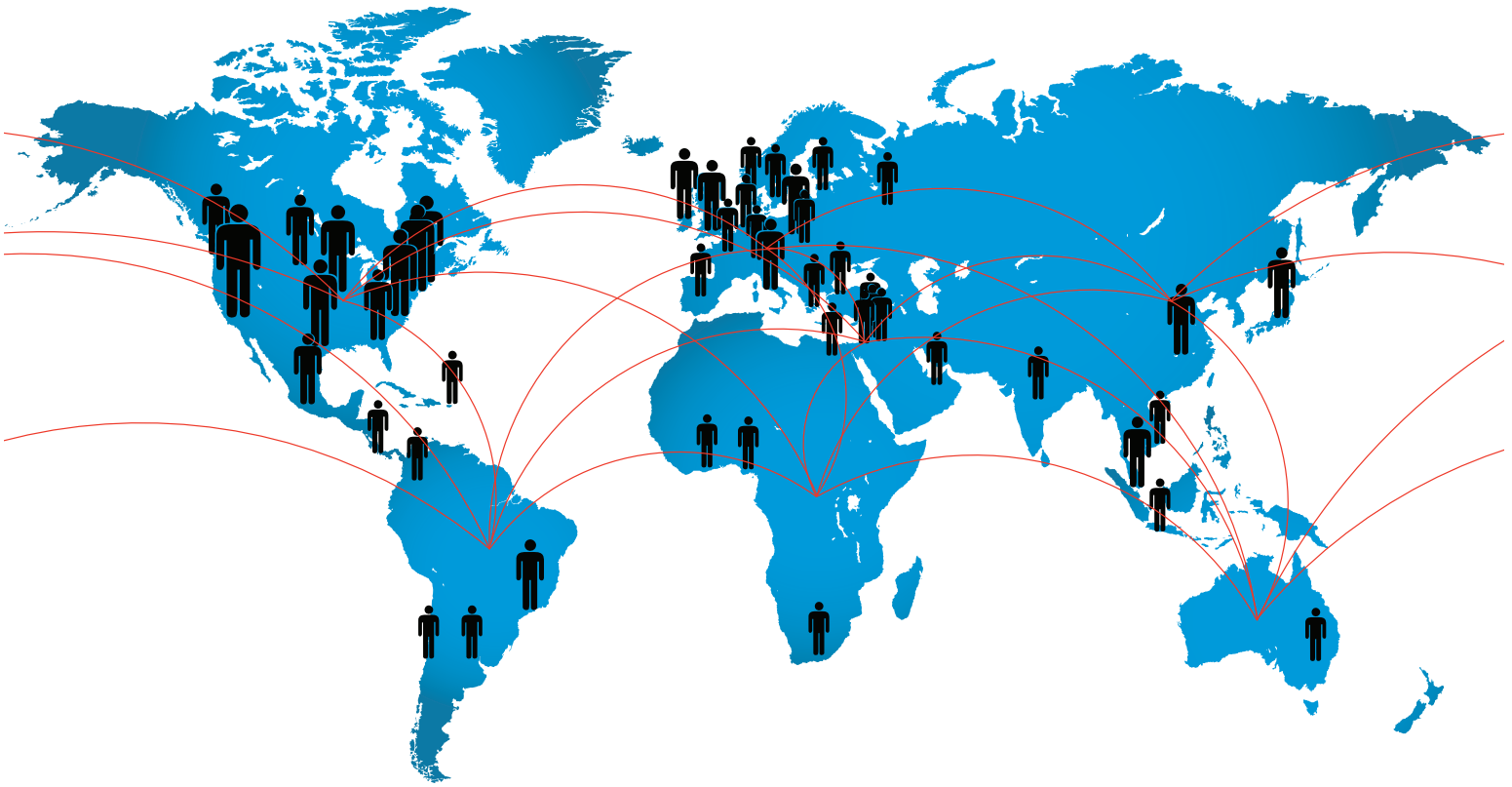

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Facilitating Pharmaceutical Licensing into Russia

Kenneth Horne

Class 17

The Russian pharmaceutical industry is the 7th largest in the world (valued at over $28 billion) and has the 3rd highest growth rate[1] (14% in 2013, 12% in 2014[2])—however, over 75% of the pharmaceutical products are imported and only 1 of the top 20 pharmaceutical companies by market share is domestic.[3] The Russian government appropriately deemed this an issue, and in 2010 launched an initiative called Pharma 2020 to support the domestic pharmaceutical industry and reduce the portion of imported drugs from 75% to 50% by 2020. To promote domestic production, the Russian government offers a 15% premium to domestically manufactured pharmaceutical assets when trying to secure government tenders.[4] Since its creation, the intiative has made significant headway with moves by several multinational pharmaceutical companies via partnerships or direct investment.[5]

My Kauffman Fellows classmate Roman Knyazev and I both worked as venture capitalists specializing in healthcare, and shared an interest in emerging markets, particularly Russia where Roman was based. Despite the governmental initiatives, we observed that Russian companies were having some difficulty in securing licenses from foreign pharmaceutical companies. Thus, a goal for our Kauffman Fellows field project emerged: analyze why licensing by Russian pharmaceutical companies was not going smoothly despite the attractive market and government initiatives. Further, it was our collective desire to have a non-academic field project, that is, one that produced a commercial outcome. So, upon analyzing the Russian business development landscape, a second goal was formulated: try and address (to some extent) the difficulties we would observe commercially.

1 JSC DSM Group, *Russian Pharmaceutical Market 2012* (n.d.), 4, http://agora.mfa.gr/agora/images/docs/rad8D976annual_report_2012_eng.pdf.

2 HIS Inc., "Russian Pharmaceutical Market Value Grows 14% in 2013," 7 March 2014, "Outlook," https://www.ihs.com/country-industry-forecasting.html?ID=1065985325.

3 JSC DSM Group, 3.

4 Ibid., 36.

5 David Yampolsky, "Russia: A Look Back at Pharma2020, and a Look Forward to its Prospects," CB Partners *Thought Hub* (blog), 1 October 2014, para. 4, http://cbpartners.com/blog/russia-a-look-back-at-pharma2020-and-a-look-forward-to-its-prospects.html.

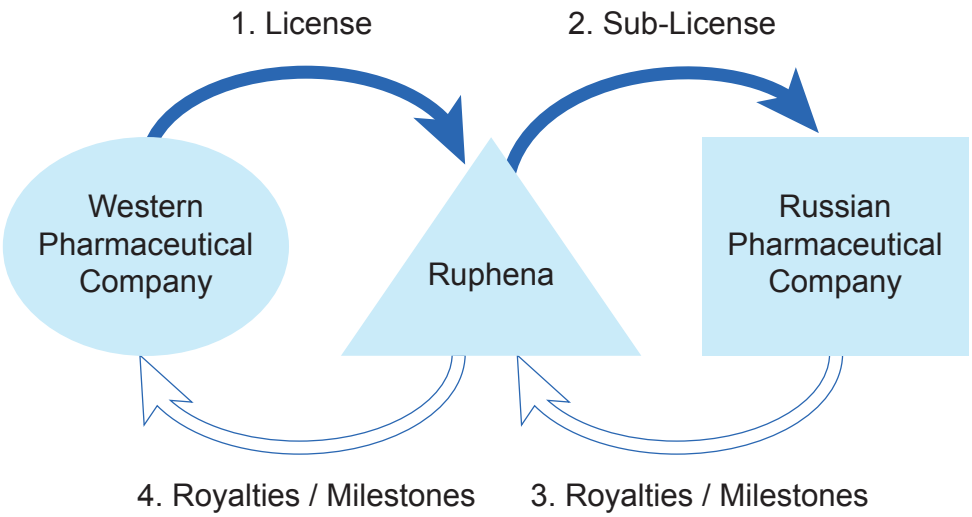

Figure 1. Direct Licensing Business Model. Author's figure.

Phase 1: Identifying Barriers to Pharmaceutical Licensing in Russia

Our first task was to understand why licensing into Russia is difficult. We leveraged our respective networks to speak to pharmaceutical executives in Russia and business development professionals in the United States and Asia. We sought advice from Garrett Vygantas (Class 13), who had founded NewBridge Pharmaceuticals, a company that licenses pharmaceutical assets for Africa, the Middle East, and Turkey. We also spoke with a business development executive from Amgen who oversees business development in Russia, thanks to another Kauffman Fellows introduction. Through these interactions we formulated two main hypotheses as to why licensing into Russia is difficult.

First, from the Russian side, we found that the deal-making dynamic is different than what Western companies are used to. The structures Western companies expect—up-front payments, royalties, term limits, and milestone payments, for example—are not necessarily considered common in Russia. Further, the potential for a win-win, altruistic deal is not assumed, or in some cases even considered. We did not reach a conclusion as to whether assuming altruistic deals is simply the Russian way of doing business, or if Russian companies' behavior is influenced by doing business with foreign entities. Either way, differences in business development standards were the first difficulty we identified.

Second, from the Western perspective, while the potential and attractiveness of the Russian market is pretty well understood, many Western companies did not know what to expect when doing pharmaceutical business in Russia. They described a fear of the "unknown unknown." In contrast, when discussing our research in Russia, China was brought up by many business development executives with emerging market experience, and they said that even though doing business in China has its challenges, at least they knew what to expect. The issue of deficient trust (we would not call it distrust) is amplified in the Russian pharmaceutical industry, as compared to tech or finance. For example, if a pharmaceutical partner in Russia were to generate bad clinical outcomes (adverse events) using a product licensed from the United States, it could impact that product on the U.S. market through commercial, clinical, or regulatory (FDA) pressures. This potential downside combined with some uncertainty seemed to outweigh the potential for upside in the Russian market.

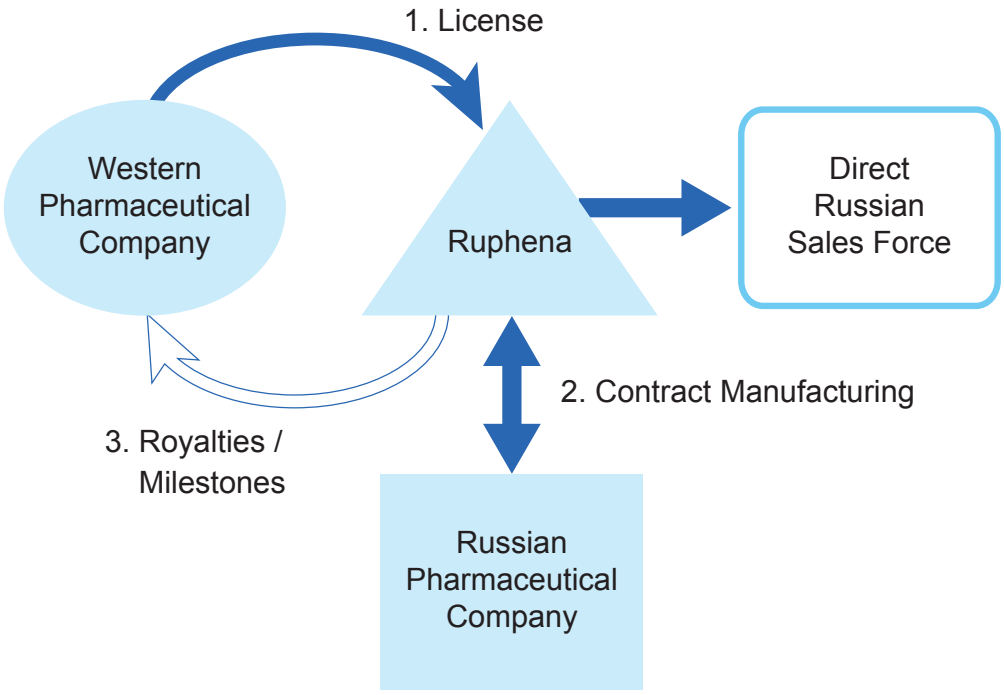

Figure 2. Direct Licensing Business Model, Contract Manufacturing with Russian Company and Ruphena Having a Direct Sales Force. Author's figure.

Phase 2: Developing Ruphena as a Potential Solution

With this new understanding of the difficulties facing pharmaceutical licensing in Russia, we investigated ways to address these difficulties. Our proposed solution was to create a commercial entity to help match Russian pharmaceutical companies and their licensing needs with Western companies seeking emerging market upside, and then to address the known business-development difficulties by facilitating the licensing negotiations. We decided to name this potential entity Ruphena.

We contemplated a variety of business models for Ruphena. The most attractive opportunity seemed to be to directly license the U.S. asset to Ruphena, which would then sublicense to Russian pharma companies (figure 1). This arrangement would allow the greatest control, and we thought it would have the greatest upside potential. The second potential arrangement was for Ruphena to do a direct license with the Western pharma company, and also be a full-service commercial entity with its own sales force and distribution in Russia (figure 2). In this second model, Ruphena would contract manufacturing with a Russian pharmaceutical company in order to fulfill the domestically manufactured mandate necessary to secure the Pharma 2020 advantages. However, the firm would obtain and use its own direct sales force to better control the clinical, regulatory, and commercial development of the product. This second model would provide better control over the product and address one of the concerns of Western pharmaceutical companies.

Although attractive options, both direct-license business models had an insurmountable upfront capital requirement (figures 1–2). Western pharma companies would undoubtedly require an upfront payment, which Ruphena would not have—and would not want to have to raise. Further, in the direct-sales-force model, the firm would need additional capital to set up its own Russian entity. Finally, Ruphena would not have any track record of success

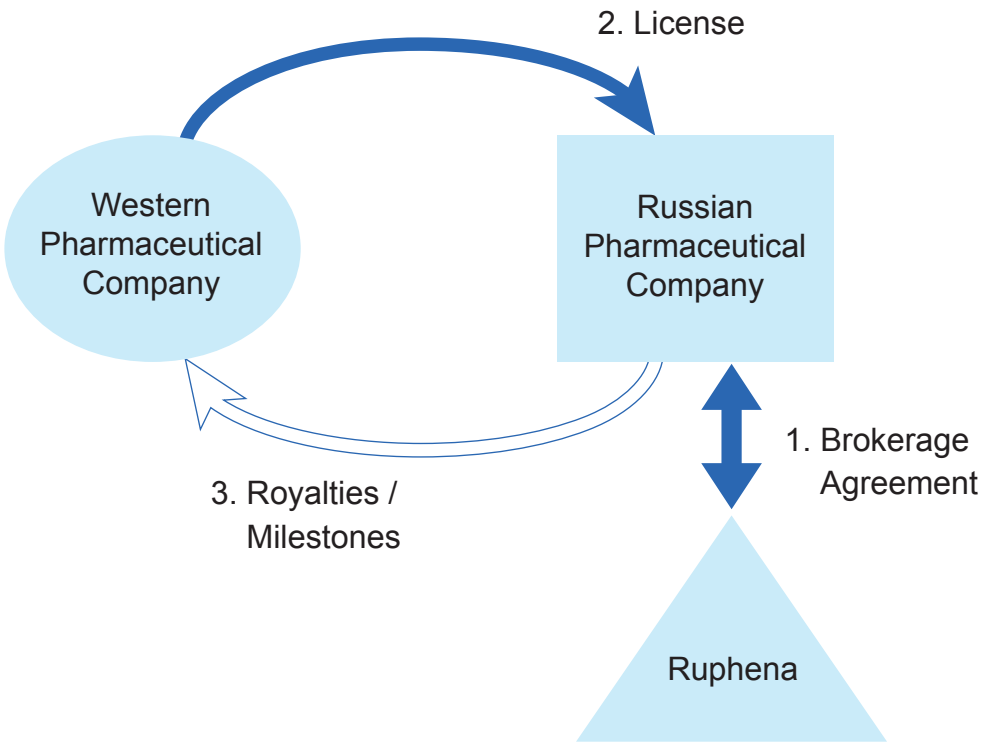

Figure 3. Broker Business Model. Author's figure.

in pharmaceutical licensing to Russia, and it would likely prove difficult to secure any direct licenses.

Therefore, we conceived of and selected a brokerage business model (figure 3). In this model, Ruphena would start by signing brokerage agreements with Russian pharmaceutical companies, and would then work on behalf of those companies to try to source licensing opportunities. This model had the lowest initial capital requirements for Ruphena, and the only thing primarily at risk was our time. For our potential clients, both Russian and Western pharmaceutical companies, there was no downside to engaging Ruphena, as any financial payouts would be success-driven.

Phase 3: Making Ruphena a Reality

Armed with a business model, we set about creating Ruphena. We spent some time considering the merits of making Ruphena an offshore company (British Virgin Isles or Cayman). There were definite potential tax benefits to doing so, and the cost trade-off seemed acceptable ($5k to setup a U.S. LLC vs. $20-30k to setup offshore). However, given the existing guarded view that Western companies have of Russian companies, we wanted to ensure that Ruphena came across as absolutely legitimate. Thus, we set up a U.S. LLC and further decided to hire Cooley LLP, a well-established and reputable Silicon Valley law firm, as Ruphena's legal representation.[6]

The first order of business was to secure brokerage agreements. Utilizing our knowledge of the Russian pharmaceutical industry, we focused on top-quality companies and prioritized those that were public or had significant government backing. We theorized that these two types of entities would appear trustworthy when viewed by the West.

We created a short PowerPoint presentation on Ruphena and were able to quickly secure interest from two Russian pharmaceutical companies: one public and one privately held.

[6] The mere fact that Cooley LLP had papered our company and was our legal counsel helped us secure a few meetings, as it definitely provided some legitimacy.

Unfortunately, it took nearly six months to get brokerage agreements signed.

This experience was very informative about navigating the different business development styles. We proposed success payments for any brokered licenses, on par with what an investment bank might charge for a similar service, and which we would use to cover Ruphena's costs. We also proposed a small percentage royalty on the licensed product, which would be Ruphena's upside. We felt this structure was very fair: the Russian pharma company paid nothing unless they got a license, they would be in complete control of that decision-making process, and if they signed the license we would participate in the upside by taking a small royalty. The strongest push-back we got was on the royalty—not the specific percentage, but the entire existence of it. Both Russian companies that had expressed interest would rather have paid for our services to get the initial license and then severed ties, even if that meant paying more than we were asking for up front. It took a lot of convincing, but ultimately we were able to show them that the future potential of the upside was good motivation, and would only be material to them if they had a very successful product—hence, this was a win-win agreement.

Armed with two brokerage agreements, we initially sought assets that we thought or knew were available for license in Russia. The Kauffman Fellows network was particularly helpful in compiling this list. When we shared the list with our Russian partners, it did not generate significant interest. It did, however, finally get them to reveal to us their specific interests, and we then sought such assets by leveraging our various networks. One of the biggest challenges we had in agreeing on assets to go after with our Russian partners was that they desired novel, patent-protected, high-potential assets, but they did not realize the clinical and regulatory development costs necessary to secure Russian approvals for such assets. However, if we brought less "desirable" assets (no patent, generic, smaller market), they were not as enthused to seek a license. It often felt like the company strategies for our Russian partners were constantly evolving.

The Future for Ruphena

As of this writing, we have a deal in the works with each Russian company, and both deals have had several rounds of term sheet negotiations. We are optimistic that we can get one or both of the deals signed sometime in 2015. Interestingly, one of the potential assets is held by a Chinese government-backed entity, which has added another dimension of business cultural differences. Also, despite the increased language barrier, it has felt easier to facilitate business discussions between the Russian and Chinese companies than it has with U.S. and Russian companies.

Our long-term goal for Ruphena is to shift toward a direct-licensing model, and eventually build a presence in Russia so that we can sell directly. In order to do this, we will need to have some success with our initial licensing deals, both to have a demonstrable track record, as well as to have some capital that we can use to grow. If any member of the Kauffman Fellows network has an interesting pharmaceutical asset looking to enter the Russian market, please reach out to me!

Kenneth Horne

Ken has 12 years of experience in the life science industry as an executive, entrepreneur, and investor. Before joining Symic Biomedical as CEO in April 2014, he was a founding member of TauTona Group, an early-stage life science VC fund. At TauTona, he founded and managed Aline Aesthetics, a biomaterial company (acquired by Allergan). Ken holds BS and MS degrees from Stanford University in mechanical engineering. Kauffman Fellow Class 17. KH@SymicBio.com

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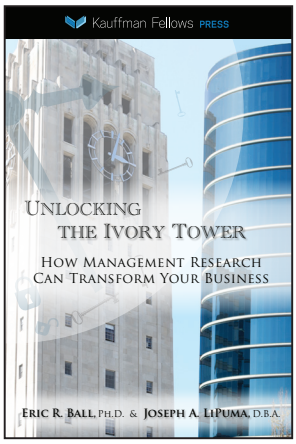

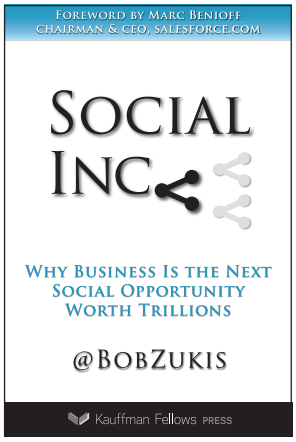

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