by Valentina Rucker and Dan Kane

# Forewarned is Forearmed

## ~ Part I ~

### Pharmaceutical Companies Considering Distribution Networks in Russia Should Take Heed of the Novo Nordisk Experience

The best advice for companies considering global expansion is perhaps the simplest: assume nothing. With the diversity of global legal regimes, it is unsurprising that, in certain jurisdictions, even the most common business practices may violate certain national laws. Russia, in particular, is causing problems for expanding businesses. While the number of potential consumers makes it an attractive market for multinational corporations, the "unique" regulation of business practices should cause these firms to enter this market with caution. As OOO "Novo Nordisk" (Novo Nordisk), the Russian subsidiary of a Danish pharmaceutical company, recently learned, certain well-established antitrust principles are not always so "well-established" in Russia.

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**Overview of the Case**

Novo Nordisk, a manufacturer of diabetes medications, entered the Russian market in 2005. Over the next three years, the company sold its product through twelve, forty, and twenty distributors, respectively. Beginning in 2008, despite interest from other distributors, Novo Nordisk limited its distribution channel and worked with only five partners.

In September 2010, Russia's Federal Antimonopoly Service ("FAS"), finding a violation of the Law "On Protection of Competition" (Clauses 5 and 8 Part 1 Article 10), fined Novo Nordisk 85.9 million rubles (approximately US$3 million) and enjoined the company from limiting its distribution network. Specifically, FAS alleged that Novo Nordisk's conduct constituted abuse of its dominant position in the insulin wholesale market.

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Novo Nordisk initially appealed this decision, though it later reached a settlement with FAS. Under the terms of the settlement, the company agreed to allow any applicant that satisfies its revised partner policy to distribute Novo Nordisk-branded insulin. Those that do not are entitled to learn where their application is deficient and are given an opportunity to remedy. In addition, Novo Nordisk was still subject to a reduced administrative fine.

While this decision affected Novo Nordisk exclusively, it has implications for other companies contemplating working in Russia. As FAS spokesman commented: "This is the first turnover-based fine by FAS as applied to a pharmaceutical company that has a dominant position in the Russian pharmaceutical market. We are sure that this case will serve as a caution tale for all other pharmaceutical companies operating in Russia." To avoid drawing similar regulatory scrutiny, therefore, multinationals planning to operate in Russia should study the nuances of FAS's decision, specifically the manner in which FAS defined the market and the conduct it considered to be anticompetitive before engaging in any specific conduct. As we discuss below, the analysis of this case likely would have been different in most other jurisdictions, particularly the United States.

**FAS Market Definition**

Under Russian law, dominant firms in their relevant national product market may not unjustifiably refuse to deal with state-approved distributors. The threshold for dominance is fairly low; generally, a firm with market share as low as 35% can be "dominant." Further complicating matters is the way that markets may be drawn in Russia. Here, FAS created a product market consisting entirely of Novo Nordisk's own branded drugs, and subsequently determined that the company possessed 100% of the relevant market.

Notably, FAS failed to specify whether it considered other insulin suppliers as potential competitors, or if branded manufacturers will always presumptively possess 100% market share in their own drugs. This lack of guidance from FAS should concern all businesses operating in Russia, as it questions the legality of any distribution-related limitations they may try to impose.

FAS Determination of Anticompetitive Conduct

As discussed above, FAS's investigation focused on the limits Novo Nordisk imposed upon its distribution network beginning in 2008. As a pharmaceuticals manufacturer, Novo Nordisk must rely upon its distributors to store its drugs safely and deliver them in a timely fashion. To regulate its distribution network, Novo Nordisk implemented a two-prong review for potential distributors beginning in 2008. This review included: (1) financial and other documentary due diligence; and (2) audits of storage facilities and transportation systems. To ensure continued compliance with these policies, each existing partner was reevaluated every two years.

During its investigation, FAS determined that Novo Nordisk subjected existing partners to a lesser level of scrutiny than new applicants. Though numerous business justifications support differing levels of scrutiny, i.e., goodwill, unbroken trust, positive customer reviews, FAS refused to accept them. Rather, the agency decided that Novo Nordisk's application review was simply a pretext to permit the company to unfairly limit its distribution network.

FAS's conclusion relied heavily upon the fact that Novo Nordisk had worked exclusively with the same five distributors since 2008, even though multiple companies had applied to distribute Novo Nordisk insulin since that time. The agency gave little weight to the realities of the industry: that the product was highly specialized, that the company was better able to monitor fewer distributors, and that consumers undoubtedly benefitted from consistent storage and delivery practices.

Instead, FAS reasoned that, because all the denied applicants were state-licensed pharmaceutical distributors, they were qualified to partner with Novo Nordisk. Furthermore, FAS determined that Novo Nordisk could not require distributors to submit to a facilities audit, as this supplanted the role of the Russian certification authorities, which have the sole authority to license qualified distributors.

**Conclusion**

Expanding companies should take precautions when it comes to entering into new jurisdictions. Business practices and regulations can easily vary across the global spectrum. Common practices in the United States may not always equate to international standards. NPT

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