



## Competition Tunnel Vision: Russia's Narrow Interpretation of Dominance

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Imagine, for a moment, that you head an American pharmaceutical company that primarily manufactures medications for diabetes. For years you have worked hard to build and grow your brand. You have conducted clinical testing to show the value of your drugs; you have streamlined the manufacturing process to cut production costs; you have worked with distributors to position your drug correctly and to market it efficiently. As with any other business, there have been setbacks, but you have established a firm presence in the market.

One day, however, you discover that a cabal of disgruntled former distributors have been complaining about your behaviour to the government. Specifically, they claim that you are a monopolist—as indeed you may be since your drugs are patented—and that you have been illegally exercising your power to deprive them of the right to distribute your pharmaceuticals. They argue that your refusal to deal is crippling their business and that, without government intervention, their businesses will disappear. A nightmare scenario

of government investigations and years of costly litigation spins through your mind. Frantic, you call up your antitrust counsel (on speed dial, of course) and ask what you should do. He tells you to relax: the distributors' claims are baseless, and no domestic authority will act on them. Your fears allayed, you hang up the phone and tend to matters far more important.

Of course, the key qualification in this advice is that it relates only to “domestic” authorities. In the United States, it has long been established that firms generally have the right to choose their business partners. Absent extreme circumstances, the government will rarely require one firm to work with another. In foreign nations, however, this principle is not as widely accepted. One such nation—Russia—recently investigated, litigated, and settled with a private pharmaceutical company whose actions essentially mirrored those described above. This case provides insight into Russia's review and unexpected application of seemingly fundamental antitrust principles.

### **An Overview of Russian Competition Law**

Russia is a relative newcomer to antitrust enforcement. In the waning days of the USSR, the representatives to the Supreme Soviet ratified legislation that became the nation's first

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antitrust law.<sup>2</sup> Following the breakup of the Soviet Union, this legislation remained national policy, though it was not codified in statute until 2006 with the adoption of The Federal Law “On Protection of Competition” (the Competition Law).<sup>3</sup> In the last six years, this law has been substantially amended twice, first in 2009 (The Second Antimonopoly Package)<sup>4</sup> and again in January of this year (The Third Antimonopoly Package).<sup>5</sup> The most recent revision, while extensive, had minimal impact on the provisions relating to the abuse of dominance, which continues to be governed by the Second Antimonopoly Package.

Generally, under Russian antitrust law, any company with market share above 35% may be

considered dominant. Even firms that fall below this threshold may be deemed dominant if they possess a larger market share than any other competitor and are able to exercise a dominant influence on the functioning of the relevant goods market. The precise determination of what qualifies as “exercising a dominant influence” is not entirely clear, though based on certain cases brought by the Russian competition authority—the Federal Antimonopoly Service of Russia (FAS)—it seems that the elements that comprise this determination are somewhat fluid. In fact, in certain instances, companies with as little as 8% of the market may be found dominant.<sup>6</sup> Once dominance is found, the affected firm is subject to a much higher degree of scrutiny. Most notably, dominant firms are required to work with all partners who wish to engage them and operate similarly to already-established partners. As such, a monopolist may not “unjustifiably” refuse to deal with a potential partner: to do so is an abuse of dominance and a violation of the Competition Law.

Some Russian practitioners believe that these market share thresholds were written specifically to target the pharmaceuticals market.<sup>7</sup> While some may dismiss this as a

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<sup>2</sup> See USSR Law on Limiting Monopoly Conduct in USSR, IZVESTIYA, July 25, 1991, at 4. Though this was a national law, the statute provided that it would be applied by antimonopoly committees in each of the USSR’s different regions, as well as at the state level. See, e.g., Rose Anne Devlin & Stylianos Perrakis, *Legislating competition in the Russian Federation: a new challenge for antitrust policy*, 40 ANTITRUST BULL. 901 (1995).

<sup>3</sup> Federal Law of the Russian Federation on Protection of Competition, ROSSIISKAIA GAZETA [ROS. GAZ.], July 27, 2006, available at <http://base.garant.ru/12148517.htm>.

<sup>4</sup> Federal Law on Amending the Code of Administrative Offences of the Russian Federation, No. 239-FZ, July 27, 2010, available at <http://base.garant.ru/12177586/>; Federal Law of the Russian Federation on Amending the Federal Law on Protection of Competition and Certain Legislative Acts of the Russian Federation, No. 164-FZ, July 17, 2009.

<sup>5</sup> Press Release, Fed. Antimonopoly Serv. of the Russ. Fed’n, The “Third Antimonopoly Package” Came into Force (Jan. 10, 2012), available at [http://en.fas.gov.ru/news/news\\_31961.html](http://en.fas.gov.ru/news/news_31961.html) (“On 6 and 7 January 2012 came into force the Federal Law ‘On Introducing Amendments to the Federal Law ‘On Protection of Competition’ and Some Legislative Acts of the Russian Federation’ and the Federal Law ‘On Introducing Amendments to the Code of the Russian Federation on Administrative Violations’ that constitute the ‘third antimonopoly package.’”).

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<sup>6</sup> Federal Law of the Russian Federation on Protection of Competition, ROSSIISKAIA GAZETA [ROS. GAZ.], July 27, 2006, available at <http://base.garant.ru/12148517.htm>. (“The position of each of several economic entities (except financial organizations) is recognized dominant if all of the conditions below apply to the entity: . . . this provision is not applied if the share of at least one of the aforementioned economic entities is less than eight per cent.”).

<sup>7</sup> Yevgeny Voevodin, CMS NEWSLETTER: SECOND ANTIMONOPOLY PACKAGE (2009), available at [http://www.aebrus.ru/application/views/aebrus/files/legalcommittee\\_files/CMS\\_newsletter\\_-\\_Second\\_Antimonopoly\\_Package\\_file\\_update\\_2009\\_10\\_06\\_13\\_52\\_03.pdf](http://www.aebrus.ru/application/views/aebrus/files/legalcommittee_files/CMS_newsletter_-_Second_Antimonopoly_Package_file_update_2009_10_06_13_52_03.pdf) (“This is an attempt by FAS to address issues surrounding retailers and pharmaceutical



conspiracy theory, FAS's record of enforcement indicates, at the very least, that it has particular concerns about the competitive conditions in this industry. Indeed, as one Danish company discovered over the course of 2009-2011, FAS's interest in this area, coupled with its expansive authority to draw relevant markets and make determinations regarding monopoly power, potentially makes Russia a risky jurisdiction in which to do business.

### ***Novo Nordisk: An Overview***

OOO "Novo Nordisk" (Novo Nordisk) is the Russian subsidiary of a large Danish pharmaceutical company with a specific focus on diabetes medication.<sup>8</sup> In line with the practices of many large pharmaceutical companies, Novo Nordisk manufactures its drugs and relies upon third parties to distribute them to end consumers. In 2005, the company's first year operating in Russia, Novo Nordisk partnered with twelve local distributors. The following year this network swelled to forty. In 2007, Novo Nordisk made a conscious decision to decrease the number of distributors to a more manageable number. That year, it partnered with twenty distributors; the following year, it partnered with only five. While the firm had a number of distributors approach it seeking to do business in this year and those following, the company decided to keep its direct distribution channel narrow. The company did not, however, impose any limitations on sub-distribution. Rejected applicants could still contract with the initial distributors and sell Novo Nordisk's products in that manner.

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companies, as whilst such entities do not hold 35% of the market share, they have a real market power and are able to influence prices.").

<sup>8</sup> Novo Nordisk, *About Novo Nordisk*, [http://www.novonordisk.com/about\\_us/default.asp](http://www.novonordisk.com/about_us/default.asp).

Following an investigation into these distribution practices, FAS notified Novo Nordisk in September 2010 that it believed the company had violated the Competition Law (Clauses 5 and 8, Part 1, Article 10).<sup>9</sup> Specifically, FAS alleged that Novo Nordisk possessed monopoly power and that it had abused its dominant position in the insulin wholesale market by restricting its distribution network to only five partners. To remedy this harm, FAS fined Novo Nordisk 85.9 million rubles (approximately US\$3 million) and enjoined the company from engaging in similar anticompetitive limitations of its distribution network in the future.

Once FAS confirmed the initial finding, Novo Nordisk appealed the agency's decision to the Moscow Arbitrazh Court. Six months after the company filed its appeal—and on the day the hearing was scheduled to commence—the parties reached a settlement.<sup>10</sup> Pursuant to the agreement, Novo Nordisk remained subject to a fine, but the court reduced it to the minimum amount allowed, 53.5 million rubles (approximately US\$1.9 million).<sup>11</sup> More

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<sup>9</sup> The Decision and Order on the Case Against Novo Nordisk, No. AK/33869, approved by the Federal Antimonopoly Service of the Russian Federation, Oct. 6, 2011 (Russ.), *available at* [http://www.fas.gov.ru/solutions/solutions\\_31980.html](http://www.fas.gov.ru/solutions/solutions_31980.html) (with the operative part of the decision announced on September, 23, 2010 and the full decision announced on October 6, 2010).

<sup>10</sup> Press Release, Fed. Antimonopoly Serv. of the Russ. Fed'n, FAS Russia and Novo Nordisk Reached an Amicable Settlement, July 29, 2011, *available at* [http://en.fas.gov.ru/news/news\\_31575.html](http://en.fas.gov.ru/news/news_31575.html).

<sup>11</sup> *Id.* It is notable that originally FAS threatened to impose a fine that was much higher, up to 15% of the company's Russian revenues. *See, e.g.,* Reuters, *Novo Nordisk A/S To Challenge Russian Anti-Trust Charges In Court-DJ* (Sept. 27, 2010), *available at* <http://www.reuters.com/finance/stocks/NOVOB.CO/key-developments/article/1986015>.



importantly, Novo Nordisk agreed to drastically alter its distribution policy as part of the settlement. Whereas before the company could exercise discretion in selecting its distributors, now Novo Nordisk is required to accept any applicant that satisfies the precise criteria delineated in the company's distribution policy.<sup>12</sup> Distributors that fail to meet the criteria are not automatically rejected; rather, they must be told where their application was deficient and given an opportunity to remedy their shortcomings.<sup>13</sup>

*Novo Nordisk* should be regarded as a signal for future antitrust review and enforcement in Russia. As a spokesman for FAS commented following the decision, "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 cautionary tale for all other pharmaceutical companies operating in Russia."<sup>14</sup> Indeed, FAS has remained heavily involved in the pharmaceutical industry since this decision. This past April, in fact, FAS participated in discussions regarding the development of a legal regime covering competitive bidding in

pharmaceutical markets and general substitutability of medical products.<sup>15</sup>

### **The Impact of *Novo Nordisk***

To avoid drawing the sort of scrutiny that Novo Nordisk did, it is imperative that multinationals planning to operate in Russia understand the nuances of FAS's decision in that case, particularly the agency's determination that Novo Nordisk possessed monopoly power and was abusing its market position. For businesses that operate primarily in jurisdictions where the behavior deemed illegal by the Russian authorities would not have been problematic, it is particularly necessary to understand the manner in which FAS defined the market, the conduct it considered to be anticompetitive, and the likely application of the laws of other jurisdictions (including the U.S.) to similar facts.

### **Market Definition**

The threshold to satisfy the "dominance" test in Russia is fairly low. In the *Novo Nordisk* matter, FAS managed to avoid tricky math calculations by drawing an incredibly restrictive market. Rather than examine the inter-brand competition in the broad market for insulin, FAS concluded that Novo Nordisk's *own* branded drugs constituted the entire relevant market. Subsequently, the agency determined that as the only manufacturer—again, the product is patented—Novo Nordisk possessed unrestricted monopoly power with 100% of the relevant market.

Unfortunately, FAS did not elaborate on the basis for its finding. The agency simply stated that Novo Nordisk possessed 100% share in the

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<sup>12</sup> Novo Nordisk, COMMERCIAL PARTNER POLICY (2010), available at [http://www.novonordisk.ru/media/pdf/contacts/NN\\_Policy\\_with\\_Commercial\\_Partners\\_261211.pdf](http://www.novonordisk.ru/media/pdf/contacts/NN_Policy_with_Commercial_Partners_261211.pdf) (Russian language). Novo Nordisk also asks its distributors to abide by best distribution practices.

<sup>13</sup> *Id.*

<sup>14</sup> Press Release, Fed. Antimonopoly Serv. of the Russ. Fed'n, FAS Russia Fined "Novo Nordisk" Over 85 Million Rubles for Unlawfully Evading Contracts for Supplies of Medicines (Jan. 24, 2011), available at [http://en.fas.gov.ru/news/news\\_31180.html](http://en.fas.gov.ru/news/news_31180.html) (statement by Deputy Head of the Department for Control over Social Sphere and Trade, Mr. Mikhail Fedoryenko).

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<sup>15</sup> Press Release, Fed. Antimonopoly Serv. of the Russ. Fed'n, FAS Russia Proposed Criteria for Substitutability of Medical Products (Apr. 28, 2012), available at [http://en.fas.gov.ru/news/news\\_32191.html](http://en.fas.gov.ru/news/news_32191.html).



wholesale market for drugs with eptacog alfa (activated) and a 100% share in the wholesale market for Novo Nordisk-branded insulin, including NovoRapid PenFill, NovoRapid FlexPen, NovoMix 30 PenFill, NovoMix 30 FlexPen, and Levemir, among others. FAS failed to specify whether it considered other Russian insulin suppliers as potential competitors,<sup>16</sup> or whether manufacturers of branded drugs will always presumptively possess 100% market share in their own branded drugs. This complete lack of guidance from FAS should be of great concern for any business operating in Russia, as it brings into question the legality of *any* limitations imposed on distribution networks.

### ***Anticompetitive Conduct***

FAS's investigation into Novo Nordisk was centered on the company's distribution process. As part of its efforts to ensure a quality distribution network, Novo Nordisk required, beginning in 2008, that all of its distributors submit to a two-prong review. New applicants were reviewed at the time of their submission of interest, and existing partners were subject to reevaluation every two years. This review included: (1) financial and other documentary due diligence; and (2) audits of storage facilities and transportation systems.

After investigating this policy, FAS concluded that Novo Nordisk did not subject existing partners to the same level of scrutiny as it subjected new applicants. FAS relied heavily upon the fact that multiple companies had applied to distribute Novo Nordisk insulin since

2008, but that the company chose to work only with the five already-confirmed distributors. The agency gave little weight to the realities of the industry or potential reasons for Novo Nordisk's decision, including that the product was highly specialized, that Novo Nordisk could better review and monitor its distribution network with fewer participants, and that consumers would benefit from consistently safe storage and delivery practices. Rather, FAS reasoned that all of the denied applicants were licensed pharmaceutical distributors in Russia and that they, therefore, had sufficient storage and transportation experience to safely handle Novo Nordisk's products. Additionally, FAS held that by asking these already-licensed pharmaceutical distributors to go through a facilities audit, Novo Nordisk had supplanted the role of the Russian certification authorities, which have the sole authority to license qualified distributors.

Though there are numerous business justifications that justify different levels of scrutiny for existing and new distribution partners—*e.g.*, goodwill, unbroken trust, positive customer reviews—FAS refused to accept them. Instead, the agency concluded that Novo Nordisk's application review was a sham and that the policy existed only as a pretext to permit the company to unfairly limit its distribution network.

### **Comparison to the United States Standard**

The FAS decision in *Novo Nordisk* stands in stark contrast to established law in the United States. Generally, in the United States, a pharmaceutical manufacturer has great discretion when selecting the members of its distribution channel. Given the presence of other diabetes medications on the market, as well as the opportunity for rejected distributors

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<sup>16</sup> See, *e.g.*, Daniel Trecroci, *Insulin Outside America*, DIABETES HEALTH (Apr. 1, 2000), <http://www.diabeteshealth.com/read/2000/04/01/1847/insulin-outside-america> (“[I]nsulins that are used in Russia include Regular and NPH made by Eli Lilly and Novo Nordisk.”).



to work as sub-distributors, it seems unlikely that the Department of Justice or Federal Trade Commission (together, the “U.S. agencies”) would have deemed Novo Nordisk’s business conduct sufficiently anticompetitive to investigate, much less litigate.

### **Market Definition**

The antitrust laws in the United States emphasize that consumer welfare is derived primarily from inter-brand competition, *i.e.*, competition between manufacturers. So long as multiple manufacturers compete on price, quality, and other variables to earn the business of the consumer, the U.S. agencies are less concerned with ensuring that there is adequate intra-brand competition, *i.e.*, competition among distributors.

In the U.S., the determination of whether Novo Nordisk possessed monopoly power likely would have been made by reviewing inter-brand competition in the market for diabetes medications in general. Specifically, the U.S. agencies likely would have assessed Novo Nordisk’s market position relative to the firms that manufacture a competitive product—firms like Eli Lilly and Sanofi-Aventis. Then, the agencies would determine whether Novo Nordisk possessed sufficient market power to raise prices and deter innovation without losing market share to competitors. Regardless of how the market analysis was conducted, it is extremely doubtful that a U.S. agency would have proposed that the relevant market was limited to Novo Nordisk-branded insulin. If, somehow, the U.S. agency had determined that this definition were proper, it most assuredly would have provided a detailed explanation of its reasoning.

### **Refusals to Deal Under U.S. Law**

Even if the U.S. agencies’ market analysis showed that Novo Nordisk possessed monopoly

power, it remains unlikely that the firm would be required to work with any distributor meeting predetermined standards. That another firm wants to deal with a monopolist does not obligate the monopolist to deal with that firm; indeed, a bedrock principle of American antitrust policy is that businesses are free to contract with the firms of their choosing. Granted, there are limitations to this principle. As explained in *Aspen Skiing*, “[t]he high value we have placed on the right to refuse to deal with other firms does not mean that the right is unqualified.”<sup>17</sup> Any hope that distributors might have held about gleaning support from *Aspen Skiing*, however, was all but dashed by the Court’s recent opinion in *Verizon Comm’ns v. Law Offices of Curtis V. Trinko, LLP* (commonly referred to as *Trinko*), which placed *Aspen Skiing* “at or near the boundary of Section 2 liability.”<sup>18</sup> While acknowledging that a monopolist’s choice to not cooperate with rivals may, on occasion, violate the antitrust laws, the Court clearly explained that these occasions are rare: “We have been very cautious in recognizing such exceptions, because of uncertain virtue of forced sharing and the difficulty of identifying and remedying anticompetitive conduct by a single firm.”<sup>19</sup>

Even ignoring *Trinko*, the U.S. agencies would still be unable to bring a case against Novo Nordisk because of the extensive list of valid business justifications that support the decision to use a smaller distribution network. Courts have previously considered, and upheld, refusals to deal based on: (1) a manufacturer’s determination that it already has adequate

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<sup>17</sup> *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985).

<sup>18</sup> *Verizon Comm’ns v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004).

<sup>19</sup> *Id.* at 408.



distribution;<sup>20</sup> (2) a manufacturer's decision to not work with a potential new distributor;<sup>21</sup> (3) a manufacturer's attempt to impose appearance and image requirements upon distributors;<sup>22</sup> and (4) a distributor's failure to meet quality standards.<sup>23</sup>

## Conclusion

Unfortunately for Novo Nordisk, this matter was raised in Russia and not the United States. And unfortunately for other multinational corporations operating in Russia, this case is unlikely to be an outlier: representatives from FAS have noted recently that the agency is particularly concerned with dominant firms that are the exclusive provider of certain products.<sup>24</sup> To combat this, FAS has stated that it will impute dominance to any firm that positions its products as exclusive.<sup>25</sup> That this presumption ignores the benefits of exclusive arrangements and barring them could in fact lead to higher prices and less innovation does not appear to be important to FAS. What is important, apparently, is that no dominant firm be allowed the freedom to run its business as it wishes, even those firms dominant only in the products they alone manufacture.

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<sup>20</sup> See e.g., *Winn v. Edna Hibel Corp.*, 858 F.2d 1517, 1520 n.5 (11th Cir. 1988) (manufacturer has right to terminate dealer when area could not support two).

<sup>21</sup> See e.g., *Tidmore Oil Co. v. BP Oil Co.*, 932 F.2d 1384, 1389 (11th Cir. 1991).

<sup>22</sup> See e.g., *Winn*, 858 F.2d at 1520 (terminating distributor to maintain image and integrity of product).

<sup>23</sup> See e.g., *Three Movies of Tarzana v. Pac. Theatres*, 828 F.2d 1395, 1399-41 (9th Cir. 1987).

<sup>24</sup> American Conference Institute, Agenda for 4th Russia and CIS Summit on Anti-Corruption (Mar. 20-21, 2012), <http://www.americanconference.com/anticorruptionrus/agenda>.

<sup>25</sup> *Id.*