No US jurisdiction over claim by Russian pharmaceutical company for violation of US antitrust laws by Hofmann-La Roche

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F.Hoffmann-La Roche (HLR) is part of the Swiss based multinational healthcare giant Roche, which manufactures leading cancer treatment drugs Avastin, Rituxan and Herceptin. Patent protection for these substances in Russia has expired, and generic company BIOCAD was successful in launching biosimilars of HLR's originator medicines in the Russian market in years 2014-2016. Roughly at the same time, Roche sharply reduced the prices of its branded medicines imported in Russia, thus hindering BIOCAD's market entry. No other company produced biosimilar products of the Roche medicines, which was in that way able to maintain its dominance in the Russian market.

BIOCAD then filed a complaint with the Federal Antimonopoly Service (FAS), Russia's competition watchdog, against HLR arguing that the latter sold its medicines below cost with exclusionary intents. However, the FAS did not find any breach of Russian competition law by HLR and rejected the complaint.

Again roughly at the same time, HLR increased its prices for the same three products in the US. BIOCAD argued that the decrease of prices in Russia coupled with their increase in the US were connected, and that HLR had aimed at compensating losses in Russia with extra margins gained in the US, as part of a single complex anticompetitive strategy.

On June 07, 2016 BIOCAD filed an antitrust claim against HLR with the US District Court for the Southern District of New York seeking compensation of damages for anticompetitive conduct alleged to have prevented its entry into the US market. BIOCAD complained in particular of the following actions by HLR: (1) discriminating pricing policies, consisting of decreasing prices in Russia and increasing prices for the same products in USA; (2) causing or permitting its Russian distributor to sell the relevant products in Russia below cost; (3) effecting or permitting kickback payments to Russian hospitals and health professionals to stimulate sales in Russia and preclude BIOCAD's participation on a level playing field in Russian government tenders and programs; (4) limiting sales of its drug samples in the US to prevent testing of BIOCAD's biosimilar products; (5) maintaining tying schemes for its drugs sold in Russia; (6) submitting below-cost bids in Russian government tenders; (7) manipulating drug dosages to drive patients into purchasing more products.

During the US proceedings BIOCAD admitted that it was not carrying out business in the US and was not actually interfered with by HLR in the US market, but nonetheless claimed that the latter's anticompetitive actions had precluded its planned entry therein (with US patent protection for the products expiring in 2018-2019 or being due to expire soon).

The US District Court dismissed BIOCAD's action for lack of jurisdiction and held that the claim was of a foreign nature and outside the scope of US antitrust laws. BIOCAD appealed. The US Court of Appeal for the Second Circuit reviewed the case and issued its judgment on November 05, 2019.

Both the District Court's and the Court of Appeal's analysis of jurisdiction rested on the Sherman Act of 1890 and the FTAIA (Foreign Trade Antitrust Improvements Act) of 1982, which exclude from the reach of US antitrust laws activities "involving trade or commerce … with foreign nations". The Court of Appeal held that the FTAIA contemplated only two exceptions to the general rule: import trade or import commerce; and conducts having a direct, substantial, and reasonable foreseeable effect on the US domestic market. Since the actions of HLR that were the object of the suit were actions of a foreign entity (Swiss) in a foreign country (Russia), the Court held that they fell within the scope of the exceptions.

More particularly, BIOCAD had argued before the District Court that the domestic effects exception was not relevant to the case, but, when its argument based on the import trade or import commerce exception was dismissed, then BIOCAD argued before the Court of Appeal that the domestic effects exception was relevant instead. The Court of Appeal dismissed the argument, as the appellant had not provided reasons for its failure to raise it before the District Court and raised that exception for the first time on appeal. Thus, the Court of Appeal limited its review only to the import trade or import commerce exception.

The Court of Appeal then analyzed literally the language of the FTAIA, and held that "the import exclusion… would not include cases where a foreign defendant fixes the price of goods sold to a foreign intermediary, with an intent to interfere with that competitor's American business, but with no demonstrable effect of the United States" as the intended effect was too removed in the causation sequence.

Besides, the Court of Appeal dismissed BIOCAD's argument that any conduct in import trade and import commerce "intended" to affect the US domestic market should fall under the exception, as otherwise "the direct effect exception would be rendered superfluous". The Court implied that to apply the import exclusion to foreign anticompetitive conduct such as that of HLR should have an immediate effect on the US domestic market; otherwise, it could fall under the separate domestic effect exception, which though required a substantial downstream effect on domestic, import, or export commerce.

Finally, the Court turned to the purpose of the FTAIA, which is to encourage American exports, by clarifying that "the Sherman Act does not prevent them (US exporters and companies doing business outside of the USA) from entering into anticompetitive business arrangements as long as *only* foreign markets are adversely affected". As a result, the Court held that the conduct of HLR with the intent to affect the import of drugs but in the absence of a direct or immediate effect on import commerce, fell outside the scope of the import trade or import commerce exception of the FTAIA and the Sherman Act. Moreover, the Court dismissed BIOCAD's motion for injunctive relief as the Russian company had admitted having no active business in US and no violation of the Sherman Act could be predicated in consequence. Therefore, the Court of Appeal fully upheld the judgement of the District Court.

The net outcome seems to be that grounds of jurisdiction and limits to the extraterritorial reach of the US antitrust legislation, ultimately prevented the antitrust merits from being adjudged, in a case where the facts prima facie strongly pointed to anticompetitive behavior. On the other hand, BIOCAD's attempt to persuade the FAS to take antitrust action in Russia had also failed. One may wonder if the combined effect of the two legislations and procedural systems ultimately produced the right result, which – in the presence of expired patents – would arguably have been to permit Russian patients and the Russian healthcare system to benefit from greater supplies of anticancer biosimilars at a lower and more accessible cost.

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