

FILED by YA D.C.

Dec 22, 2016

STEVEN M. LARIMORE
CLERK U.S. DIST. CT.
S.D. OF FLA. - MIAMI

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

CASE NO. **16-20968-CR-MORENO/O'SULLIVAN**

18 U.S.C. § 371
15 U.S.C. § 78m(b)(2)(B)
15 U.S.C. § 78m(b)(5)
15 U.S.C. § 78ff(a)

UNITED STATES OF AMERICA

v.

**TEVA PHARMACEUTICAL
INDUSTRIES LTD.,**

Defendant.

_____ /

INFORMATION

The United States charges that, at all times relevant to this Information, unless otherwise specified:

GENERAL ALLEGATIONS

Relevant Statutory Background

1. The Foreign Corrupt Practices Act of 1977, as amended, Title 15, United States Code, Sections 78dd-1, et seq. ("FCPA"), was enacted by Congress for the purpose of, among other things, making it unlawful to act corruptly in furtherance of an offer, promise, authorization, or payment of money or anything of value, directly or indirectly, to a foreign official for the purpose of obtaining or retaining business for, or directing business to, any person. The FCPA's accounting provisions, among other things, require that any issuer make and keep books, records, and accounts that accurately and fairly reflect the transactions and disposition of the company's assets, prohibit the knowing and willful falsification of an issuer's

books, records, or accounts, and prohibit the knowing and willful failure to implement an adequate system of internal accounting controls. 15 U.S.C. §§ 78m(b)(2), 78m(b)(5), and 78ff(a).

TEVA and Relevant Entities and Individuals

2. TEVA PHARMACEUTICAL INDUSTRIES LTD. (“TEVA”) was an Israeli limited liability company with its headquarters in Petah Tikva, Israel. TEVA was the world’s largest manufacturer of generic pharmaceutical products. TEVA also manufactured patented pharmaceutical products, including Copaxone, which was used in the treatment of multiple sclerosis. TEVA owned and controlled numerous consolidated subsidiaries through which it marketed and sold pharmaceutical products in various countries around the world. TEVA’s American Depository Receipts (“ADRs”) were traded on the Nasdaq National Market from October 1987 until May 2012, when TEVA’s ADRs began to be traded on the New York Stock Exchange (“NYSE”). Accordingly, since October 1987, TEVA has been an “issuer” as that term is used in the Foreign Corrupt Practices Act (“FCPA”), Title 15, United States Code, Sections 78dd-1(a) and 78m(b).

3. Teva LLC (“Teva Russia”) was a limited liability company incorporated in the Russian Federation in 2010 and was a wholly-owned subsidiary of TEVA. Teva Russia, and its predecessor entities, operated on behalf, for the benefit, and under the control of TEVA, and was principally responsible for the sale and marketing of TEVA pharmaceutical products in Russia. Teva Russia was an “agent” of an issuer, TEVA, within the meaning of the FCPA, Title 15, United States Code, Section 78dd-1(a).

4. Teva Ukraine LLC (“Teva Ukraine”) was a limited liability company incorporated in Ukraine and was a wholly-owned subsidiary of TEVA. Teva Ukraine operated

on behalf, for the benefit, and under the control of TEVA, and was principally responsible for the sale and marketing of TEVA pharmaceutical products in Ukraine. Teva Ukraine was an “agent” of an issuer, TEVA, within the meaning of the FCPA, Title 15, United States Code, Section 78dd-1(a).

5. Lemery S.A. de C.V., Sicor de Mexico S.A., Teva Pharmaceutical Mexico S.A. de C.V., Lemery Desarrollo y Control S.A. de C.V., Inmobiliaria Lemery S.A. de C.V., IVAX Pharmaceuticals Mexico S.A. de C.V., and Vitrium Division Farmaceutica S.A. de C.V. (collectively, “Teva Mexico”) were companies incorporated in Mexico and wholly-owned subsidiaries of TEVA. Teva Mexico was principally responsible for the sale and marketing of TEVA pharmaceutical products in Mexico.

6. Teva International Group (“TIG”) was a unit of TEVA that was principally responsible for overseeing TEVA’s operations in regions outside of the United States and Western Europe, including in the Russian Federation, Ukraine, and Mexico. TIG was in operation from in or about 2002 until in or about mid-2010, at which point TEVA underwent a corporate reorganization and TIG’s responsibilities were absorbed by other TEVA units.

7. “Teva Executive,” an Israeli citizen whose identity is known to the United States and the Company, was the senior TEVA executive responsible for overseeing TIG between 2002 and 2010, and left the Company in 2014. Teva Executive was an “officer,” “director,” “employee,” and “agent” of an issuer, TEVA, within the meaning of the FCPA, Title 15, United States Code, Section 78dd-1(a).

8. “Teva Russia Executive,” a citizen of the Russian Federation whose identity is known to the United States and the Company, was a high-level executive at Teva Russia from in or about January 2006 until he left Teva Russia in or about September 2012. Teva Russia

Executive was an “agent” of an issuer, TEVA, within the meaning of the FCPA, Title 15, United States Code, Section 78dd-1(a).

9. “Russian Official,” a citizen of the Russian Federation whose identity is known to the United States and the Company, was a high-ranking government official in the Russian Federation, who held official positions on government committees. By virtue of his official position, Russian Official had the ability to influence matters related to the purchase of pharmaceutical products by the Russian government, including purchases made during annual auctions held by the Russian Ministry of Health. Russian Official was a “foreign official” within the meaning of the FCPA, Title 15, United States Code, 78dd-1(f)(1)(A).

10. “Russian Company” was a group of companies incorporated in the Russian Federation, the identity of which is known to the United States and the Company. Russian Company was a distributor, manufacturer and re-packager of pharmaceutical products in the Russian Federation. Russian Company was owned, controlled and managed by Russian Official. From at least in or about 2003 until at least 2013, Russian Company’s controlling shares were held in the name of Russian Official’s spouse, who was not involved in Russian Company’s business operations.

11. “Ukrainian Official,” a Ukrainian citizen whose identity is known to the United States and the Company, was a high-ranking official within the Ukrainian Ministry of Health, who held official positions at government agencies and on government committees from at least 2001 to 2011. By virtue of his official positions, Ukrainian Official could take official action on, and exert official influence over, matters related to the registration and pricing of pharmaceutical products in Ukraine. Ukrainian Official was a “foreign official” within the meaning of the FCPA, Title 15, United States Code, 78dd-1(f)(1)(A).

12. “Mexican Official,” a Mexican citizen whose identity is known to the United States and the Company, from at least 2005 to 2012 was a well-known and influential neurologist in Mexico who treated patients suffering from multiple sclerosis. Mexican Official was employed by an instrumentality of the Mexican government and held senior positions at hospitals and other healthcare facilities owned and controlled by that instrumentality. Mexican Official was a “foreign official” within the meaning of the FCPA, Title 15, United States Code, 78dd-1(f)(1)(A).

13. “Mexican Company,” a limited liability company incorporated in Mexico whose identity is known to the United States and the Company, was a distributor of pharmaceutical products in Mexico. In 2011 and 2012, Mexican Company was retained by Teva Mexico to distribute Copaxone to state-owned and state-managed hospitals and healthcare facilities in Mexico.

Background on TEVA International Pharmaceutical Sales

14. The manufacture, registration, distribution, sale and prescription of pharmaceuticals were highly-regulated activities throughout the world. Countries typically established regulatory schemes that required, among other things, the registration of pharmaceuticals. In certain countries, including the Russian Federation, Ukraine, and Mexico, government entities were responsible for selecting which pharmaceuticals would be purchased by government institutions or ministries and for approving which pharmaceuticals would be eligible for government reimbursement.

15. Copaxone was the brand-name of glatiramer acetate, a drug used in the treatment of multiple sclerosis, and was one of the few non-generic products sold by TEVA. A yearly prescription of Copaxone, which patients were required to take as a once-daily injection, cost up

to tens of thousands of dollars. During the relevant time period, Copaxone was TEVA's most profitable product.

The Unlawful Schemes

Overview of the Schemes

16. From 2006 through at least 2012, TEVA, through its employees and agents, together with others, agreed that TEVA would make corrupt payments to Russian Official, intending that Russian Official would use his official position and ability to influence the Russian government to purchase Copaxone through tender offers. The payments were made through the high profit margins that Russian Company earned as TEVA's repackager and distributor of Copaxone for sales to the Russian Ministry of Health pursuant to the central government's drug purchase program.

17. In addition, between 2001 and 2011, TEVA, through its employees and agents, together with others, agreed to pay and provide things of value to Ukrainian Official to corruptly influence the Ukrainian government in approving the registration of TEVA pharmaceutical products in Ukraine, which thereby allowed TEVA to market and sell its products in the country.

18. In furtherance of the schemes in Russia and Ukraine, employees and agents of TEVA sent emails through the United States. In furtherance of the improper payments in the Ukraine, TEVA caused wire transfers to be made through U.S. financial institutions.

19. TEVA marketed and sold pharmaceutical products in countries with high corruption risks, including, among other places, Mexico. Despite being aware of red flags and prior corruption-related misconduct at TEVA's subsidiary in Mexico, TEVA knowingly failed to implement an adequate system of internal accounting controls and failed to enforce the internal accounting controls it did have in place, including those requiring adequate due diligence of

distributors and other third party agents, which resulted in improper payments being made in Mexico.

20. TEVA's total profits from the conduct described above in Russia, Ukraine and Mexico, were approximately \$221,232,303.

Russian Federation

21. The Russian Federation had a socialized public healthcare system that provided universal healthcare to Russian citizens, with the cost of medical care and drug treatments shared between the central, regional and local governments. In or around late 2007, the Ministry of Health designated seven illnesses and conditions as rare and expensive to treat and created a program whereby the central government would procure and supply to patients the necessary medications for treating these illnesses and conditions. Among the covered illnesses was multiple sclerosis and treatment by Copaxone. Since in or around 2008, Russian government purchases of Copaxone were primarily made by the Ministry of Health at usually bi-annual auctions.

22. Employees of TEVA, based in Israel, and employees of Teva Russia, at the direction of Teva Executive and others, sought to increase sales of Copaxone to the Russian government, including by doing business with companies owned and controlled by Russian Official, knowing that he was a high-level Russian government official at the time.

23. On or about October 26, 2006, Teva Russia Executive emailed Teva Executive and another senior TIG Manager about a recent meeting with Russian Official, providing them with "an idea of the caliber of the person [by] citing below just a few of his formal titles and

personal achievements.”¹ Teva Russia Executive described Russian Official’s official position and explained that Russian Official was “the key lobbyist of pharma-related questions and issues” as well as a “key contact person for Knesset,” the Israeli parliament. Teva Russia Executive explained that Russian Official was the “owner of the local wholesaling company [Russian Company]” along with several other pharmaceutical companies. Teva Russia Executive’s email further noted that Russian Official’s “influence in the industry” could benefit TEVA by, among other things, allowing TEVA to obtain “more speedy and straightforward registration of products.” Teva Russia Executive cautioned, however, that “the results [of Russia’s] 2008 presidential elections can affect the status and scope of [Russian Official]’s influence.”

24. On or about October 26, 2006, Teva Executive replied to Teva Russia Executive that he “support[ed] exploring any kind of initiative which could strengthen our position in Russia.”

25. On or about February 8, 2008, Teva Russia Executive sent Teva Executive an email attaching a report about Russian Company. In a section of the report detailing Russian Company’s “management and corporate governance,” Teva Russia Executive explained that “[t]ransparency of [Russian Company] should be considered low.... Participation of [Russian Official] and probably some local government officials in the ownership structure is well-known.”

¹ Unless bracketed, all quotations appear as in the original document without corrections or indications of misspellings or typographical errors.

26. In or about early October 2008, TEVA managers, including Teva Executive, met with Russian Official and a Russian Company executive in Israel. The meeting had been arranged by Russian Company's Director of Sales and Marketing.

27. On or about October 7, 2008, Russian Company's Director of Sales and Marketing emailed Teva Executive to follow-up on matters discussed during the meeting. The email reiterated that Russian Company was "interested to participate in the delivery and distribution of Copaxone," and explained that the Russian government had already "defined" the government's order for Copaxone for 2009. The email also mentioned possible "future scenarios" that could affect the "decision making" related to Copaxone sales, reminded Teva Executive that Russian Official had had "personal involvement ... in the introduction of Copaxone and other important healthcare initiatives in Russia," and explained that "it will be beneficial for TEVA to grant the distribution of Copaxone to [Russian Company] in full or partially."

28. Between in or around October 2008 and in or around January 2009, TEVA employees, including Teva Executive, learned that the Russian Company executive was under investigation in Russia for corruption and that TEVA's risk insurance provider had decided to stop insuring transactions with Russian Company.

29. In or around late 2008 or early 2009, after the meeting and email described in Paragraphs 26 and 27, Teva Executive, Teva Russia Executive, and others agreed that TEVA would grant Russian Company the right to distribute Copaxone in Russia, intending that Russian Official would use his official position and ability to influence to increase sales of Copaxone to the Russian government. From early 2009 until in or about mid-2010, TEVA employees explored various possibilities for Russian Company to sell Copaxone.

30. On or about March 7, 2009, Russian Company's Director of Sales and Marketing emailed Teva Executive with information about a public tender for the purchase of Copaxone that had been announced by the Russian Academy of Medical Sciences ("RAMS"). The email explained that Russian Company's "top management has first hand relations with RAMS" and that the tender offered "a very good chance to push further up Copaxone positioning in Russia, since RAMS and its President have [a] significant role in influencing the opinion of medical and political stratum in Russia."

31. On or about March 8, 2009, Teva Executive forwarded the foregoing email to a senior TIG executive with the note, "[t]his is an interesting offer as this is [Russian Official]'s domain/specialty. Pls look into this and advise soonest."

32. On or about March 10, 2009, the senior TIG executive forwarded Teva Executive's email to Teva Russia Executive, who confirmed that Russian Company had "a strong position in this establishment." Teva Russia Executive explained that he was aware of the issue and was already dealing with a Russian Company employee who "reports directly to [Russian Official]." In or around mid-2009, the Russian government announced a new strategy for the Russian Federation's domestic pharmaceutical industry, known as "Pharma 2020." The goals of the new strategy involved, among other things, an import phase-out and changes to the procurement of pharmaceutical products, primarily by establishing a preference for domestic products. These changes started to apply in early 2009 and affected purchases made through the Russian government's annual procurement auction program. Under the law, as announced, repackaging of a foreign pharmaceutical product inside the Russian Federation could qualify for the domestic preference under Pharma 2020.

33. In or around mid-2010, TEVA reorganized its business and eliminated the TIG business unit. Teva Russia was put under the newly-created EMIA business unit.

34. In or around mid-2010, Teva Russia employees, including Teva Russia Executive, agreed with Russian Official and others on a plan for Russian Company to be TEVA's repackager and distributor for Copaxone sales to the Russian government. Russian Company would repackage and distribute Copaxone on behalf of TEVA. As set forth below, TEVA hoped that Russian Official would use his political network and official influence to benefit TEVA to support maintaining or increasing the amount of Copaxone sold to the Russian government.

35. In or around early August 2010, a Russian Company employee emailed Teva Russia Executive to request that Russian Company receive a larger discount on sales to a Russian government customer. On or about August 5, 2010, Teva Russia Executive forwarded the complaint to the manager of Teva Russia's Innovative Business Unit, requesting that Russian Company be granted a larger discount. The Teva Russia manager opposed giving Russian Company "any additional concessions," but Teva Russia Executive wrote back, suggesting that Teva Russia should consider the request as "the cost of building a relationship with [Russian Official]," as "this year, there was a substantial increase in the Copaxone requests from the [RAMS]," and Teva Russia "may benefit from [Russian Official's] support in other areas as well."

36. In or around late August 2010, Teva Russia employees provided a draft of the proposed Copaxone repackaging and distribution agreement between TEVA and Russian Company to TEVA employees in Israel.

37. On or about September 12, 2010, a Teva Russia executive emailed the Finance Director for TEVA's Copaxone business unit and other TEVA managers and executives in Israel

to provide the “rationale for the new scheme of Copaxone business in Russia.” The email explained that “this year the Russian Government has been continuing to interfere into pharmaceutical market functioning. Thus it has been continuing its pressure on prices especially on those products that being of high price are paid by the state budget.” The email further explained that the focus of this price pressure had been “expensive imported products paid by the government,” including Copaxone, and that the Russian government was seeking to “encourage[] competition intensification by both fast track registration of the new competing products (one was registered this summer for MS treatment and we expect it takes part in the MS tender this fall) and supporting fast development and introduction of the local glatiramoids (they call them, of course, ‘Copaxone’s generics’).” In the email, the Teva Russia executive stated that this “and some other new factors produced a serious threats for the Copaxone business in 2011.” As a result, “partnership with a robust influential local player was identified as the proper solution to the above challenges.” The email stated that the partner was “supposed to lobby Copaxone in the state tender.” He explained that Russian Company “was found as the right company capable to assure keeping Copaxone’s share and its price and even r[a]ising them both up.”

38. In his email to TEVA executives, the Teva Russia executive asked for their approval of the proposed Russian Company repackaging and distribution agreement “as soon as possible.” The email explained that “if we do not have the supply agreement approved and signed by [the] mid[dle] of this week we will encounter very real threat of losing a 100 million USD Copaxone business in 2011.”

39. On or about September 12, 2010, a Teva Russia manager emailed TEVA executives in Israel with additional information supporting Teva Russia’s request. The email

noted that Russian Company was headed by Russian Official, listed Russian Official's official positions on various government committees, and explained that "the plan" was to use Russian Official's contacts, including at the Ministry of Health, to maintain Copaxone's share of the market, including by minimizing the risk that a generic version of Copaxone would be approved by the Russian government, thereby reducing TEVA's market share.

40. On or about September 12 and 13, 2010, Teva Russia Executive sent emails to senior TEVA executives in Israel requesting them to sign off on the agreement with Russian Company immediately.

41. On or about September 14, 2010, a Teva Russia senior manager emailed Teva Russia Executive and described a meeting he had just had with Russian Official. The email said that Russian Official had told him that the Minister of Health "had returned from a vacation and asked in the morning if there was a confirmation that the entire project ... would take place." The email explained that Russian Official was concerned that TEVA would refuse to approve the agreement with Russian Company, and that Russian Official had threatened that "both the price and the supply volumes would be purposefully 'lowered' if a partnership with him was not established."

42. On or about September 15, 2010, TEVA executives agreed to enter into the Copaxone repackaging and distribution agreement with Russian Company.

43. On or about October 7, 2010, Teva Russia's Legal Director initiated the internal process to formally enter into the agreement with Russian Company. Consistent with TEVA's anti-corruption policy as it related to third-party agreements, the Legal Director submitted a completed questionnaire about the Russian Company agreement to TEVA for review and approval. In transmitting the materials, the Legal Director stated that the "deal value is about

US\$ 100 million for 2011 sales” and asked for immediate review, calling the deal “rather urgent.” The email and supporting information stated that Russian Official’s wife was the owner of the company but did not include that Russian Official ran the business. The email also omitted facts known to Teva Russia Executive and other Teva Russia employees, including details about the corruption investigation by Russian authorities against the Russian Company executive and information from Russian news media reports on Russian Official’s alleged involvement in corruption related to Russian government drug procurement auctions going back to 2006.

44. On or about October 8, 2010, a TEVA Finance Department manager with responsibility for approving compliance-related requests for the EMIA region directed a Finance employee to forward the compliance questionnaire concerning the Russian Company agreement to the Regional Compliance Officer and to Teva Russia’s CFO for, among other things, due diligence to be conducted.

45. On or about October 9, 2010, in response to an inquiry about the status of due diligence on Russian Company, a senior EMIA executive sent an email to another high-ranking EMIA executive explaining that Teva Russia Executive would be leading the due diligence process. As set forth above, at the time, Teva Russia Executive had been pushing for the agreement between Teva Russia and Russian Company.

46. On or about October 21, 2010, the EMIA Regional Compliance Officer approved the agreement between TEVA and Russian Company.

47. On or about October 28, 2010, TEVA executed the framework agreement with Russian Company, which included granting Russian Company the right to repackage and distribute Copaxone in the Russian Federation as well as an incentive agreement with payments

tied to increasing sales targets. At the same time TEVA entered into the distribution agreement with Russian Company, TEVA terminated an agreement with the Russian company that had distributed Copaxone at several prior Ministry of Health auctions and agreed to pay that company a substantial “bonus” payment as part of the termination.

48. On or about November 12, 2010, the Russian Ministry of Health awarded Russian Company the contract to supply the Russian government with glatiramer acetate for its tender.

49. On or about December 13, 2010, a Teva Russia executive communicated via email with a senior manager at Russian Company regarding matters related to the recently-awarded contract to supply Copaxone to the Russian government.

50. On or about December 30, 2010, Teva Russia Executive emailed a senior EMIA executive about a meeting the executive was scheduled to have with Russian Official. In preparing the executive for the meeting, Teva Russia Executive explained Russian Official’s position and influence in the Russian government and stated that the “state channel is a key one for his businesses.” Teva Russia Executive explained that “the dilemma [Russian Official] faces is how to protect his positions under conditions when state funded business in Russia is becoming transparent.” Among other things, Teva Russia Executive asked the senior EMIA executive to “push [Russian Official] to demand more funding for Copaxone [] in early 2011” and to “obtain his commitment in protecting Copaxone (access to the Minister [of Health] and [Ministry of Health] decision makers, leveraging Senate capabilities).”

51. On or about January 2, 2011, the senior EMIA executive emailed Teva Russia Executive about his meeting with Russian Official, stating that Russian Official “strongly encourages us to strengthen our influence with Regional Government Neurologist Representatives, to ensure in the future Copaxone volumes are protected.”

52. On or about January 24, 2012, Russian Company was awarded another contract by the Russian Ministry of Health to supply the government with Copaxone.

53. TEVA terminated its repackaging and distribution relationship with Russian Official and Russian Company in the middle of 2013 as a result of Russian Company's refusal to follow TEVA's due diligence procedures.

54. During the time that Russian Company was TEVA's repackager and distributor for Copaxone, TEVA earned profits of approximately \$204,167,303 on sales made by Russian Company to the Russian government.

Ukraine

55. Ukraine had a socialized healthcare system, with the national Ministry of Health coordinating the provision of healthcare to its citizens with regional and local counterparts. Most healthcare services were provided through government-owned healthcare facilities. Pharmaceutical products were regulated by agencies under the Ukrainian Ministry of Health. In Ukraine, drugs were permitted for marketing and sale in Ukraine only after registration by the state, which included clinical testing and examination as part of the approval process. In Ukraine, medications for certain socially significant or especially serious illnesses, including multiple sclerosis, were dispensed free by the government.

56. During the relevant time period, Ukrainian Official held senior positions within the agencies under the Ukrainian Ministry of Health responsible for registering and approving drugs for marketing and sale in Ukraine. In those official positions, Ukrainian Official had the ability to influence the Ukrainian government's decision to approve the registration of pharmaceutical products.

57. TEVA operated directly in Ukraine until in or around 2007, at which time TEVA began operating through subsidiaries, including Teva Ukraine in 2010.

58. In or around August 2001, TEVA, through its employees and agents, engaged Ukrainian Official as a third-party “registration consultant” and entered into consulting agreements to pay Ukrainian Official a monthly “consultancy fee.” In addition to the monthly payments, TEVA, through its employees and agents, provided Ukrainian Official with cash bonuses, travel expenses and other things of value. The consulting agreement between TEVA and Ukrainian Official was renewed annually, on the same terms, until in or around late 2011.

59. The payments under the agreements between TEVA and Ukrainian Official were made for the purpose of inducing Ukrainian Official to use his official position within the Ukrainian government to improperly influence the registration of TEVA pharmaceutical products in Ukraine.

60. On or about May 26, 2003, an invoice prepared at Ukrainian Official’s direction asked TEVA “to transfer to me by cash \$15,000 as the follow-up fee payment for registration of Insulins in Ukraine.”

61. On or about June 8, 2003, TEVA entered into an agreement extending Ukrainian Official’s engagement. The agreement was signed by Teva Executive on behalf of TEVA.

62. On or about May 24, 2004, an invoice prepared at Ukrainian Official’s direction asked TEVA “to transfer to me by cash \$20,000 as the last follow-up payment for registration of Insulins in Ukraine after reception of Registration certificate.”

63. On or about March 26, 2006, the TIG manager responsible for approving expenses related to the agreement between TEVA and Ukrainian Official approved a request that TEVA pay for Ukrainian Official’s travel expenses to Israel. The request stated that Ukrainian

Official “is a great help to us in the promotion of Copaxone and insulins in the Ukrainian market. One way we can repay him is by financing his visits to Israel once a year.” The approved request included approximately \$4,400 worth of travel expenses for Ukrainian Official and his wife.

64. On or about October 5, 2006, an invoice prepared at Ukrainian Official’s direction asked TEVA to “transfer to my [] account \$10,000 for the expenses of Copaxone registration in Ukraine.” The TEVA employee responsible for making the payment identified the amount as a “Bonus for Copaxone registration.”

65. In or around January 2008, TEVA, through Teva Ukraine, sought registration of one of its products from the Ukrainian governmental authority responsible for the registration of pharmaceutical products. Teva Ukraine’s submission was addressed and sent to Ukrainian Official, who was then a high-level official at the governmental authority.

66. On or about April 24, 2008, Ukrainian Official was appointed by the President of Ukraine to become the Deputy Chairman of a Ukrainian government committee responsible for issues of “price-formation for drugs and other medicinal products, public purchases and drugs registration.”

67. On or about June 29, 2008, an invoice prepared at Ukrainian Official’s direction asked TEVA to “transfer to my [] account \$10,000 for the expenses of Copaxone promotion in the Ukraine.”

68. On or about July 21, 2008, TEVA sent a wire transfer totaling \$10,000 through an intermediary bank account in New York, which was subsequently paid onward to a bank account in Ukraine held by Ukrainian Official.

69. On or about May 20, 2009, an invoice prepared at Ukrainian Official's direction requested payment for \$16,500 as a "consultancy fee" from TEVA for September 2008 through June 2009.

70. On or about June 25, 2009, TEVA sent a wire transfer totaling \$16,500 through an intermediary bank account in New York which was subsequently paid onward to an account in Ukraine held by Ukrainian Official.

71. TEVA stopped paying Ukrainian Official at the end of 2009. Thereafter, Teva Ukraine took over payments to Ukrainian Official under the agreement until the expiration of the agreement until March 2011.

72. From in or around June 2002 through approximately March 2011, TEVA and Teva Ukraine paid cash and provided other things of value to Ukrainian Official worth a total of approximately \$200,000.

TEVA's Failure to Implement Adequate Internal Accounting Controls in Mexico

73. At all relevant times, TEVA marketed and sold pharmaceutical products in countries with high corruption risks, including, among other places, Mexico. Despite understanding the nature of the corruption risks presented by doing business in Mexico and awareness of red flags and prior corruption-related misconduct at TEVA's subsidiary in Mexico, TEVA knowingly and willfully failed to implement an adequate system of internal accounting controls and failed to enforce the internal accounting controls it did have in place, which in turn failed to prevent improper payments from being made in Mexico.

74. For example, in or around 2011 and 2012, Teva Mexico, through its executives, employees and agents, used its third-party distributor, Mexican Company, to make payments to physicians and other healthcare providers (collectively "HCPs"). Some of the HCPs paid by

Mexican Company had received payments from Teva Mexico and its predecessor entities in exchange for prescribing Copaxone since at least 2005. The existence and improper nature of these payments was known to TEVA executives who were responsible for developing and approving the Company's anti-corruption internal controls in 2009.

75. On or about November 6, 2008, Mexican Official emailed a TEVA employee responsible for the Copaxone business to complain about Teva Mexico's failure to make certain payments. Mexican Official wrote, "Teva Mexico was promises promises & promises and there was never any interest in order to improve our relationship." Mexican Official said the lack of payment was "really strange when I'm your best client in Mexico." In the email, Mexican Official noted that he was prescribing Copaxone to approximately 170 patients, making him one of the largest prescribers in the region. On or about November 12, 2008, the email was forwarded to Teva Executive, who then emailed a senior Teva Mexico executive, "I'd appreciate having your good inputs and trust that [Mexican Official's] problem can be resolved. After all, [it's] not every day we get a complaint from a professor that has 170 Copaxone patients."

76. In or around December 30, 2008, the senior Teva Mexico executive emailed Teva Executive and explained, "[t]he growth of Copaxone in this market, until very recently, was not due to scientific/academic support but mostly to other incentives." These "other incentives," which included payments in exchange for prescribing Copaxone, were paid out of Teva Mexico's Copaxone marketing and promotions budget.

77. Numerous TEVA executives involved in developing, approving and implementing the Company's anti-corruption program, including Teva Executive, were aware that the policies and procedures they approved were not adequate to prevent or detect improper payments to foreign officials. These executives also understood that the internal controls were

not adequate to meet the risks posed by TEVA's business and, indeed, had intended such a result.

78. TEVA executives also put in place managers to oversee the compliance function who were unable or unwilling to enforce the Company's anti-corruption policies. For example, on or about January 17, 2011, at a meeting of the Company's compliance team that oversaw Teva Mexico, while discussing whether the compliance department would approve certain payments, the Regional Compliance Officer expressed an opinion that "Compliance[']s role will be [to] not interfere with the ultimate decision made by Business Heads." During this same time period, the Regional Compliance Officer also "emphasized that the compliance program, current local policy and Sales and Marketing guidelines were not relevant for the [Latin America] region and were to be ignored."

79. On or about April 12, 2011, a TEVA employee responsible for overseeing the implementation of the anti-corruption controls emailed a senior executive responsible for overseeing compliance in Latin America. The email explained that a senior TEVA executive had "specifically instructed not to implement a robust system that will enable us to monitor and assure that the same doctor wasn't invited to a meal more than three times (for example)" and that the purpose of a system to track payments was "mainly to automate the manual forms."

80. In or around early 2011, TEVA reduced the budget for marketing and promotion of Copaxone in various countries, including Mexico. As a result, Teva Mexico no longer had sufficient funds to pay the government HCPs to whom it had been making payments. In or around early 2011, after the reduction in their marketing and promotions budget, employees in the Teva Mexico group responsible for sales of Copaxone agreed to continue the payments to the

government HCPs in the form of cash payments made by Mexican Company, which was a Teva Mexico distributor for sales of Copaxone to government institutions.

81. On or about November 15, 2011, a TEVA employee with responsibility for financial controls over Teva Mexico prepared a memorandum detailing perceived deficiencies in the internal accounting controls for TEVA operations in Latin America. The memorandum concluded: “[w]e cannot guarantee that we are not (1) executing payments that would violate FCPA anti-bribery provisions and (2) properly accounting for any such payments under the books and records provision of the FCPA.”

82. In or around January 2012, employees of Teva Mexico met with employees of Mexican Company, and agreed to provide Mexican Company with an additional margin of 2% on sales by Mexican Company to its government customers. The purpose of the 2% margin was to pay the government HCPs in exchange for their writing prescriptions of Copaxone.

83. Between on or about February 16, 2012 and March 6, 2012, using the additional margins provided under the agreement with Teva Mexico, a Mexican Company employee delivered cash payments to at least seven HCPs employed by Mexican state-owned or state-managed hospitals and healthcare facilities.

84. On or about March 15, 2012, a Mexican Company employee emailed a Teva Mexico employee with “a report as to how the delivery to the physicians was made.” In the email, the Mexican Company employee detailed the time and place of the improper payments, including approximately \$30,000 paid to Mexican Official at Mexican Official’s office on or about the morning of February 17, 2012. In total, the Mexican Company employee’s email detailed approximately \$159,000 in cash payments to the government HCPs. Teva Mexico

described these improper payments, funded through the provision of the additional 2% margin to Mexican Company, as legitimate reductions of revenue in its books and records.

85. Prior to engaging Mexican Company as a distributor, Teva Mexico conducted no due diligence on Mexican Company, did not have a written distribution agreement in place, did not require Mexican Company to certify its compliance with TEVA's anti-corruption policies, and knew there was no legitimate purpose for an increased margin Mexican Company had received on sales to Mexican government customers.

COUNT ONE
(Conspiracy to Violate the FCPA)

86. Paragraphs 1 through 85 are realleged and incorporated by reference as though fully set forth herein.

87. From at least in or around 2001 through at least in or around 2012, in the Southern District of Florida and elsewhere, TEVA, the defendant, together with Teva Executive, Teva Russia Executive, Russian Company, and others known and unknown to the United States, willfully and knowingly did combine, conspire, confederate, and agree together and with each other to commit offenses against the United States, that is, as an issuer, to make use of the mails and means and instrumentalities of interstate commerce corruptly in furtherance of an offer, payment, promise to pay, and authorization of the payment of any money, offer, gift, promise to give, and authorization of the giving of anything of value to a foreign official and to a person, while knowing that all or a portion of such money and thing of value would be and had been offered, given, and promised, directly and indirectly, to a foreign official, for purposes of: (i) influencing acts and decisions of such foreign official in his or her official capacity; (ii) inducing such foreign official to do and omit to do acts in violation of the lawful duty of such official; (iii)

securing any improper advantage; and (iv) inducing such foreign official to use his or her influence with a foreign government and agencies and instrumentalities thereof to affect and influence acts and decisions of such government and agencies and instrumentalities, in order to assist TEVA in obtaining and retaining business for and with, and directing business to, TEVA and others, in violation of Title 15, United States Code, Section 78dd-1(a).

Object of the Conspiracy

88. The object of the conspiracy was to secure sales with foreign government agencies, including the Russian Ministry of Health, by making improper payments and giving other things of value to foreign officials who agreed to use their official positions to influence their governments with respect to TEVA products.

Manner and Means of the Conspiracy

89. The manner and means by which TEVA and its coconspirators sought to accomplish the purposes of the conspiracy included, among other things, the following:

a. TEVA, through certain of its employees and agents, sought to have TEVA enter into a distribution agreement with Russian Company intending that Russian Official would exercise his influence to increase Copaxone sales.

b. Employees and agents of TEVA concealed negative information about Russian Company when TEVA was undertaking due diligence, including information about Russian Official's alleged involvement in corruption related to Russian government drug procurement auctions.

c. TEVA, through its employees and agents, entered into an agreement with Russian Company whereby Russian Company became TEVA's repackager and distributor of Copaxone in sales of the drug to the Russian government.

d. TEVA, through its employees and agents, together with others, paid or caused to be paid more than \$65 million in profits to Russian Company in connection with sales of Copaxone to the Russian government, intending that some or all of the monies be given to Russian Official and others.

e. TEVA, through its employees and agents, entered into consulting agreements with Ukrainian Official, and later caused Teva Ukraine to enter into a consulting agreement with Ukrainian Official, under which TEVA (and later Teva Ukraine) made payments and provided things of value to Ukrainian Official to induce Ukrainian Official to corruptly influence the Ukrainian government in approving the registration of TEVA pharmaceutical products, thereby allowing TEVA to market and sell its products in the country.

Overt Acts

90. In furtherance of the conspiracy and to achieve its purpose and object, at least one of the coconspirators committed, and caused to be committed, in the United States, and elsewhere, the following overt acts, among others:

a. On or about October 7, 2008, Russian Company's Director of Sales and Marketing sent an email to Teva Executive memorializing a recent meeting with Russian Official and others, which explained that "it will be beneficial for TEVA to grant the distribution of Copaxone to [Russian Company] in full or partially."

b. On or about March 8, 2009, Teva Executive sent an email to Teva Russia Executive, an executive of the Teva Russia, and others, instructing Teva Russia Executive to explore entering into an agreement with Russian Company to sell Copaxone in an upcoming Russian government tender.

c. On or about August 5, 2010, Teva Russia Executive sent an email to an employee of Teva Russia instructing him to grant Russian Company an increased profit margin on sales of Copaxone to the Russian government, explaining that this should be considered “the cost of building a relationship with [Russian Official].”

d. In or around late August 2010, Teva Russia employees provided a draft of the proposed Copaxone distribution agreement between TEVA and Russian Company to TEVA employees in Israel.

e. On or about September 12, 2010, a Teva Russia manager emailed TEVA executives in Israel with additional information about the proposed distribution agreement, noting that Russian Company was headed by Russian Official, listing the official positions held by Russian Official on various government committees, and explaining that “the plan” was to use the official positions held by Russian Official to maintain Copaxone’s share of the market.

f. On or about October 28, 2010, TEVA executed the framework agreement with Russian Company, which included granting Russian Company the right to distribute Copaxone in the Russian Federation as well as an incentive agreement with payments tied to increasing sales targets.

g. On or about December 13, 2010, a Teva Russia executive communicated via email with a senior manager at Russian Company regarding matters related to the recently-awarded contract to supply Copaxone to the Russian government.

h. On or about December 30, 2010, Teva Russia Executive emailed a senior EMIA executive about a meeting the executive was scheduled to have with Russian Official. Among other things, Teva Russia Executive asked the executive to “push [Russian Official] to demand more funding for Copaxone [] in early 2011” and to “obtain his commitment in

protecting Copaxone (access to the Minister [of Health] and [Ministry of Health] decision makers, leveraging Senate capabilities).”

i. On or about July 21, 2008, TEVA wired \$10,000 from TEVA’s bank account in Israel through an intermediary bank account in New York, which was subsequently paid onward to a bank account in Ukraine held by Ukrainian Official.

j. On or about June 25, 2009, TEVA wired \$16,500 from TEVA’s bank account in Israel through an intermediary bank account in New York, which was subsequently paid onward to a bank account in Ukraine held by Ukrainian Official.

All in violation of Title 18, United States Code, Section 371.

COUNT TWO
(Violation of the Internal Controls Provisions of the FCPA)

91. Paragraphs 1 through 85 and 87 through 90 are realleged and incorporated by reference as though fully set forth herein.

92. From in or around 2005, and continuing through in or around 2013, in the Southern District of Florida and elsewhere, the defendant,

TEVA PHARMACEUTICAL INDUSTRIES LTD.,

knowingly and willfully failed to implement a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions were executed in accordance with management’s general or specific authorization; (ii) transactions were recorded as necessary to (A) permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (B) maintain accountability for assets; (iii) access to assets was permitted only in accordance with management’s general or specific authorization; and (iv) the recorded accountability for assets was compared with the

existing assets at reasonable intervals, and appropriate action is taken with respect to any differences, to wit: the defendant knowingly and willfully failed to implement, among other internal accounting controls, controls that: (a) required adequate due diligence for the retention of third-party consultants and agents; (b) required a fully executed contract with a third-party before payment could be made to it; (c) required documentation or other proof that services had been rendered by a third-party before payment could be made to it; or (d) implemented oversight of the payment process to ensure that payments were made pursuant to appropriate controls, including those described above.

All in violation of Title 15, United States Code, Section 78m(b)(2)(B), 78m(b)(5), and 78ff(a).

ANDREW WEISSMANN
Chief, Fraud Section

BY: 

ROHAN A. VIRGINKAR
JOHN-ALEX ROMANO
Trial Attorneys, Fraud Section
Criminal Division
United States Department of Justice
1400 New York Ave., N.W.
Washington, D.C. 20005
(202) 598-2253

UNITED STATES OF AMERICA

CASE NO. 16-CR-20968 Moreno/O'Sullivan

vs.

CERTIFICATE OF TRIAL ATTORNEY*

**TEVA PHARMACEUTICAL
INDUSTRIES LTD.,**

Defendant.

Superseding Case Information:

Court Division: (Select One)

New Defendant(s) Yes No
 Number of New Defendants _____
 Total number of counts _____

Miami Key West
 FTL WPB FTP

I do hereby certify that:

- I have carefully considered the allegations of the indictment, the number of defendants, the number of probable witnesses and the legal complexities of the Indictment/Information attached hereto.
- I am aware that the information supplied on this statement will be relied upon by the Judges of this Court in setting their calendars and scheduling criminal trials under the mandate of the Speedy Trial Act, Title 28 U.S.C. Section 3161.
- Interpreter: (Yes or No) No
 List language and/or dialect _____
- This case will take 0 days for the parties to try.
- Please check appropriate category and type of offense listed below:

(Check only one)		(Check only one)
I 0 to 5 days	<input checked="" type="checkbox"/>	Petty <input type="checkbox"/>
II 6 to 10 days	<input type="checkbox"/>	Minor <input type="checkbox"/>
III 11 to 20 days	<input type="checkbox"/>	Misdem. <input type="checkbox"/>
IV 21 to 60 days	<input type="checkbox"/>	Felony <input checked="" type="checkbox"/>
V 61 days and over	<input type="checkbox"/>	

- Has this case been previously filed in this District Court? (Yes or No) No
 If yes: Judge: Case No. _____
 (Attach copy of dispositive order)
 Has a complaint been filed in this matter? (Yes or No) No
 If yes: Magistrate Case No. _____
 Related Miscellaneous numbers: _____
 Defendant(s) in federal custody as of _____
 Defendant(s) in state custody as of _____
 Rule 20 from the District of _____
 Is this a potential death penalty case? (Yes or No) No

- Does this case originate from a matter pending in the Northern Region of the U.S. Attorney's Office prior to October 14, 2003? Yes No
- Does this case originate from a matter pending in the Central Region of the U.S. Attorney's Office prior to September 1, 2007? Yes No


 ROHAN A. VIRGINKAR
 TRIAL ATTORNEY, DEPT OF JUSTICE
 CRIMINAL DIVISION

*Penalty Sheet(s) attached

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

PENALTY SHEET

Defendant's Name: Teva Pharmaceutical Industries Ltd.

Case No: 14-CR-20968 Moreno / O'Sullivan

Count #: 1 Conspiracy to Violate the Foreign Corrupt Practices Act
18 U.S.C. § 371

*Max. Penalty: Fine of up to \$500,000 or Twice the Gross Gain

Count #: 2 FCPA – Failure to Implement Internal Controls
15 U.S.C. §§ 78m(b)(2)(B), 78m(b)(5), and 78ff(a)

*Max. Penalty: Fine of up to \$25,000,000 or Twice the Gross Gain

Count #:

*Max. Penalty: _____

Count #:

*Max. Penalty: _____

Count #:

*Max. Penalty: _____

*Refers only to possible term of incarceration, does not include possible fines, restitution, special assessments, parole terms, or forfeitures that may be applicable.

AO 455 (Rev. 01/09) Waiver of an Indictment

UNITED STATES DISTRICT COURT

for the
Southern District of Florida

United States of America)
v.)
Teva Pharmaceutical Industries Ltd.)
Defendant)

Case No. 16-CR-20968 Moreno/O'Sullivan

WAIVER OF AN INDICTMENT

I understand that I have been accused of one or more offenses punishable by imprisonment for more than one year. I was advised in open court of my rights and the nature of the proposed charges against me.

After receiving this advice, I waive my right to prosecution by indictment and consent to prosecution by information.

Date: 12/22/2016

TEVA PHARMACEUTICAL INDUSTRIES, LTD by
Defendant's signature

Signature of defendant's attorney

Martin J. Weinstein

Printed name of defendant's attorney

Judge's signature

Judge's printed name and title