

United States Courts
Southern District of Texas
FILED

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

July 24, 2024

Nathan Ochsner, Clerk of Court

UNITED STATES OF AMERICA

v.

SANJAY KUMAR,

Defendant.

CR. NO. 4:24-cr-00385

18 U.S.C. §§ 2320(a)(4) and (b)(3)(A)

INDICTMENT

THE GRAND JURY CHARGES:

COUNT 1

(Conspiracy to Traffic in Counterfeit Goods)

A. INTRODUCTION

At all times material to this Indictment:

1. The United States Food and Drug Administration (“FDA”) was the agency charged with protecting the health and safety of the American public by ensuring, among other things, that drugs sold for administration to humans bear labels containing true and accurate information. The FDA’s responsibilities include regulating the distribution and labeling of prescription drugs shipped or received in interstate and foreign commerce.

2. Under the Food, Drug and Cosmetic Act (FDCA), the definition of a “drug” includes articles which (1) are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man, and (2) are intended to affect the structure or function of the body of man. Due to their toxicity and other potential harmful effects, certain drugs are not considered safe for use except under the supervision of a practitioner licensed by law to administer such drugs. These drugs are known as prescription drugs.

3. Keytruda was a prescription oncology drug that was approved by the FDA for distribution within the United States. Keytruda is a humanized antibody used in cancer immunotherapy that treats melanoma, lung cancer, head and neck cancer, Hodgkin lymphoma, stomach cancer, cervical cancer, and certain types of breast cancer. It is administered by slow intravenous injection.

4. The U.S. Patent and Trademark Office (USPTO) was an agency of the United States that, among other functions, examined and registered trademarks. A trademark is a word, name, symbol or device that is intended to identify and distinguish one producer's goods from those manufactured or sold by others and to indicate the source of the goods so that consumers are not confused about the source of the goods.

5. Merck Sharp & Dohme LLC formerly known as Merck Sharp & Dohme Corp. ("Merck") had the exclusive right to authorize the manufacture of Keytruda for distribution within the United States. The following trademarks were owned by Merck and were registered on the principal register in the United States Patent and Trademark Office.

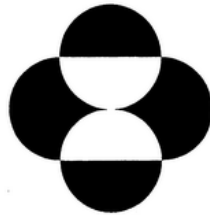
6. The trademark KEYTRUDA was registered under Registration Number 4,263,031. The word mark consists of standard characters without claim to any particular font style, size, or color and is registered for pharmaceutical preparations for the prevention and treatment of cancer.

7. The trademark MERCK was registered under Registration Number 2,169,031. The word mark consists of standard characters without claim to any particular font style, size, or color and is registered for a full line of pharmaceuticals.

8. The trademark MSD was registered under Registration Number 922,205. The trademark partly consists of the literal element “MSD” and is registered for human medicinal, pharmaceutical, and biological preparations for internal and topical medical use. The trademark is stylized as follows:

MSD

9. The trademark MSD Logo was registered under Registration Number 1,973,165. The MSD logo trademark consists of four overlapping, partially shaded circles and is registered for a full line of pharmaceuticals for human and veterinary use. The trademark is stylized as follows:



B. CO-CONSPIRATORS AND OTHER INDIVIDUALS

10. Sanjay Kumar (“KUMAR”), defendant herein, was an Indian national who sold counterfeit pharmaceutical products from Chandigarh, India.

11. Unindicted Co-Conspirator 1 (“UCC-1”) was an Indian national and KUMAR’s partner who sold counterfeit pharmaceutical products from Chandigarh, India.

12. An individual (“Person 1”) was KUMAR’s wife. Person 1 was registered to a bank (“Bank 1”) account ending in 6604 (“Account 1”). KUMAR was listed as the joint holder on Account 1.

13. An individual (“Person 2”) was KUMAR’s brother and was registered to an account at Bank 1 that was used to receive funds from customers in the United States.

C. THE CONSPIRACY

14. From in or around August 2018 until on or about June 26, 2024, in the Houston Division of the Southern District of Texas and elsewhere,

SANJAY KUMAR,

defendant herein, did intentionally, unlawfully, and knowingly conspire with others known and unknown to the Grand Jury, including UCC-1, to commit an offense against the United States, namely: To intentionally traffic and attempt to traffic in drugs and knowingly use a counterfeit mark, that is, the Merck marks with Registration Numbers 4,263,031, 2,169,031, 922,205, and 1,973,165, as described above, on or in connection with such drugs, in violation of Title 18, United States Code, Sections 2320(a)(4) and (b)(3)(A).

D. OBJECT OF THE CONSPIRACY

15. It was an object of the conspiracy for the defendant and his co-conspirators to unlawfully enrich themselves by selling counterfeit pharmaceutical drug products that bore counterfeit marks.

E. MANNER AND MEANS OF THE CONSPIRACY

The manner and means of the conspiracy included, but were not limited to the following:

16. It was part of the conspiracy that KUMAR and his co-conspirators would and did knowingly sell counterfeit pharmaceuticals to United States customers.

17. It was part of the conspiracy that KUMAR and his co-conspirators would and did arrange for the shipment, into the United States, of counterfeit pharmaceutical drug products not manufactured for the U.S. market nor approved by the FDA.

18. KUMAR and his co-conspirators would and did accept wire transfers as payment for the shipments of counterfeit pharmaceuticals that they sent to United States customers.

19. The pharmaceuticals were counterfeit in that they were packaged in boxes with labels that falsely represented the contents to be genuine Merck/MSD brand Keytruda. The boxes bore counterfeit versions of the Merck trademarks described above. Neither KUMAR nor any other member of the conspiracy had any authorization or license from Merck to use its registered trademarks or manufacture, make, sell, or traffic in Keytruda.

20. Defendant and UCC-1 negotiated sales of counterfeit pharmaceuticals with one or more agents of the United States acting in an undercover capacity (UCA-1). UCA-1 texted with members of the conspiracy concerning the placement of orders, payments, and shipments of pharmaceuticals to the United States. UCA-1 held themselves out as a buyer not working for law enforcement.

21. Defendant and UCC-1 negotiated sales of counterfeit pharmaceuticals with one or more agents of a private company (PC-1) working in part and at times on behalf of UCA-1. Beginning in and around August 2018, PC-1 texted with members of the conspiracy concerning the placement of orders, payments, and shipments of pharmaceuticals to the United States. PC-1 held itself out as a buyer not working with law enforcement.

22. The co-conspirators completed sales with UCA-1 and PC-1 on several occasions and received tens of thousands of dollars from UCA-1 and PC-1. KUMAR also sold counterfeit Adcetris and Opdivo, which are other prescription oncology drugs, to UCA-1.

F. OVERT ACTS

23. In furtherance of the conspiracy and to affect the objects thereof, the following Overt Acts, among others, were committed in the Southern District of Texas and elsewhere.

24. In or around December 2019, UCC-1 negotiated with UCA-1 the sale of one purported 50 mg vial of Keytruda to UCA-1 for approximately \$2,750.

25. In or around December 2019, UCC-1 instructed UCA-1 to wire approximately \$2,750 to Account 1 for the order.

26. In or around December 2019, UCC-1 arranged for the shipment of the purported Keytruda to Houston, Texas. UCA-1 received one 50 mg vial of Keytruda in Houston, Texas. Merck analyzed the purported Keytruda sold by UCC-1 and determined it to be chemically inconsistent with genuine Keytruda. This purported Keytruda sold by UCC-1 was packaged in a box bearing the four Merck trademarks described above.

27. On or about January 3, 2019, after UCA-1 received the 50 mg vial of purported Keytruda from the December 2019 order, and after UCA-1 then informed UCC-1 that a “doctor” in the United States advised UCA-1 that the purported Keytruda was counterfeit and that UCC-1 should not sell it, UCC-1 responded, “Yes sir I understand that.”

28. On or about January 9, 2020, UCC-1 negotiated with PC-1 the sale of one 50 mg and one 100 mg vial of purported Keytruda to PC-1 for approximately \$6,700.

29. On or about January 9, 2020, UCC-1 instructed PC-1 to wire transfer a total of approximately \$6,700 to two bank accounts in India for the January 2020 order: Account 1 and a Bank 1 account in the name of Person 2.

30. In or around January 2020, UCC-1 arranged for the shipment of the two vials of purported Keytruda. On or about January 30, 2020, PC-1 received one 50 mg and one 100 mg vial of purported Keytruda. The 50 mg vial of purported Keytruda UCC-1 sold to UCA-1 in or about December 2019—that UCA-1 had informed UCC-1 was counterfeit—and the 50 mg vial of purported Keytruda UCC-1 sold to PC-1 in or about January 2020 used the same German-language packaging and bore the same lot number and expiry date. Merck analyzed this 50 mg vial of purported Keytruda sold by UCC-1 in or around January 2020 and determined it to be chemically inconsistent with genuine Keytruda. This

purported Keytruda sold by UCC-1 was packaged in a box bearing the four Merck trademarks described above.

31. In or around March 2022, KUMAR negotiated with PC-1 the sale of one 100 mg vial of purported Keytruda and 50 mg of purported Adcetris to PC-1 for approximately \$8,597.

32. In or around March 2022, KUMAR instructed PC-1 to wire a total of approximately \$8,597 for the order to a third party.

33. In or around April 2022, KUMAR arranged for the shipment of the purported Keytruda and Adcetris to Houston, Texas. KUMAR was the listed shipper on the parcel and Person 1 was the receiver of the parcel. U.S. Customs and Border Patrol (CBP) seized the package on or about April 21, 2022. This purported Keytruda and Adcetris sold by KUMAR were analyzed, and both were found to lack the active ingredients contained in the legitimate drugs. This purported Keytruda was packaged in a box bearing the four Merck trademarks described above. On or about May 12, 2022, CBP mailed a Notice of Seizure by certified mail to Person 1.

34. On or about May 16, 2022, KUMAR received a copy of the May 12, 2022, Notice of Seizure from PC-1. The Notice of Seizure stated that the purported Keytruda and Adcetris seized were counterfeit and in violation of Title 18, United States Code, Section 2320(a). PC-1 told KUMAR that the drugs would not be returned because they were counterfeit. KUMAR advised PC-1 to “offer them some money,” that the next order would be shipped differently, and the defendant would “take extra care.”

35. On or about March 13, 2023, while negotiating a purchase of purported Keytruda, KUMAR sent UCA-1 a message stating, “at this price,” that is, \$3,500 for two 100 mg vials of purported Keytruda, “we can’t deliver real or genuine Keytruda.” “Product will look like same but it’s not real.” “So before making the payment please think twice”.

36. In or around March 2023, KUMAR sold two 100 mg vials of counterfeit Keytruda to UCA-1 for approximately \$3,500.

37. In or around March 2023, KUMAR instructed UCA-1 to wire approximately \$3,500 for the order to a Bank 1 account registered under KUMAR's name.

38. In or around March 2023, KUMAR arranged for the shipment of the counterfeit Keytruda to Houston, Texas. On or about March 28, 2023, UCA-1 received two 100 mg vials of counterfeit Keytruda in Houston, Texas. Merck analyzed this counterfeit Keytruda sold by KUMAR and determined that it lacked the active ingredient found in the legitimate drug. This counterfeit Keytruda sold by UCC-1 was packaged in a box bearing the four Merck trademarks described above.

39. In or around May 2023, KUMAR negotiated with PC-1 the sale of two 100 mg vials of purported Keytruda to PC-1 for approximately \$5,998.

40. In or around May 2023, KUMAR instructed PC-1 to wire approximately \$5,998 to an account registered to a third party.

41. In or around May 2023, KUMAR arranged for the shipment of purported Keytruda to Houston, Texas. On or about May 8, 2023, UCA-1 received the two 100 mg vials of purported Keytruda in Houston, Texas, that KUMAR believed he was sending to PC-1. Merck analyzed this purported Keytruda sold by KUMAR and determined that it lacked the active ingredient found in the legitimate drug. This purported Keytruda sold by UCC-1 was packaged in a box bearing the four Merck trademarks described above.

42. The counterfeit Keytruda KUMAR sold to UCA-1 in or about March 2023, and the purported Keytruda KUMAR sold to PC-1 in or about May 2023, used the same Turkish-language packaging and bore the same lot number and invalid expiry date. Although KUMAR informed UCA-1 that the counterfeit Keytruda KUMAR sold UCA-1 in or around March 2023 would be counterfeit, KUMAR did not inform PC-1 that the sale of purported Keytruda in or around May 2023 would be for counterfeit Keytruda.

43. In or around June 2023, KUMAR sold two 100 mg vials of counterfeit Keytruda to UCA-1 for approximately \$3,500.

44. In or around June 2023, KUMAR instructed UCA-1 to wire approximately \$3,500 for the order to an account registered to a third party.

45. In or around June 2023, KUMAR arranged for the shipment of the counterfeit Keytruda to Houston, Texas. On or about June 20, 2023, UCA-1 received two 100 mg vials of counterfeit Keytruda in Houston, Texas labeled with the same lot number and invalid expiry as other sales, including the sales in or around March 2023 and May 2023. Merck analyzed this counterfeit Keytruda sold by KUMAR and determined that it lacked the active ingredient found in the legitimate drug. This counterfeit Keytruda sold by UCC-1 was packaged in a box bearing the four Merck trademarks described above.

COUNTS 2 THROUGH 5

46. The Grand Jury re-alleges paragraphs 1—13 and 15—45 of Count 1 of this Indictment and incorporates them as if fully set forth in Counts 2–5.

COUNT TWO

(Trafficking in Counterfeit Drugs)

In or around January 2020, in the Houston Division of the Southern District of Texas and elsewhere, defendant,

SANJAY KUMAR,

did intentionally traffic and attempt to traffic in drugs, and knowingly used counterfeit marks on and in connection with such drugs that is, the Merck marks with Registration Numbers 4,263,031, 2,169,031,

922,205, and 1,973,165, as described above, which counterfeit marks were identical with and substantially indistinguishable from the genuine marks in use and registered for that drug on the principal register in the United States Patent and Trademark Office, and the use of which mark was likely to cause confusion, mistake and deception regarding said marks.

In violation of Title 18, United States Code, Sections 2320(a)(4).and (b)(3)(A).

COUNT THREE

(Trafficking in Counterfeit Drugs)

In or around March 2023, in the Houston Division of the Southern District of Texas and elsewhere, defendant,

SANJAY KUMAR,

did intentionally traffic and attempt to traffic in drugs, and knowingly used counterfeit marks on and in connection with such drugs that is, the Merck marks with Registration Numbers 4,263,031, 2,169,031, 922,205, and 1,973,165, as described above, which counterfeit marks were identical with and substantially indistinguishable from the genuine marks in use and registered for that drug on the principal register in the United States Patent and Trademark Office, and the use of which mark was likely to cause confusion, mistake and deception regarding said marks.

In violation of Title 18, United States Code, Sections 2320(a)(4) and (b)(3)(A).

COUNT FOUR

(Trafficking in Counterfeit Drugs)

In or around May 2023, in the Houston Division of the Southern District of Texas and elsewhere, defendant,

SANJAY KUMAR,

did intentionally traffic and attempt to traffic in drugs, and knowingly used counterfeit marks on and in connection with such drugs that is, the Merck marks with Registration Numbers 4,263,031, 2,169,031, 922,205, and 1,973,165, as described above, which counterfeit marks were identical with and substantially indistinguishable from the genuine marks in use and registered for that drug on the principal register in the United States Patent and Trademark Office, and the use of which mark was likely to cause confusion, mistake and deception regarding said marks.

In violation of Title 18, United States Code, Section 2320(a)(4).

COUNT FIVE

(Trafficking in Counterfeit Drugs)

In or around June 2023, in the Houston Division of the Southern District of Texas and elsewhere, defendant,

SANJAY KUMAR,

did intentionally traffic and attempt to traffic in drugs, and knowingly used counterfeit marks on and in connection with such drugs that is, the Merck marks with Registration Numbers 4,263,031, 2,169,031, 922,205, and 1,973,165, as described above, which counterfeit marks were identical with and substantially indistinguishable from the genuine marks in use and registered for that drug on the principal

register in the United States Patent and Trademark Office, and the use of which mark was likely to cause confusion, mistake and deception regarding said marks.

In violation of Title 18, United States Code, Section 2320(a)(4) and (b)(3)(A).

Notice of Criminal Forfeiture

Pursuant to Title 18, United States Code, Section 2323(a) and (b), the United States gives notice to the defendant,

SANJAY KUMAR,

that upon his conviction for a violation of Title 18, United States Code, Section 2320, the United States intends to seek forfeiture of any article, the making or trafficking of which is prohibited by that section; any property used, intended to be used, in any manner or part to commit or facilitate the commission of such offense; and all property constituting or derived from proceeds obtained directly and indirectly as a result of such offense.

Money Judgment

The defendant is notified that upon conviction, a money judgment may be imposed equal to the total value of the property subject to forfeiture.

Substitute Assets

In the event that the property subject to forfeiture as a result of any act or omission of the defendant:

- a. cannot be located upon exercise of due diligence;
- b. has been placed beyond the jurisdiction of the Court;
- c. has been transferred or sold to, or deposited with a third party;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty;

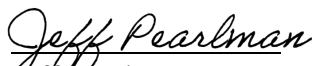
it is the intent of the United States to seek forfeiture of any other property of the defendant up to the value of such property pursuant to Title 21, United States Code, Section 853(p) incorporated by reference in Title 18, United States Code, Section 2320(b)(3)(A), Title 18, United States Code, Section 2320(c), and Title 28, United States Code, Section 2461(c).

TRUE BILL:


Original Signature on File
FOREPERSON OF THE GRAND JURY

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By:


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