

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

---

**U.S. SECURITIES AND EXCHANGE  
COMMISSION,  
100 F. Street, NE  
Washington, D.C. 20549**

**Plaintiff,**

v.

**BIOMET, INC.  
56 East Bell Drive  
Warsaw, Indiana 46582**

**Defendant.**

---

Case: 1:12-cv-00454  
Assigned To : Collyer, Rosemary M.  
Assign. Date : 3/26/2012  
Description: General Civil

**COMPLAINT**

Plaintiff, U.S. Securities and Exchange Commission (the "Commission"), alleges:

**SUMMARY**

1. This matter concerns violations of the Foreign Corrupt Practices Act ("FCPA") by Biomet, Inc. ("Biomet") and four of its subsidiaries to obtain sales for their medical device business.

2. Biomet is a global medical device company with operations around the world. From 2000 through August 2008, Biomet and its four subsidiaries paid bribes to public doctors employed by public hospitals and agencies in Argentina, Brazil, and China.

3. Biomet violated Section 30A of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. § 78dd-1] by making illicit payments to foreign government officials in order to obtain or retain business. Biomet violated Section

## RELATED ENTITIES AND INDIVIDUALS

7. **Biomet Argentina SA** (“Biomet Argentina”) is an Argentine corporation and a wholly-owned subsidiary of Biomet. Biomet conducts all of its sales in Argentina through Biomet Argentina. Biomet Argentina’s financial statements are consolidated into the statements of Biomet.

8. **Biomet International Corporation** (“Biomet International”) is a Delaware corporation and a wholly-owned subsidiary of Biomet. Biomet conducts all of its sales in Brazil through Biomet International. Biomet International used a Brazilian distributor to make the sales to public doctors and public hospitals. Biomet International’s financial statements are consolidated into the statements of Biomet.

9. **Biomet China** is a Chinese company and a wholly-owned subsidiary of Biomet. Biomet conducts most of its sales in China through Biomet China. Biomet China’s financial statements are consolidated into the statements of Biomet.

10. **Scandimed AB** is a wholly-owned Swedish subsidiary of Biomet. Scandimed was used by Biomet to make sales into China and elsewhere. Scandimed’s financial statements are consolidated into the statements of Biomet.

11. **Director of Internal Audit**, a U.S. citizen, was an auditor at Biomet and was based in Warsaw, Indiana.

12. **Latin America Auditor**, a U.S. citizen, was an auditor at Biomet and was based in Warsaw, Indiana.

13. **Senior Vice President**, a U.S. citizen, was a senior vice president for Biomet, and was based in Warsaw, Indiana.

14. **Operations Manager**, a U.S. citizen, was an operations manager for Biomet, and was based in Warsaw, Indiana.
15. **Managing Director** was the managing director of Biomet Argentina.
16. **Sales and Marketing Manager** was the sales and marketing manager for Latin America for Biomet.
17. **Finance and Administration Manager** was a finance and administration manager for Biomet Argentina.
18. **Associate Regional Manager**, a U.S. citizen, was the Associate Regional Manager for Biomet International in Asia/Pacific, and was based in Hong Kong SAR.
19. **President of International Operations**, a U.S. citizen, was the President of International Operations for Biomet and was based in Warsaw, Indiana.
20. **Brazilian Distributor**, a Brazilian company, had exclusive distribution rights for Biomet reconstructive products in Brazil.
21. **Chinese Distributor**, a Chinese company, acted as a distributor of Biomet products in China.
22. **Doctor**, a citizen of the People's Republic of China, was the head of orthopedics at a Chinese public hospital in Shanghai.

## **FACTS**

### **A. Argentina**

23. Since as early as 2000 to August 2008, Biomet Argentina employees paid bribes to doctors employed by publicly owned and operated hospitals in Argentina in exchange for sales of Biomet's medical device products. The doctors were paid approximately 15-20 percent of each sale.

24. Prior to 2000, Argentine tax authorities required all companies, including Biomet Argentina, to keep records of all payments made to doctors. In order to conceal the illicit purpose of the payments, Biomet Argentina employees obtained phony invoices from doctors stating that the payments were for professional services or consulting, when in fact, no such services occurred. Biomet Argentina recorded the payments falsely as “consulting fees” or “commissions.” Starting in 2000, after the Argentine tax authorities forbade tax-free payments to surgeons, Biomet Argentina employees recorded the payments falsely as “royalties” or “other sales and marketing.”

25. Executives and auditors at Biomet’s Indiana headquarters were aware of the Argentine payments to doctors as early as 2000. For example, on February 7, 2000, Operations Manager circulated a memo in Biomet’s Miami office discussing the opening of a direct-sales operation in Argentina, in which he included a budget allocation of “13-20% commission to surgeon[s].” In 2001, Biomet purchased a company in Argentina through which it would operate its direct sales business. The practice of paying the commissions to doctors continued.

26. In 2003, Biomet’s U.S.-based auditors conducted an audit of Biomet Argentina. On February 28, 2003, Director of Internal Audit circulated an internal audit report on Argentina to Senior Vice President and others in Biomet in Indiana in which he stated, “[R]oyalties are paid to surgeons if requested. These are disclosed in the accounting records as commissions.” The internal audit report described the payments to surgeons, but only in the context of confirming that the amount paid to the surgeon was the amount recorded on the books.

27. Internal audit took no steps to determine why royalties were paid to doctors purchasing Biomet medical devices, or why the payments to the doctors were 15-20 percent of sales. The internal auditors did not obtain any evidence of services provided for the payments. In fact, the internal audit report concluded that there were adequate controls in place to properly account for royalties paid to surgeons without any supporting documentation.

28. In August 2005, Managing Director of Biomet Argentina raised concerns regarding potential payments to customs officials and requested an internal audit. From September 2005 to October 2005, Director of Internal Audit, Latin America Auditor, and others from the Internal Audit, Legal, and Compliance Departments of Biomet conducted an investigation into the allegations.

29. On January 10, 2006, Managing Director of Biomet Argentina sent an email to Latin America Auditor in Indiana that attached a monthly list of payments to doctors that were a percentage of the cost of products purchased by the doctors during the month.

30. On February 22, 2006, Latin America Auditor circulated an internal report on the audit to Senior Vice President, Operations Manager, and others, which stated, "Other allegations being investigated by Biomet's legal team include fraudulent product registration certificates, bribery of customs officials, and other charges as reported to legal via electronic media. It was later determined that certificates were fraudulent and bribes were made [sic]."

31. In November 2006, Latin America Auditor sent her report on the audit of Biomet Argentina to Senior Vice President, Operations Manager and others in Indiana,

which stated, “The commission expense recorded on the income statement is actually royalties paid to doctors for using Biomet products. This account should be renamed to royalty’s [sic] expense.” Thus, despite the bribery, Latin America Auditor’s only recommendation was to change the journal entry from “commission expenses” to “royalties.”

32. Biomet’s U.S.-based auditors continued to get information about payments to doctors, including payments made in cash. For example, on February 26, 2007, Finance and Administration Manager at Biomet Argentina emailed Latin America Auditor information regarding cash disbursements, which stated, “Payments for surgeon commissions: the payments for surgeon commissions will be made on the 20th of each month.”

33. In September 2007, the Commission staff sent a letter to Biomet inquiring of payments made to public doctors. While the inquiry was underway in certain countries, additional conduct was occurring at Biomet Argentina.

34. For example, on December 7, 2007, Sales and Marketing Manager for Latin America sent a report on a visit to Biomet Argentina to Operations Manager, in which he noted as an area of concern, “Doctors receive a ‘consulting fee’ for every surgery.” On February 19, 2008, a Biomet Argentina employee also sent a list of payments made to physicians to Managing Director of Biomet Argentina.

35. In March 2008, Managing Director of Biomet Argentina again reported the payments to surgeons to internal compliance personnel but no efforts were made by compliance to stop the practice.

36. On August 7, 2008, Finance and Administration Manager sent Biomet Argentina's financial report, which continued to openly reflect the 15-20% commissions paid to surgeons, to Operations Manager and others in Indiana.

37. In August 2008, Biomet distributed new compliance guidelines that emphasized the FCPA and related issues to its employees, including employees in Argentina. Managing Director of Biomet Argentina reviewed the guidelines and contacted Biomet's attorneys to inform them of Biomet Argentina's payments to doctors to use Biomet products.

38. Within days, Biomet suspended the payments to Argentine doctors and sent outside counsel to investigate the issue. In December 2008, Biomet suspended all sales in Argentina. Biomet gradually re-entered the market in 2009. In all, Biomet paid approximately \$436,000 in payments that were provided to doctors in return for the doctors' use of Biomet products.

**B. Brazil**

39. Biomet sold medical devices in Brazil through its U.S. subsidiary, Biomet International. Biomet International engaged in a scheme in which its distributor, Brazilian Distributor, paid bribes to doctors employed by publicly owned and operated hospitals to purchase Biomet's implants. Brazilian Distributor paid the doctors bribes in the form of "commissions" of 10-20 percent of the value of the medical devices purchased.

40. As early as 2001, Biomet employees were aware of Brazilian Distributor's payments to doctors in exchange for purchasing Biomet implants. The payments were openly discussed in documents between Brazilian Distributor, Biomet International, and

Biomet's executives and auditors in the U.S. For example, on August 15, 2001, Brazilian Distributor sent an email to Senior Vice President in Indiana, copying Director of Internal Audit and others, noting that Brazilian Distributor was paying "commission [sic] to doctors." In February 2002, Director of Internal Audit sent a memorandum to Senior Vice President and Operations Manager regarding a limited audit performed of the books and records of Brazilian Distributor, in which he stated:

"Brazilian Distributor makes payments to surgeons that may be considered as a kickback. These payments are made in cash that allows the surgeon to receive income tax free.... The accounting entry is to increase a prepaid expense account. In the consolidated financials sent to Biomet, these payments were reclassified to expense in the income statement."

41. In another example, on August 21, 2003, Brazilian Distributor emailed Senior Vice President, copying Operations Manager, Director of Internal Audit, and others, stating "Prepaid now was fully reclassified to expenses accounts, commissions to doctors continue to be the major item...."

42. On February 19, 2004, a Biomet Argentina employee forwarded to Operations Manager the 2003 financial statements of Brazilian Distributor, which included the 20% commissions to doctors as "commissions." The next day, Operations Manager forwarded the financial statements of Brazilian Distributor to Senior Vice President. During this entire period, no efforts were made to stop the bribery.

43. In April 2008, Biomet decided to purchase Brazilian Distributor. Biomet sent accountants and outside counsel to Brazil to conduct due diligence on Brazilian Distributor. During the due diligence, the accountants identified cash payments to doctors and debit card purchases on behalf of doctors that raised red flags of bribery. When questioned by Biomet's outside counsel, Brazilian Distributor admitted that they

paid doctors for buying Biomet products and described the payments as “scientific incentives.” Brazilian Distributor said that Biomet executives knew about the payments.

44. Biomet terminated its relationship with Brazilian Distributor in May 2008. Biomet withdrew its sales from the Brazilian market and wrote off \$4.2 million in accounts receivables owed by Brazilian Distributor. In 2009, Biomet re-entered the Brazilian market and hired new Brazilian distributors to sell its medical implants. In all, Biomet paid approximately \$1.1 million in payments that were provided to doctors in return for the doctors’ use of Biomet products.

**C. China**

45. Biomet sold its medical device products in China through its subsidiaries, Biomet China and Scandimed. Biomet China and Scandimed used Chinese Distributor to funnel bribes to doctors employed at publicly owned and operated hospitals. Chinese Distributor provided the doctors with money and travel in exchange for their purchases of Biomet medical device products.

46. From at least 2001, Chinese Distributor exchanged emails with Biomet employees that explicitly described the bribes that he was paying on Biomet China’s behalf. For example, on February 1, 2001, Chinese Distributor sent an email to Associate Regional Manager for Asia/Pacific in Hong Kong SAR stating that Chinese Distributor was paying a 10-15% “rebate” to surgeons on the sale of Biomet artificial hips. The next day, Associate Regional Manager sent an email to a Biomet employee in the United Kingdom, noting that Scandimed “offer[s] higher-than-average ‘commission’ to surgeons....”

47. On February 6, 2001, a Scandimed employee emailed President of International Operations in Indiana and Biomet employees in the United Kingdom, stating, "Re. 'commission' to surgeons, Scandimed has no control over this... as we understand it, giving commission [sic] or gifts of various kinds to surgeons is common in China." That same day, President of International Operations responded, copying Operations Manager, stating, "[T]he only problem with a company paying high commissions in a tight market is that the prices must be low enough to the dist[ributor] to allow for these high commissions..."

48. On April 10, 2001, Chinese Distributor sent an email to President of International Operations, copying Associate Regional Manager, discussing a doctor who was trying to stop commissions being paid to physicians by medical device companies.

49. On May 18, 2001, Chinese Distributor sent an email copying Associate Regional Manager, stating "[Doctor] will become the most loyal customer of Biomet if we send him to Switzerland."

50. On May 21, 2001, Chinese Distributor sent another email to Associate Regional Manager, copying Senior Vice President, President of International Operations, and Operations Manager, stating:

"[Doctor] is the department head of [public hospital]. [Doctor] uses about 10 hips and knees a month and it's on an uptrend, as he told us over dinner a week ago.... Many key surgeons in Shanghai are buddies of his. A kind word on Biomet from him goes a long way for us. Dinner has been set for the evening of the 24th. It will be nice. But dinner aside, I've got to send him to Switzerland to visit his daughter."

51. Some emails described the way that vendors would deliver cash to surgeons upon the completion of surgery. Other emails discussed the amount of payments. For example, on January 29, 2002, Associate Regional Manager prepared a

summary of distribution in China, noting, “Chinese surgeons typically receive a commission on sales, which can range from 5% to 25%. Distributors are expected to hold banquets for surgeons, and to sponsor meetings.”

52. On April 21, 2002, Chinese Distributor sent an email to Associate Regional Manager discussing payments to surgeons, stating,

“When we say ‘Surgeon Rebate included’, it means the invoice price includes a predetermined percentage for the surgeon. For example, a vendor invoices the hospital for a set of plate & screws at RMB 3,000.00. The vendor will have to deliver RMB 750.00 (25% in this case) in cash to the surgeon upon completion of surgery [sic].”

53. The bribery of Chinese doctors continued into 2005. For example, on March 14, 2005, Director of Internal Audit instructed an auditor to code improper payments being made to doctors in connection with clinical trials as “entertainment.” In addition, on December 28, 2005, an employee of Biomet China emailed Associate Regional Manager, noting that doctors conducting clinical trials are paid a 10-15% “consulting fee.”

54. In late 2006, Biomet made a business decision to end the relationship with Chinese Distributor and to hire its own sales staff to sell Biomet medical devices into China. From October 6 through October 13, 2007, Biomet China sponsored the travel of 20 surgeons to Barcelona and Valencia for training, including a substantial portion of the trip being devoted to sightseeing and other entertainment at Biomet’s expense.

55. On October 11, 2007, the product manager for Biomet China sent an email to Associate Regional Manager discussing ways to evade efforts by the Chinese government to halt corruption in health care by requiring all international companies to declare actual cost for import to the government. In the email the product manager

stated, “Obviously, China government [sic] doesn’t have ability to forbid the corruption from hospitals & surgeons...,” and then the product manager went on to propose four methods for avoiding the regulation, including the use of falsified invoices. The product manager was referring to efforts made in 2006 and 2007 by the Chinese authorities to crack down on bribery, including the December 2006 arrest and July 2007 execution of the former head of China’s drug regulator.

**D. Anti-Bribery Violations**

56. Biomet and its four subsidiaries knowingly allowed its employees and third parties to pay Argentine, Brazilian and Chinese public doctors for the purpose of obtaining or retaining business. Public doctors in Argentina, Brazil, and China are “foreign officials” as the term is defined in the FCPA, 15 U.S.C. § 78dd-2(h)(2)(A).

57. Biomet employees who were U.S. nationals approved the payments to Argentine doctors and the arrangements with the Brazilian Distributor and Chinese Distributor that included payments to doctors. The mails and instrumentalities of interstate commerce were used in furtherance of the bribery schemes in Argentina, Brazil and China.

**E. Failure to Maintain Books and Records**

58. Biomet, through its subsidiaries Biomet Argentina, Biomet International, Biomet China, and Scandimed, made numerous illicit payments for years to public doctors in Argentina, Brazil, and China. Biomet’s books and records did not reflect the true nature of those payments. The payments were improperly recorded as “commissions,” “royalties,” “consulting fees,” “other sales and marketing,” “scientific incentives,” “travel,” and “entertainment.”

**F. Failure to Maintain Adequate Internal Controls**

59. Biomet failed to implement internal controls to detect or prevent bribery. Biomet and four subsidiaries were involved in bribery that lasted for over a decade. The conduct involved employees and managers of all levels involved in Biomet's sales in Argentina, Brazil and China. False documents were routinely created or accepted that concealed the improper payments.

**CLAIMS FOR RELIEF**

**FIRST CLAIM**

**[Violations of Section 30A of the Exchange Act]**

60. Paragraphs 1 through 56 are realleged and incorporated by reference.

61. As described above, Biomet, through its officers, employees, and agents, corruptly offered, promised to pay, or authorized payments to one or more persons, while knowing that all or a portion of those payments would be offered, given, or promised, directly or indirectly, to foreign officials for the purpose of influencing their acts or decisions in their official capacity, inducing them to do or omit to do actions in violation of their official duties, securing an improper advantage, or inducing such foreign officials to use their influence with foreign governments or instrumentalities thereof to assist Biomet in obtaining or retaining business.

62. By reason of the foregoing, Biomet violated, and unless enjoined will continue to violate, Section 30A of the Exchange Act. [15 U.S.C. § 78dd-1]

**SECOND CLAIM**

**[Violations of Section 13(b)(2)(A) of the Exchange Act]**

63. Paragraphs 1 through 59 are realleged and incorporated by reference.

64. As described above, Biomet, through its officers, employees, and agents, failed to keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflected its transactions and dispositions of its assets.

65. By reason of the foregoing, Biomet violated, and unless enjoined will continue to violate, Section 13(b)(2)(A) of the Exchange Act. [15 U.S.C. § 78m(b)(2)(A)]

### **THIRD CLAIM**

#### **[Violations of Section 13(b)(2)(B) of the Exchange Act]**

66. Paragraphs 1 through 62 are realleged and incorporated by reference.

67. As described above, Biomet failed to devise and maintain 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; and (ii) transactions were recorded as necessary (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (II) to maintain accountability for its assets.

68. By reason of the foregoing, Biomet violated, and unless enjoined will continue to violate, Section 13(b)(2)(B) of the Exchange Act. [15 U.S.C.

§ 78m(b)(2)(B)]

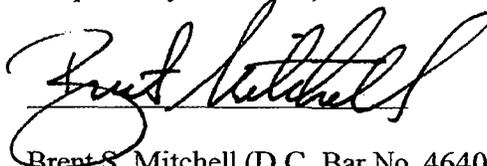
**PRAYER FOR RELIEF**

WHEREFORE, the Commission respectfully requests that this Court enter a final judgment:

- A. Permanently restraining and enjoining Biomet from violating Sections 30A, 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78dd-1, 78m(b)(2)(A), and 78m(b)(2)(B)];
- B. Ordering Biomet to disgorge ill-gotten gains wrongfully obtained as a result of its illegal conduct, along with prejudgment interest; and
- C. Granting such further relief as the Court may deem just and appropriate.

Dated: March 26, 2012

Respectfully submitted,



Brent S. Mitchell (D.C. Bar No. 464083)  
Tracy L. Price  
Reid A. Muoio  
Kara Novaco Brockmeyer

Attorneys for Plaintiff,  
U.S. Securities and Exchange Commission  
100 F Street, NE  
Washington, DC 20549  
(202) 551-4495 (Mitchell)