



3. Orthofix violated Section 13(b)(2)(A) of the Securities Exchange Act of 1934 (“Exchange Act”) by failing to accurately record these improper payments on its books and records. Orthofix violated Section 13(b)(2)(B) of the Exchange Act by failing to maintain an adequate system of internal accounting controls to detect and prevent the illicit payments.

### **JURISDICTION AND VENUE**

4. This Court has jurisdiction over this action pursuant to Sections 21(d) and 27 of the Exchange Act [15 U.S.C. §§ 78u(d) and 78aa]. Defendant Orthofix’s common stock is traded on the Nasdaq Global Select Market, and Orthofix has, directly or indirectly, made use of the means or instrumentalities of interstate commerce, of the mails, or of the facilities of a national securities exchange in connection with the transactions, acts, practices and courses of business alleged in this Complaint.

5. Venue is proper in this district pursuant to Section 27 of the Exchange Act [15 U.S.C. § 78aa], because Orthofix’s corporate administrative offices are located in Lewisville, Texas.

### **DEFENDANT**

6. Orthofix International N.V. is a limited liability company formed under the laws of Netherlands Antilles. Its corporate administrative offices are located in Lewisville, Texas. Orthofix’s common stock is registered with the Commission pursuant to Section 12 of the Exchange Act and is traded on the Nasdaq Global Select Market under the symbol “OFIX.”

### **OTHER RELEVANT ENTITY**

7. Promeca S.A. de C.V. is a wholly-owned subsidiary of Orthofix headquartered in Mexico City, Mexico.

## **FACTUAL ALLEGATIONS**

### **Background**

8. Orthofix is an orthopedic medical device company that provides surgical and non-surgical medical products for various market sectors, such as spine, orthopedics, and sports medicine. The company distributes its products both domestically in the United States and internationally in multiple countries.

9. During 2003 to 2010, Promeca, Orthofix's wholly-owned subsidiary based in Mexico City, sold Orthofix's products to government and private hospitals in Mexico. Approximately 60% of Promeca's revenues came from IMSS, the Mexican government-owned medical care and social services provider.

10. During the relevant time, Promeca was subject to Orthofix's control, including the implementation of internal controls at Promeca. Additionally, the financial results of Promeca were a component of the consolidated financial statements included in Orthofix's filings with the Commission.

### **The Bribery Scheme**

11. From at least 2003 to 2007, Orthofix's subsidiary, Promeca, regularly paid bribes to IMSS hospital employees in the form of cash and/or gifts, in order to secure sales contracts from IMSS hospitals.

12. The bribe amounts, referred to internally at Promeca as "chocolates," ranged from 5% to 10% of the collected sales for the hospital in question.

13. In order to obtain cash for the illicit payments, Promeca executives wrote checks to themselves, which they justified as cash advances.

14. They later submitted falsified receipts for imaginary expenses including meals and new car tires, which were accounted for in Promeca's books and records. As the bribes

increased, it became difficult for Promeca executives to invent new receipts to justify the advances. Eventually, the bribes became too large, forcing the Promeca executives to devise another justification methodology, and hence they began falsely accounting for the payments as promotional and training expenses.

15. Because of the bribery scheme, Promeca's training and promotional expenses were significantly over budget. In one instance, Orthofix launched an inquiry into these expenses, but did not control them.

16. In 2008, IMSS began purchasing medical products under a new national tender system, where a special IMSS committee, rather than the individual hospitals, selected the winning bidder who would cover IMSS nationally. Promeca then established a new system of bribery to ensure that it was awarded the business under the national tender system. To achieve this, Promeca made payments to three front companies, which were controlled by certain IMSS officials. Promeca won the national tenders for 2008 and 2009 and paid the front companies 5% and 3%, respectively, of the collected sales from those tenders. The front companies concealed these bribes by submitting false invoices, characterizing them as training and other promotional expenses that Promeca never received. Promeca falsely recorded the bribes on its books as payments for training courses, meetings and congresses, and promotional costs.

17. In addition, between 2003 and 2010, Promeca expended approximately \$80,050 on gifts and travel packages, some of which were intended to corruptly influence IMSS employees in order to retain their business. The various gifts included vacation packages, televisions, laptops, appliances, and in one case, the lease of a Volkswagen Jetta. These payments were falsely accounted for in Promeca's books and records as promotional and training expenses.

18. In all, the improper payments, totaling about \$317,000, generated approximately \$8.7 million in gross revenues and resulted in illicit net profits to Orthofix of about \$4.9 million.

### **Orthofix's Remedial Measures to Prevent Corrupt Payments**

19. Prior to the discovery of the bribery schemes, Orthofix did not have an effective FCPA compliance policy or FCPA-related training.

20. Although Orthofix disseminated some code of ethics and anti-bribery training to Promeca, the materials were only in English, and it was unlikely that Promeca employees understood them as most Promeca employees spoke minimal English.

21. Additionally, even though Promeca's training and promotional expenses, that included the improper payments, were often over budget, Orthofix did very little to investigate or diminish the excessive spending.

22. Upon discovery of the bribe payments through a Promeca executive, Orthofix immediately self-reported the matter to the Commission staff, and conducted an internal investigation.

23. Orthofix also implemented significant remedial measures. Specifically, it terminated the Promeca executives that orchestrated the bribery scheme, wound up Promeca's operations, enhanced its overall FCPA compliance program with mandatory annual FCPA training for all employees and third-party agents, expanded internal audit functions, and implemented other internal control measures.

### **Orthofix's Violations**

24. Orthofix's subsidiary characterized their payments to IMSS as cash advances or training and promotional expenses even though those payments were used as bribes. Orthofix's books and records did not reflect the true nature of those payments.

25. Orthofix failed to implement adequate internal controls to prevent the bribery or to ensure that transaction were properly recorded. Orthofix failed to implement an FCPA compliance and training program commensurate with the extent of its international operations and particularly its ownership of Promeca, a subsidiary that had substantial sales to government-owned enterprises. Further, even though Orthofix knew that Promeca's training and promotional expenses were often over budget, it did nothing to act on the red flag.

### **FIRST CLAIM FOR RELIEF**

#### **Violation of Exchange Act Section 13(b)(2)(A)**

#### **[15 U.S.C. § 78m(b)(2)(A)]**

26. The Commission realleges and incorporates by reference paragraphs 1 through 25.

27. As described above, Orthofix, through its subsidiary, failed to keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflected its transactions and disposition of its assets.

28. By reason of the foregoing, Orthofix 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)].

### **SECOND CLAIM FOR RELIEF**

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

#### **[15 U.S.C. § 78m(b)(2)(B)]**

29. The Commission realleges and incorporates by reference paragraphs 1 through 28.

30. As described above, Orthofix 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.

31. By reason of the foregoing, Orthofix 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 the Court enter a final judgment:

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

Dated: July 10, 2012  
Fort Worth, Texas

Respectfully submitted,

/s/ Toby M. Galloway

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