

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

COMMISSIONERS: **Edith Ramirez, Chairwoman**
 Maureen K. Ohlhausen
 Terrell McSweeney

In the Matter of

**Victrex plc,
a corporation,**

**Invibio Limited,
a corporation, and**

**Invibio, Inc.,
a corporation.**

Docket No. C-

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41, et seq., and by virtue of the authority vested in it by said Act, the Federal Trade Commission (“Commission”), having reason to believe that Victrex plc, Invibio, Inc., and Invibio Limited (hereinafter collectively referred to as “Invibio” or “Respondents”) have violated the provisions of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges as follows:

NATURE OF THE CASE

1. Invibio is the dominant supplier of implant-grade polyetheretherketone (“PEEK” or “implant-grade PEEK”), a specialty polymer used by medical device makers to construct spinal, orthopedic, and other human implants.
2. Invibio’s only competitors in the sale of implant-grade PEEK are Solvay Specialty Polymers LLC (“Solvay”) and Evonik Corporation (“Evonik”). Solvay and Evonik each began to sell PEEK after Invibio had established market dominance, offering prices significantly below the prices charged by Invibio.

3. Invibio supplies PEEK to medical device makers primarily pursuant to long-term supply contracts. Both before and after entry by Solvay and Evonik, Invibio included exclusivity terms in these contracts. Invibio employed various strategies to coerce or induce device makers to accede to exclusivity terms, including threatening to discontinue PEEK supply or to withhold access to regulatory support.
4. Invibio's insistence on exclusivity terms has been a deliberate and successful strategy to hinder its competitors and to maintain its monopoly power. In 2014, years after entry by Solvay and Evonik, and despite Solvay's and Evonik's lower prices, Invibio still accounted for over 90 percent of PEEK sales worldwide. A substantial majority of these sales have been foreclosed from Solvay and Evonik due to the exclusivity terms in Invibio's long-term supply contracts.
5. Due to Invibio's conduct, Solvay and Evonik have been hampered in their efforts to compete against Invibio, including in developing valuable customer relationships that would bolster the entrants' reputations, and in realizing sufficient returns to justify further investment in the business. For their part, purchasers of PEEK have been deprived of a meaningful choice among suppliers and have been denied the full benefits of competition.

RESPONDENTS

6. Respondent Victrex plc ("Victrex") is headquartered in the United Kingdom and its shares are traded on the London Stock Exchange. Its principal place of business is located at Technology Centre, Hillhouse International, Thornton Cleveleys, Lancashire FY5 4QD, England.
7. Respondent Invibio Limited is a wholly-owned subsidiary of Victrex and its principal place of business is located at Technology Centre, Hillhouse International, Thornton Cleveleys, Lancashire FY5 4QD, England.
8. Respondent Invibio, Inc. is a wholly-owned subsidiary of Victrex and is a corporation organized, existing, and doing business under and by virtue of the laws of Delaware, with its main office and principal place of business located at 300 Conshohocken State Road, Suite 120, West Conshohocken, Pennsylvania 19428.

JURISDICTION

9. At all times relevant herein, each Respondent has been, and is now, a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
10. The acts and practices of each Respondent, including the acts and practices alleged herein, are in commerce or affect commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

INDUSTRY BACKGROUND

11. PEEK is a high-performance polymer used in a number of applications. A predecessor company to Victrex developed industrial-grade PEEK in the late 1970s. Industrial-grade PEEK is now used in a number of industries, including aerospace, automotive, and energy.
12. Respondents later developed implant-grade PEEK, which is manufactured under conditions that assure its purity. The principal use of implant-grade PEEK is in medical devices used in spinal interbody fusion, a procedure used to treat degenerative spinal disorders and similar conditions. Spinal interbody fusion devices and other medical devices that use PEEK must be cleared by the United States Food and Drug Administration (“FDA”) and by regulatory authorities in other countries.
13. As of the late 1990s, spinal interbody fusion devices were made primarily of titanium and other metals, along with autograft (a patient’s own bone) or allograft (cadaver bone). Around this time, medical device makers sought alternative implant materials.
14. In or about 1999, Invibio began to market a grade of PEEK suitable for implants. When Invibio launched implant-grade PEEK, it was the only supplier of this grade of PEEK. Invibio soon found willing buyers for its product.
15. When Invibio began marketing implant-grade PEEK, the company entered into supply contracts with its medical device maker customers. Many of these contracts included an exclusivity term of some kind. These terms generally required that the customer use Invibio PEEK for all PEEK-containing medical devices, for a broad category of devices, or for a list of identified devices.
16. When Invibio was the only PEEK supplier, its exclusivity terms went unchallenged by customers. This dynamic started to change in the late 2000s, when medical device makers became aware of competing suppliers.

COMPETITIVE ENTRY

17. In 2006, Solvay, a large chemical company, acquired assets to facilitate its entry into the sale of industrial-grade PEEK. Solvay also sold non-PEEK polymers to medical device makers. Device makers (customers of Invibio) informed Solvay that they desired another implant-grade PEEK supplier in order to inject competition into the market, including price and product development competition. In response to this encouragement from device makers, Solvay expanded into implant-grade PEEK.
18. The FDA cleared the first spinal implant device using Solvay PEEK in 2010.
19. In 2005, Evonik, also a large chemical company, began producing industrial-grade PEEK. Like Solvay, Evonik supplied non-PEEK polymers to medical device makers. As with Solvay, device makers encouraged Evonik to produce implant-grade PEEK. In response to this encouragement, Evonik expanded into implant-grade PEEK.
20. The FDA cleared the first spinal implant device using Evonik PEEK in 2013.
21. Solvay and Evonik have offered to sell PEEK at prices significantly lower than the prices charged by Invibio. Invibio was aware of this price gap.

INVIBIO'S USE OF EXCLUSIVITY TO IMPEDE COMPETITORS

22. Invibio decided to adopt a strategy of expanding the scope and coverage of exclusivity terms in PEEK supply contracts to prevent Solvay and Evonik from developing into effective competitors. Invibio was concerned that if it did not block rivals, it would be forced to engage in painful price competition with Solvay and Evonik.
23. Invibio recognized that it was particularly important to lock up the largest and most sophisticated medical device makers with exclusive contracts, as doing so would prevent Solvay and Evonik from achieving success at these device makers and then building on that success with other customers. If Solvay's or Evonik's PEEK were used successfully by leading medical device makers, this would validate the rival in the eyes of other device makers, thereby enhancing competition in the market.
24. Invibio implemented its exclusivity strategy through negotiations with existing and potential customers. During these negotiations, Invibio sought to broaden its exclusivity terms in several ways, including by: (1) inserting more explicit exclusivity provisions into supply contracts; (2) expanding the scope of and limiting the exceptions to exclusivity requirements; and (3) employing restrictive contract terms that impeded customers' ability to switch to an alternative PEEK supplier for existing products even upon contract expiration.
25. For their part, after entry by Solvay and Evonik, a number of PEEK purchasers sought to negotiate supply terms with Invibio that did not require exclusivity. These device makers wanted to arrange a second source of PEEK supply in order to reduce the risk of a supply interruption and to obtain lower prices.
26. Invibio responded by insisting on exclusivity terms. Invibio's message was that if customers were going to use Invibio PEEK, they must use only Invibio PEEK.
27. Because device makers could not quickly obtain regulatory clearance to use a new source of PEEK for all of their devices, device makers generally had no choice but to sign an exclusive contract with Invibio.
28. Invibio enforced its position by threatening to withhold needed supply or regulatory support and, where necessary, offering minor inducements in exchange for exclusivity.
29. Invibio's threats in support of its exclusivity demands took several forms. For example, Invibio threatened to cut off PEEK supply for all of a device maker's existing products. Invibio also threatened not to sell Invibio's new brands of PEEK to a device maker unless the device maker agreed to buy Invibio's main brand of PEEK on an exclusive basis. And Invibio threatened to withhold access to Invibio's FDA Master File and other regulatory support if device makers did not agree to exclusivity.
30. Other device makers, while not explicitly threatened by Invibio, were too fearful of a supply interruption or other retaliatory tactics to resist Invibio's demand for exclusivity.
31. Where necessary, Invibio was prepared to provide a small price discount or other benefit in exchange for exclusivity. Invibio recognized that limited discounts were a small price to pay for the benefit of cutting off Solvay and Evonik from key customer accounts.

32. As a result of Invibio's efforts, nearly all medical device makers that purchase PEEK from Invibio do so under contracts containing some form of exclusivity. These exclusivity terms take one of three forms: (1) requiring that the customer use Invibio PEEK for all PEEK-containing medical devices; (2) requiring that the customer use Invibio PEEK for a broad category of PEEK-containing devices; or (3) requiring that the customer use Invibio PEEK for a list of identified PEEK-containing devices—with the list often including nearly every device in the customer's portfolio. Whatever the form, these exclusivity terms have prevented medical device makers from sourcing significant volumes of PEEK from Invibio's rivals.

INVIBIO'S MONOPOLY POWER

33. Invibio has exercised and continues to exercise monopoly power with respect to implant-grade PEEK.
34. Invibio has been able to price its PEEK substantially higher than competing versions of PEEK and to hamper competitors through its exclusive contracting practices.
35. Additionally, Invibio has maintained a high share of a relevant market with substantial barriers to entry.
36. The relevant product market is no larger than implant-grade PEEK: that is, PEEK that has been used in at least one device cleared by the United States Food and Drug Administration.
37. Other materials used in spinal and other implants are not close enough substitutes to prevent a monopolist supplier of PEEK from profitably raising PEEK prices. The choice of an implant device is typically determined by the physician rather than by the patient. Such selection is based in substantial part upon the characteristics of the implant material. PEEK has unique characteristics compared to other implant materials, including as to radiolucence, machinability, and elasticity. Physicians are unlikely to alter implant device selection patterns in response to a small but significant and non-transitory increase in PEEK prices. Device makers also are unlikely to alter PEEK purchasing patterns in response to a small but significant and non-transitory increase in PEEK prices.
38. Because implant-grade PEEK can be and is manufactured throughout the world, the relevant geographic market is worldwide.
39. There are three competitors in the worldwide market for implant-grade PEEK: Invibio, Solvay, and Evonik. Invibio has consistently maintained a market share of approximately 90 percent or greater.
40. The relevant market has significant barriers to entry and significant barriers to expansion. Such barriers include: (i) significant capital outlays needed to develop the capacity to manufacture PEEK; (ii) testing time and costs to develop new grades of PEEK; and (iii) regulatory requirements. In addition to these structural barriers, Invibio's exclusivity practices have created an additional barrier to entry and expansion by shrinking the volume of sales available to would-be rivals.

41. The experiences of Solvay and Evonik after entering the relevant market confirm the durability of Invibio's monopoly power. In 2014, years after Solvay and then Evonik announced plans to enter the market, the combined market share of Solvay and Evonik was less than 10 percent.

ANTICOMPETITIVE EFFECTS OF INVIBIO'S EXCLUSIVE CONTRACTS

42. Invibio has maintained its monopoly power through the use of exclusive supply contracts. Invibio's conduct has harmed competition by enabling Invibio to maintain supracompetitive prices, by reducing consumer choice, and by impeding rivals from becoming effective competitors.
43. Invibio used its monopoly power to maintain high prices for PEEK. Although Solvay and Evonik have offered significantly lower prices for PEEK, the typical Invibio customer did not see any significant price decrease after entry by Solvay and Evonik. Even in the rare instances in which customers received a price discount in exchange for exclusivity, the customers still paid more for Invibio PEEK than they would have paid for PEEK supplied by Solvay or Evonik.
44. Invibio used its monopoly power to impede device makers from contracting with alternative suppliers of PEEK. Medical device makers prefer to have multiple sources of PEEK for risk mitigation and other commercial benefits. Solvay and Evonik offer an alternative to Invibio, one that many device makers are eager to explore. Invibio's exclusive contracts, however, prevent device makers from doing so. Absent Invibio's exclusivity requirement, a significant number of device makers would contract with these alternative suppliers to secure lower-priced PEEK and to mitigate risk.
45. Invibio used its monopoly power to impede Solvay and Evonik from developing into fully effective rivals. Invibio's exclusive contracts have foreclosed from competitors a substantial portion of the worldwide PEEK market, including key customer accounts that would validate the entrants' reputations.
46. Invibio succeeded in its plan to hamper its rivals' growth with exclusive contracts. Solvay and Evonik have been forced to focus sales efforts on small device makers without exclusive contracts with Invibio. Due to the pervasiveness of Invibio's exclusivity terms, each firm has missed sales targets. Without sufficient returns to justify further investment in the business, including in next generation technologies, there is a significant risk that continued enforcement of Invibio's exclusive contracts would cause Solvay and Evonik to become even less effective competitors in the future.
47. The acts and practices of Respondents as alleged herein have had the purpose, capacity, tendency, and effect of restraining competition unreasonably and of maintaining Invibio's monopoly power.
48. There are no legitimate procompetitive efficiencies that justify Invibio's conduct or that outweigh the substantial anticompetitive effects thereof.
49. Any legitimate objectives of Invibio's conduct as alleged herein could have been achieved through significantly less restrictive means.

VIOLATION OF FTC ACT

- 50. The allegations in all of the paragraphs above are re-alleged and incorporated by reference as though fully set forth herein.
- 51. Invio has willfully engaged in anticompetitive and exclusionary acts and practices to enhance or maintain its monopoly power. These acts and practices constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this ____ day of _____, 2016, issues its complaint against Respondents.

By the Commission.

Donald S. Clark
Secretary

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