

Complaint

IN THE MATTER OF

**VICTREX PLC,
INVIBIO LIMITED,
AND
INVIBIO, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4586; File No. 141 0042
Complaint, July 13, 2016 – Decision, July 13, 2016*

This consent order addresses Victrex plc's, Invibio, Inc.'s and Invibio Ltd.'s use of exclusive supply contracts. The complaint alleges that respondents violated of Section 5 of the Federal Trade Commission Act by using exclusive supply contracts to maintain monopoly power in the market for implant-grade polyetheretherketone ("PEEK"). The consent order requires Invibio to cease and desist from enforcing most exclusivity terms in current supply contracts and generally prohibits Invibio from requiring exclusivity in future contracts. The order also prevents Invibio from adopting other mechanisms, such as market-share discounts or retroactive volume discounts, to maintain its monopoly power.

Participants

For the *Commission*: Dana Abrahamsen, Wes Carson, Mika Ikeda, Kristin Shaffer, and Charlotte Slaiman.

For the *Respondents*: Barbara Sicalides, Pepper Hamilton LLP.

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

Complaint

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.

Complaint

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

Complaint

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.

Complaint

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

Complaint

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

Complaint

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

Complaint

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

Complaint

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.

Decision and Order

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. Invibio 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 thirteenth day of July, 2016, issues its complaint against Respondents.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of Victrex plc, Invibio Limited, and Invibio, Inc. (hereinafter collectively referred to as "Respondents"), and Respondents having been furnished thereafter with a copy of a draft of the Complaint that the Bureau of Competition proposed to present to the Commission

Decision and Order

for its consideration and which, if issued, would charge Respondents with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of the Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having found reason to believe that Respondents have violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues the following Decision and Order (“Order”):

1. Respondent Victrex plc is a corporation organized, existing and doing business under and by virtue of the laws of the United Kingdom, with its office and principal place of business located at Victrex Technology Centre, Hillhouse International, Thornton Cleveleys, Lancashire FY5 4QD.
2. Respondent Invibio Limited is a wholly-owned subsidiary of Victrex plc and is a corporation organized, existing and doing business under and by virtue of the laws of the United Kingdom, with its office and principal place of business located at

Decision and Order

Victrex Technology Centre Hillhouse International,
Thornton, Cleveleys, Lancashire FY5 4QD.

3. Respondent Invibio, Inc. is a wholly-owned subsidiary of Victrex plc and is a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at 300 Conshohocken State Rd, Suite 120, West Conshohocken, Pennsylvania 19428.
4. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and over Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

THE PARTIES

- A. “Victrex” means Victrex plc, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Victrex plc, including without limitation Invibio Limited and Invibio, Inc.; and the respective directors, officers, employees, agents, consultants, representatives, successors, and assigns of each.
- B. “Invibio Limited” means Invibio Limited, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Invibio Limited including without limitation Invibio, Inc.; and the respective directors, officers, employees, agents, consultants, representatives, successors, and assigns of each.

Decision and Order

- C. “Invibio, Inc.” means Invibio, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Invibio, Inc.; and the respective directors, officers, employees, agents, consultants, representatives, successors, and assigns of each.
- D. “Respondents” means Victrex, Invibio Limited, and Invibio, Inc.
- E. “Commission” means the Federal Trade Commission.

OTHER DEFINITIONS

- F. “Antitrust Compliance Program” means the program to ensure compliance with this Order and with the Antitrust Laws, as required by Paragraph III of this Order.
- G. “Antitrust Laws” means the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et. seq.*, the Sherman Act, 15 U.S.C. § 1 *et. seq.*, and the Clayton Act, 15 U.S.C. § 12 *et. seq.*
- H. “Competing PEEK” means any PEEK manufactured or sold by any Person other than the Respondents.
- I. “Competing PEEK Supplier” means any Person other than Respondents that manufactures, markets, sells, offers to sell, or seeks to sell Competing PEEK.
- J. “Custom Component” means a Customer-specific component of a Customer Product or near net shape that (i) is composed of PEEK; (ii) is manufactured by Respondents to the specifications of, and at the request of, a single Customer; (iii) is the only component or near net shape of the same specifications sold to any Customer; (iv) requires for its manufacture the development and maintenance of tooling by Respondents; and (v) requires the development and

Decision and Order

maintenance by Respondents of a validation report for use by the Customer with the FDA.

- K. “Customer” means any Person who purchases, seeks to purchase, or otherwise takes delivery or receives, PEEK from one or more Respondents for use in any Customer Product sold or cleared for use in the United States, regardless of where the PEEK is manufactured or sold, regardless of where the Customer Product is manufactured, and regardless of whether the Customer also purchases PEEK for use in Customer Products sold outside of the United States. For the avoidance of doubt, “Customer” does not include any Person who purchases or seeks to purchase PEEK from one or more Respondents solely for use in Customer Products that are not manufactured in or imported into the United States.
- L. “Customer Product” means any medical device, implant, medical instrument, or similar item intended for use inside of or in contact with a human body that contains PEEK and is sold, offered for sale, or distributed by a Customer. For the avoidance of doubt, Customer Product includes Custom Components and Jointly Developed Products. For the further avoidance of doubt, other than Custom Components and Jointly Developed Products, products with different part numbers, SKUs, or other differentiating identifiers are distinct Customer Products, even if they have identical indications for use.
- M. “Dual Source” or “Dual Sourcing” means selling, offering for sale, or distributing two or more units of a Customer Product, some of which are manufactured from Respondents’ PEEK and some of which are manufactured from Competing PEEK.
- N. “Exclusivity,” “Exclusive,” or “Exclusively” means any requirement, whether formal or informal, that a Customer purchase or use only Respondents’ PEEK in

Decision and Order

all or any individual or group of Customer Products, or any other requirement that a Customer refrain from purchasing or using, or limit its purchase or use of, any Competing PEEK in one or more Customer Products. For the avoidance of doubt, “Exclusivity,” “Exclusive,” or “Exclusively” includes any limitations on Dual Sourcing.

- O. “Executive and Sales Staff” means the President, all Vice-Presidents, the Chief Financial Officer, and members of the Executive Committees of each Respondent (or their equivalent positions regardless of job title); and the officers, directors, and employees, and contractors of each Respondent whose duties relate primarily to the marketing, promotion, or sale of PEEK to Customers.
- P. “Extraordinary Support” is a subset of Product Support provided by Respondents to a Customer that (i) is requested by a Customer; (ii) is not made generally available to other Customers; and (iii) is needed to enable a Customer to introduce a new Customer Product. For the avoidance of doubt, the following activities are not Extraordinary Support: (i) granting a Customer a right to reference Respondents’ FDA Master File(s) before, during, and after FDA review and clearance of a Customer Product; (ii) maintaining biocompatibility data regarding Respondents’ PEEK; (iii) generating, maintaining, and updating Respondents’ FDA Master File(s) in accordance with standard practice and regulatory requirements; (iv) providing Respondents’ data, test results, or other information in response to questions or requests from the FDA or any other regulatory body regarding Respondents’ PEEK; (v) providing technical support associated with using Respondents’ PEEK in a Customer Product; (vi) examining, identifying, and developing solutions related to any problems or complaints associated with the application to or performance of Respondents’ PEEK; and (vii)

Decision and Order

providing information to enable Dual Sourcing of PEEK.

- Q. “FDA” means the U.S. Food and Drug Administration.
- R. “Jointly Developed Product” means a new Customer Product containing PEEK that is developed jointly by Respondents and the Customer, the development of which resulted from a contribution of significant capital, intellectual property rights, labor, or other things of value by both Respondents and the Customer.
- S. “Legacy Contract” means any agreement or contract for the sale and purchase of Respondents’ PEEK in effect as of February 1, 2016, and any subsequent renewal or extension of the agreement or contract, so long as: (i) the term of such renewal or extension does not extend beyond one (1) year after this Order is issued and (ii) such renewal or extension is terminable by the Customer upon thirty (30) days’ notice.
- T. “Mutual Exclusivity” means an agreement in writing and executed by both Respondent(s) and the Customer that, for a specified and concurrent period of time, (i) a Customer purchases or uses only Respondents’ PEEK in a specified Custom Component or specified Jointly Developed Product; and (ii) Respondents do not manufacture, market, sell, or offer to sell the specified Custom Component or specified Jointly Developed Product other than to such Customer.
- U. “New Contract” means any agreement or contract for the sale and purchase of Respondents’ PEEK that is entered into after February 1, 2016.
- V. “PEEK” means polyetheretherketone of any grade or form (including, but not limited to, granules, rods, near net shapes, and components) used or intended for continuous or discontinuous use in a medical device, implant, medical instrument, or similar item intended

Decision and Order

for use inside of or in contact with a human body for longer than 24 hours.

- W. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or governmental entity, and any subsidiary, division, group, or affiliate thereof.
- X. “Product Support” means any service, assistance, or other support provided by Respondents to a Customer, including but not limited to support related to (i) a Customer’s regulatory filings involving Respondents’ PEEK; (ii) technical support related to the performance of Respondents’ PEEK; or (iii) the qualification or validation process associated with using Respondents’ PEEK in a Customer Product.
- Y. “Respondents’ PEEK” means any PEEK manufactured, marketed, or sold by the Respondents.
- Z. “Sales Term” means the retail or wholesale price, resale price, purchase price, price list, credit term, delivery term, service term, including but not limited to any price reduction, rebate, promotional assistance, or other incentive that provides pecuniary value to a Customer, or any other contract term defining, setting forth, or relating to the money or compensation paid by a Customer to Respondents, or the service, delivery, credit, or other terms provided by Respondents to a Customer, in connection with the purchase or sale of any of Respondents’ PEEK.
- AA. “Unit Payments” mean any payments owed to Respondents that are calculated based on the number of units of Customer Products sold or manufactured by or on behalf of the Customer.

Decision and Order

II.

IT IS FURTHER ORDERED that, acting directly or indirectly, or through any corporate or other device, in or affecting commerce, as “commerce” is defined by the Federal Trade Commission Act, in connection with the development, production, manufacture, marketing, promotion, purchase or sale of PEEK:

- A. Respondents shall cease and desist from inviting, entering into, implementing, continuing, enforcing, or attempting thereto, any condition, policy, practice, agreement, contract, contract term, or understanding or any other requirement that has the effect of achieving Exclusivity with a Customer. Examples of practices prohibited under this Paragraph include but are not limited to:
1. Requiring a Customer to purchase from Respondents all of the Customer’s PEEK requirements;
 2. Requiring a Customer to purchase from Respondents all of the Customer’s PEEK requirements for a particular category or group of Customer Products;
 3. Requiring a Customer to purchase from Respondents all of the Customer’s PEEK requirements for a particular Customer Product, including but not limited to:
 - a. Requiring a Customer to purchase from Respondents all of the Customer’s PEEK requirements for any Customer Product for which Respondents have granted the Customer a right to reference one or more of Respondents’ FDA Master Files during FDA review and clearance of the Customer Product; or

Decision and Order

- b. Requiring a Customer to purchase from Respondents all of the Customer's PEEK requirements for any Customer Product for which the Customer obtained FDA clearance using Respondents' PEEK;
- 4. Conditioning the availability or applicability of a flat or lump sum payment of monies or any other item(s) of pecuniary value from Respondents (including but not limited to Sales Terms or Product Support) on Exclusivity;
- 5. Conditioning the sale or availability of one type of PEEK on a Customer's commitment to purchase all of its requirements for another type of PEEK;
- 6. Conditioning the availability of Sales Terms or Product Support on a Customer not testing or seeking FDA clearance for any Customer Product using Competing PEEK, or otherwise preventing or impeding a Customer from testing or seeking FDA clearance for any Customer Product using Competing PEEK;
- 7. Charging Unit Payments on units of Customer Products not made with Respondents' PEEK; and
- 8. Prohibiting, restraining, limiting or impeding the ability of a Customer to Dual Source any Customer Product, including by:
 - a. requiring a Customer to reference Respondents' brand name or trademark in the Customer's labeling and marketing materials (except as required by law);
 - b. restricting the amount of Respondents' PEEK that a Customer is allowed to purchase and maintain in its inventory; or

Decision and Order

- c. requiring that a Customer return Respondents' PEEK that is purchased but not already incorporated into a Customer Product after expiration of a contract or other agreement with the Customer.
- B. Respondents shall cease and desist from discriminating against, penalizing, or otherwise retaliating against any Customer for the reason, in whole or in part, that the Customer engages in, or intends to engage in, the research, development, testing, manufacture, production, distribution, purchase, marketing, promotion, or sale of any Customer Product using a Competing PEEK, or otherwise refuses to enter into or continue any condition, agreement, contract, understanding, or other requirement that imposes Exclusivity. Examples of practices prohibited under this Paragraph include but are not limited to the following, when the result, in whole or in part, of prohibited discrimination or retaliation for use of Competing PEEK or refusal to accede to Exclusivity:
1. Terminating, suspending, delaying, or threatening or proposing thereto, sales of Respondents' PEEK to the Customer, either generally or with respect to particular forms or grades of PEEK;
 2. Denying, or threatening or proposing to deny, the Customer access to Respondents' FDA Master File;
 3. Auditing the Customer's purchases or sales of Competing PEEK;
 4. Withdrawing or modifying, or threatening or proposing thereto, favorable Sales Terms or Product Support to the Customer;
 5. Providing, or threatening or proposing thereto, less favorable Sales Terms or Product Support to the Customer;

Decision and Order

6. Withholding from the Customer any form or grade of Respondents' PEEK;
7. Refusing to deal with the Customer on terms and conditions generally available to other Customers; and
8. Notwithstanding the existence or non-existence of any severability or other provisions in Respondents' agreement(s) or contract(s) with any Customer(s), terminating, suspending, or requiring renegotiation of any term of any agreement or contract for the purchase and sale of Respondents' PEEK, as a result of the Exclusivity terms or other terms inconsistent with this Order being waived, invalid, illegal, or unenforceable.

For the avoidance of doubt, it shall not constitute, in and of itself, a violation of this Order for Respondents to engage in the conduct described in Paragraph II.B(1-7) above, when such conduct results from independent and verifiable business reasons unrelated to a Customer's use of Competing PEEK or refusal to accede to Exclusivity.

- C. As to any New Contract, Respondents shall not invite, enter into, implement, enforce, or attempt thereto, any condition, policy, practice, agreement, contract, contract term, understanding, or any other requirement that:
 1. Requires a Customer to purchase or use minimum amounts (by units, revenue, product group, Customer Product, proportion, or any other measure) of Respondents' PEEK;
 2. Conditions any Sales Term, Product Support, or the availability of a particular type of PEEK on the Customer purchasing or using Respondents' PEEK for a specified proportion or percentage of the Customer's requirements for all Customer

Decision and Order

Products, for a group of Customer Products, or for a particular Customer Product; or

3. Provides a retroactive discount as a flat or lump-sum payment of monies (or any other item(s) of pecuniary value) if the Customer's sales or purchases of Respondents' PEEK reach a specified threshold (in units, revenues, or any other measure), or otherwise reduces the price of one unit of Respondents' PEEK because of the purchase or sale of an additional unit. For example, Respondents may not offer or provide a discount of X% on all Respondents' PEEK if sales exceed Y kilograms. For the avoidance of doubt, Respondents may offer a discount that is volume-based, above average variable cost, and not retroactive, *i.e.*, a discount of X% on those sales in excess of Y kilograms.

Provided, however, that it shall not be a violation of this Paragraph II.C for Respondents to provide discounts, rebates, or other price or non-price incentives to purchase Respondents' PEEK that are designed to meet competition, if Respondents determine in good faith that one or more Competing PEEK Suppliers are offering terms of sale for Competing PEEK that Respondents need to match in order to win contested business. For the avoidance of doubt, under no circumstances may Respondents tie any such incentives to Exclusivity.

- D. Notwithstanding any other provision of this Order, it shall not constitute a violation of this Order for Respondents to condition the provision of Extraordinary Support for a Customer Product or Customer Products on a requirement that a Customer purchase or use Respondents' PEEK for a specified volume or percentage of the Customer's annual PEEK requirements for the Customer Product(s) receiving the Extraordinary Support ("minimum purchase requirement"), so long as:

Decision and Order

1. the minimum purchase requirement is no more than 30% of the Customer's PEEK requirements (in units, revenues, or any other measure, over any period of time) for the identified Customer Product(s) that receive(s) the Extraordinary Support; and
 2. the minimum purchase requirement period for any Customer Product for which Extraordinary Support is provided shall not extend beyond three (3) years in length after the date of FDA approval for sale of that Customer Product(s).
- E. Notwithstanding any other provision of this Order, it shall not constitute a violation of this Order for Respondents to maintain or enter into a contract or agreement with a Customer providing for Mutual Exclusivity (i) for the research, development, manufacture, marketing, or sale of a Jointly Developed Product, or (ii) for the sale of a Custom Component, provided that:
1. the Mutual Exclusivity requirement applies only to the Jointly Developed Product or the Custom Component, as applicable, and is not tied to the availability of other products containing PEEK or other forms, grades, or types of PEEK;
 2. for any Jointly Developed Product, the Mutual Exclusivity term does not extend beyond five (5) years in length after the date of the first FDA approval for sale of the Jointly Developed Product;
 3. for any Custom Component, the Mutual Exclusivity term does not extend beyond three (3) years from (i) the date of first FDA approval for sale of the Customer Product(s) within which the Custom Component is incorporated, or (ii) if the Custom Component is incorporated into a Customer Product previously approved by the FDA, the first commercial sale of the Custom

Decision and Order

Component following completion of the validation master plan; and

4. Respondents' sales allowed under this Paragraph II.E do not exceed thirty (30) percent of all PEEK sales by Respondents in any twelve-month period, as measured either in units or in revenues.

F. Notwithstanding any other provision of this Order, if:

1. Respondents timely deliver the Order and Exhibits B and C to a Customer with an applicable Legacy Contract as required by Paragraph III(G); and
2. the Customer has not indicated that it will comply with the terms of Exhibit C by counter-signing and delivering Exhibit C to Respondents,

it shall not constitute a violation of this Order for Respondents to (i) enforce existing Exclusivity terms in a Legacy Contract, but only as applied to Customer Products for which the Customer has made a submission for regulatory clearance as of the date this Order is issued, or (ii) enforce terms under a Legacy Contract that prohibit Dual Sourcing of any Customer Product.

Provided, however, that as to any Customer that has counter-signed and delivered Exhibit C to Respondents, Respondents shall submit to the Commission written notice of any communication from any Respondent to the Customer that the Customer has breached the terms set forth in Exhibit C. Respondents shall submit any such notice to the Commission at least sixty (60) days prior to exercising any right of termination resulting from the alleged breach, during which time the Customer shall be given the opportunity to cure the alleged breach.

Decision and Order

III.

IT IS FURTHER ORDERED that Respondents shall design, maintain, and operate an Antitrust Compliance Program that sets forth the policies and procedures Respondents have implemented to comply with this Order and with the Antitrust Laws. So long as Respondents are under common ownership, they may operate under a single Antitrust Compliance Program. This program shall include, but not be limited to:

- A. Respondents' designation and retention for the duration of the Order of an antitrust compliance officer or director to supervise the design, maintenance, and operation of this program;
- B. Training regarding Respondents' obligations under this Order and the Antitrust Laws for Respondents' Executive and Sales Staff to occur:
 - 1. Within thirty (30) days after this Order becomes final, or for any subsequently hired Executive and Sales Staff, within thirty (30) days of their employment start date; and
 - 2. At least annually to all Executive and Sales Staff of Respondents.
- C. Policies and procedures for employees and representatives of Respondents to ask questions about, and report violations of, this Order and the Antitrust Laws confidentially and without fear of retaliation of any kind;
- D. Policies and procedures for disciplining employees and representatives of Respondents for failure to comply with this Order and the Antitrust Laws;
- E. The retention of documents and records sufficient to record Respondents' compliance with its obligations under this Paragraph III of this Order, including but not limited to records showing that employees and

Decision and Order

representatives of Respondents have received all trainings required under this Order during the preceding two (2) years;

- F. Distribution of a copy of this Order and Exhibit A to this Order to all Executive and Sales Staff:
 - 1. Within thirty (30) days of the date this Order is issued;
 - 2. Annually within thirty (30) days of the anniversary of the date this Order is issued until the Order terminates; and
 - 3. Within thirty (30) days of any Person first becoming a member of Executive and Sales Staff.
- G. Within ten (10) days of the date this Order is issued, delivery to each Customer that has a current contract with any Respondent, of a copy of: (1) this Order; and (2) as applicable, either: (a) for a Customer with a contract that includes Exclusivity terms, Exhibits B and C; or (b) for a Customer with a contract that does not include Exclusivity terms, Exhibit D. Delivery under this Paragraph III.G shall be made (i) to the Customer's President, CEO, chief legal counsel, or senior executive overseeing PEEK purchasing; and (ii) to Respondents' primary contact with the Customer for contract negotiations.

IV.**IT IS FURTHER ORDERED** that:

- A. Within thirty (30) days after the date this Order is issued, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which the it has complied, is complying, and will comply with this Order. So long as Respondents are under common ownership, their reports may be filed jointly. For the

Decision and Order

period covered by this report, the reports shall include, but not be limited to:

1. The name, title, business address, e-mail address, and business telephone number of the officer(s) or director(s) designated by each Respondent to design, maintain, and operate its Antitrust Compliance Program; and
 2. For each Customer to whom Respondents sent Exhibits B and C or Exhibit D, as applicable, provide the following information: name, address, telephone number, addressee(s), date(s) of delivery, and identification of whether the Customer received Exhibits B and C or Exhibit D.
- B. Ninety (90) days after the date this Order is issued, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it has complied, is complying, and will comply with this Order. So long as Respondents are under common ownership, their reports may be filed jointly. For the period covered by this report, the reports shall include, but not be limited to:
1. The name, title, business address, e-mail address, and business telephone number of the officer(s) or director(s) designated by each Respondent to design, maintain, and operate its Antitrust Compliance Program; and
 2. For each Customer to whom Respondents sent Exhibits B and C, provide the following information: name, address, telephone number, addressee(s), date(s) of delivery, and whether such Customer has returned a signed copy of Exhibit C.
- C. One (1) year after the date this Order is issued, and annually for the following four (4) years on the anniversary of the date this Order is issued, as well as

Decision and Order

at any other such times as the Commission may require, each Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order. So long as Respondents are under common ownership, their reports may be filed jointly. For the periods covered by these reports, these reports shall include, but not be limited to:

1. The name, title, business address, e-mail address, and business telephone number of the officer(s) or director(s) designated by Respondents to design, maintain, and operate Respondents' Antitrust Compliance Program; and
2. For each Customer to whom Respondents sent Exhibits B and C, the following information: name, address, telephone number, addressee(s), and date(s) of delivery, and whether such customer has returned a signed copy of Exhibit C.
3. For any contract or agreement permitted under Paragraph II.E of this Order that was not included in a prior written report, the following information: Customer with whom the contract or agreement was entered, date the contract or agreement was entered, term of the contract or agreement, a brief description of the Jointly Developed Product or Custom Component that is the subject of the contract or agreement, a brief description Respondents' contributions or investments, and the nature and scope of exclusivity terms.

V.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of a Respondent;

Decision and Order

- B. Any proposed acquisition, merger or consolidation of a Respondent; or
- C. Any other change in any Respondent, including but not limited to, assignment, the creation or dissolution of subsidiaries, or if such change may affect compliance obligations arising out of this Order.

VI.

IT IS FURTHER ORDERED that for the purpose of determining or securing compliance with this order, upon written request, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of any Respondent relating to any matters contained in this Order, which copying services shall be provided by Respondents at the request of the authorized representative(s) of the Commission and at the expense of Respondents; and
- B. Upon five (5) days' notice to a Respondent and without restraint or interference from Respondents, to interview officers, directors, or employees of any Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order shall terminate on July 13, 2036.

By the Commission.

Decision and Order

Exhibit A**EXHIBIT A**
[Internal Notice]

The Federal Trade Commission ("FTC") has been investigating various practices used by Victrex plc, Invibio, Inc., and Invibio Limited (hereinafter collectively referred to as "Invibio") in the marketing and sale of implant- and medical-grade polyetheretherketone ("PEEK"). The purpose of the FTC's investigation has been to determine if any of those practices violate United States antitrust laws.

Invibio does not believe that its past or present practices violate any state or federal laws. However, to end the investigation quickly, and without admitting to any violations of any law, Invibio has signed a consent agreement with the FTC agreeing that the FTC can issue and Invibio will be bound by a Decision and Order ("Order") issued by the FTC.

It is very important to Invibio that all of its executives, employees and contractors understand and comply with the Order. We are providing this notice as a first step to help you do that by telling you about the Order, describing a few of its most important terms, and telling you how you can learn more about the Order and get answers to any questions you may have about it.

Generally, the Order prohibits Invibio and its employees from, directly or indirectly, formally or informally, entering agreements or engaging in practices that require its customers to purchase PEEK exclusively from Invibio. The terms of the Order affect how Invibio can offer discounts, product development support, and regulatory support to its customers. The Order prohibits Invibio from using its pricing and marketing policies and programs to retaliate against or punish customers who refuse to purchase Invibio's PEEK exclusively.

Invibio management wants to help you better understand Invibio's rights and obligations under the Order. Therefore, as required by the Order, Invibio has appointed [name and title] to oversee a program to train Invibio's executives and sales staff on the Order and the antitrust laws. You will be contacted soon to schedule your training, which must be conducted by [insert date 30 days from the date the Order is issued]. In the meantime, if you have any questions at any time about the Order or your training, please contact [identify contact person] at [e-mail or telephone].

Decision and Order

Exhibit B**EXHIBIT B***[Letter to Customers with Exclusivity Terms]*

[Invibio letterhead]

[Name and address of customer]

Dear [name of customer]:

The Federal Trade Commission ("FTC") has been investigating various practices used by Victrex plc, Invibio, Inc., and Invibio Limited (hereinafter collectively referred to as "Invibio") in the marketing and sale of implant- and medical-grade polyetheretherketone ("PEEK"). The purpose of the FTC's investigation has been to determine if any of those practices violate United States antitrust laws.

Invibio does not believe that its past or present practices violate any state or federal laws. However, to end the investigation quickly, and without admitting to any violations of any law, Invibio has signed a consent agreement with the FTC agreeing that the FTC can issue and Invibio will be bound by a Decision and Order ("Order") issued by the FTC.

Generally, the Order prohibits Invibio, directly or indirectly, formally or informally, from requiring its customers to purchase PEEK exclusively from Invibio for any customer product or group of products, subject to certain narrow exceptions set forth in the Order. The Order also prohibits Invibio from retaliating against or penalizing customers who use an alternative source of PEEK.

Accordingly, notwithstanding any provision to the contrary in the supply agreement between you and Invibio, you may use an alternative source of PEEK as the sole source of PEEK for any product that you submit to the FDA for clearance after [date Order is issued]. In addition, *if you sign Attachment 1 to this letter and return it to Invibio at the name and address indicated on Attachment 1*, you may:

1. switch to an alternative PEEK supplier for any existing product that you currently source with Invibio PEEK; and
2. Dual Source PEEK for any of your products.

The term "Dual Source" is defined in the Order and in Attachment 1 to this letter.

A copy of the Order is enclosed. You also may read and download a copy of the Order from the FTC at its web site at [web link to case on FTC website]. Invibio's obligations under the Order are set out in Paragraph II of the Order, beginning on page 6. Capitalized terms used in the Order are defined in Paragraph I of the Order, which begins on page 2.

Decision and Order

If you have concerns in the future about whether Invibio is complying with its obligations under the Order, Invibio invites you to contact us, the FTC, or both. You may contact Invibio through the sales staff with whom you do business, or contact our corporate offices directly by phoning or e-mailing [name] at [phone number and e-mail address]. Alternatively or additionally, you may contact the FTC directly to express your concerns by phoning or e-mailing [name] at [phone number and e-mail address].

Thank you again for your continued support and the confidence you have shown for Invibio products.

Sincerely,

[name and title]

Encl.

Decision and Order

Exhibit C**EXHIBIT C***[Attachment 1 to Letter to Customers with Exclusivity Terms]*

_____ (“Customer”) hereby agrees to comply with the terms set forth below modifying all agreements, including supply agreements between Customer and Invibio. These terms shall remain in effect for so long as Customer has in its possession Invibio PEEK purchased under agreements between Customer and Invibio that has not been integrated into Customer’s products.

Whether or not Customer agrees to the terms below, Invibio has waived any term in the current supply agreement between Customer and Invibio that could otherwise be construed to prevent Customer from using a Competing PEEK as its sole source of PEEK for any Customer product that Customer submits to the FDA for clearance after [date Order is issued].

In exchange for Customer agreeing to the terms set forth below, when Customer delivers a signed copy of this Exhibit C, which shall become material terms to Customer’s existing contract, to Invibio at the address below, Invibio will waive any term in the supply agreement between Customer and Invibio that could otherwise be construed to prevent Customer from (a) for any existing Customer product, switching to a Competing PEEK; or (b) for any existing or new Customer product, Dual Sourcing PEEK.

1. Customer shall not Commingle PEEK.
2. Customer shall maintain or have maintained, for the expected life of the applicable Customer product, records sufficient to identify the source of PEEK used in each Batch of any Customer product (a) that is Dual Sourced; or (b) as to which Customer has switched from using Invibio PEEK to using a Competing PEEK.
3. As to any Customer product (a) that is Dual Sourced; or (b) as to which Customer has switched from Invibio PEEK to a Competing PEEK, Customer shall give prompt written notice after Customer becomes aware of any adverse facts or issues relating to the safety or efficacy of Invibio PEEK in a Customer product. Further, upon request by Invibio, Customer shall promptly inform Invibio whether a Customer product subject to a publicly disclosed recall contains Invibio PEEK.

“Batch” means a specific quantity of medical device, implant, medical instrument, or similar item intended for use inside of or in contact with a human body, which (i) is intended to have uniform character and quality, within specified limits; and (ii) is produced according to a single manufacturing order during the same cycle of manufacture.

“Commingle” or “Commingleing” means the use or mixing of Invibio PEEK and Competing PEEK within a single unit of a Customer product. For the avoidance of doubt, Customer may satisfy the no-commingling requirement in Paragraph 1 above by

Decision and Order

using only one source of PEEK in a single Batch.

“Competing PEEK” means any PEEK manufactured or sold by any entity other than Invibio.

“Dual Source” or “Dual Sourcing” means selling, offering for sale, or distributing two or more units of a Customer product with the same product name and part number, some of which are manufactured from Invibio PEEK and some of which are manufactured from Competing PEEK.

“PEEK” means polyetheretherketone of any grade or form (including, but not limited to, granules, rods, near net shapes, and components) used or intended for continuous or discontinuous use in a medical device, implant, medical instrument, or similar item intended for use inside of or in contact with a human body for longer than 24 hours.

FOR INVIBIO:

Signature: _____

Printed Name: _____

Title: _____

Date: _____

FOR CUSTOMER:

Signature: _____

Printed Name: _____

Title: _____

Date: _____

AFTER SIGNING, DELIVER TO:

[NAME]

[TITLE]

[ADDRESS]

Decision and Order

Exhibit D**EXHIBIT D***[Letter to Customers with No Exclusivity Terms]*

[Invibio letterhead]

[Name and address of customer]

Dear [name of customer]:

The Federal Trade Commission ("FTC") has been investigating various practices used by Victrex plc, Invibio, Inc., and Invibio Limited (hereinafter collectively referred to as "Invibio") in the marketing and sale of implant- and medical-grade polyetheretherketone ("PEEK"). The purpose of the FTC's investigation has been to determine if any of those practices violate United States antitrust laws.

Invibio does not believe that its past or present practices violate any state or federal laws. However, to end the investigation quickly, and without admitting to any violations of any law, Invibio has signed a consent agreement with the FTC agreeing that the FTC can issue and Invibio will be bound by a Decision and Order ("Order") issued by the FTC.

Generally, the Order prohibits Invibio, directly or indirectly, formally or informally, from requiring its customers to purchase PEEK exclusively from Invibio for any customer product or group of products, subject to certain narrow exceptions set forth in the Order. The Order also prohibits Invibio from retaliating against or penalizing customers who use an alternative source of PEEK.

A copy of the Order is enclosed. You also may read and download a copy of the Order from the FTC at its web site at [web link to case on FTC website]. Invibio's obligations under the Order are set out in Paragraph II of the Order, beginning on page 6. Capitalized terms used in the Order are defined in Paragraph I of the Order, which begins on page 2.

If you have concerns in the future about whether Invibio is complying with its obligations under the Order, Invibio invites you to contact us, the FTC, or both. You may contact Invibio through the sales staff with whom you do business, or contact our corporate offices directly by phoning or e-mailing [name] at [phone number and e-mail address]. Alternatively or additionally, you may contact the FTC directly to express your concerns by phoning or e-mailing [name] at [phone number and e-mail address].

Thank you again for your continued support and the confidence you have shown for Invibio products.

Sincerely,

[name and title]

Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT****I. Introduction**

The Federal Trade Commission has accepted, subject to final approval, an Agreement Containing Consent Order with Victrex plc and its wholly owned subsidiaries Invibio Limited and Invibio, Inc. (collectively, “Invibio”). Invibio makes and sells implant-grade PEEK, a high-performance polymer contained in implantable devices used in spinal interbody fusion and other medical procedures. The proposed consent order seeks to address allegations that Invibio used exclusive supply contracts to maintain its monopoly power in the market for implant-grade PEEK, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

The proposed order contained in the consent agreement requires Invibio to cease and desist from enforcing most exclusivity terms in current supply contracts and generally prohibits Invibio from requiring exclusivity in future contracts. The order also prevents Invibio from adopting other mechanisms, such as market-share discounts or retroactive volume discounts, to maintain its monopoly power.

The proposed order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the consent agreement and the comments received and will decide whether it should withdraw from the consent agreement and take appropriate action or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint, the consent agreement, or the proposed order, or to modify their terms in any way. The consent agreement is for settlement purposes only and does not constitute an admission by Invibio that the law has been violated as alleged in the complaint or that the facts alleged in the complaint, other than jurisdictional facts, are true.

Analysis to Aid Public Comment

II. The Complaint

The complaint makes the following allegations.

A. Industry Background

Implant-grade PEEK has properties, such as elasticity, machinability, and radiolucency, that are distinct from other materials used in implantable medical devices, such as titanium and bone. These properties make PEEK especially suitable for many types of implantable medical devices, particularly spinal interbody fusion devices. Invibio was the first company to develop and sell implant-grade PEEK. The United States Food and Drug Administration (“FDA”) first cleared a medical device containing Invibio PEEK in 1999. Upon introducing implant-grade PEEK, Invibio sold the product to its medical device maker customers under long-term supply contracts, many of which included exclusivity requirements.

For a number of years, Invibio was the only supplier of implant-grade PEEK. In the late 2000s, however, first Solvay Specialty Polymers LLC (“Solvay”) and then Evonik Corporation (“Evonik”) took steps to enter the market. The FDA cleared the first spinal implant device containing Solvay PEEK in 2010, and the first one containing Evonik PEEK in 2013.

B. Invibio’s Use of Exclusivity Terms to Impede Competitors

Invibio responded to Solvay’s and Evonik’s entry by tightening and expanding the scope of exclusivity provisions in its supply contracts with medical device makers. Invibio did this to impede Solvay and Evonik from developing into effective rivals. Invibio knew that if Solvay and Evonik could gain reputation and experience, in particular, by developing supply relationships with leading medical device makers, this would validate their status as PEEK suppliers with other potential PEEK buyers and ultimately lead to significant price competition—painful for Invibio but beneficial to medical device makers.

Analysis to Aid Public Comment

Invibio extracted exclusivity terms from customers both by threatening to withhold critical supply or support services and by offering minor inducements. For example, Invibio threatened to withhold access to new brands of its PEEK and to Invibio's FDA master file if a customer declined to purchase exclusively from Invibio. Where necessary, Invibio offered small price discounts in exchange for exclusivity.

Due to Invibio's efforts, nearly all medical device makers that purchase PEEK from Invibio do so under contracts that impose some form of exclusivity. Although precise exclusivity terms vary, they generally take one of three forms: (1) requiring the use of Invibio PEEK for all PEEK-containing devices; (2) requiring the use of Invibio PEEK for a broad category of PEEK-containing devices; or (3) requiring the use of Invibio PEEK for a list of identified PEEK-containing devices. Even where exclusivity terms apply at the device level, *i.e.*, to a list of specified devices, the foreclosure effect is substantial: the list often includes nearly every device in the customer's portfolio and the customer thus cannot source substantial volumes of PEEK from Invibio's competitors. Taken together, Invibio's exclusive contracts foreclose a substantial majority of PEEK sales from Invibio's rivals.

C. Invibio's Monopoly Power

Both direct and indirect evidence demonstrate that Invibio has monopoly power in the market for implant-grade PEEK. Invibio has priced its PEEK substantially higher than competing versions of PEEK, without ceding material market share, and has impeded competitors through its exclusive contracts. In addition, Invibio has consistently held an over-90% share of a relevant market with substantial entry barriers, which indirectly evidences its monopoly power. PEEK has distinctive properties from other materials used in spinal and other implants. Physician preferences typically drive the choice of materials used in an implant, and these preferences largely reflect material properties rather than price. Other materials are therefore not sufficiently close substitutes to prevent a monopolist PEEK supplier from profitably raising prices. The relevant product market is therefore no broader than implant-

Analysis to Aid Public Comment

grade PEEK, *i.e.*, PEEK that has been used in at least one device cleared by the FDA.

D. Competitive Impact of Invibio's Conduct

Through its exclusive contracting strategy, Invibio has maintained its monopoly power and harmed competition by marginalizing its competitors. In addition, Invibio's exclusive contracts have prevented its customers from exercising a meaningful choice between implant-grade PEEK suppliers and from enjoying the full benefits of competition, including price competition.

Invibio's exclusivity terms have prevented Solvay and Evonik from achieving a significant volume of implant-grade PEEK sales, notwithstanding their offering of significantly lower prices. Invibio has also excluded Solvay and Evonik from forming supply relationships with key medical device makers. As a result, Solvay and Evonik have been unable to achieve significant market share and have consistently missed sales targets. There is a significant risk that continued enforcement of Invibio's exclusive contracts would preclude Solvay and Evonik from achieving sufficient returns to justify future investments, including in innovative technologies. Without those investments, the firms would be even less effective competitors in the future.

Additionally, Invibio's exclusive contracts have deprived medical device makers of the opportunity to make a meaningful choice among competing suppliers and thereby enjoy the benefits of price, innovation, and quality competition. Even medical device makers that would not have switched to a competitor of Invibio would have benefited from a more competitive market. In addition, many medical device makers prefer to have more than one source of PEEK in order to mitigate risk and for other commercial benefits. Absent Invibio's exclusivity requirements, a significant number of device makers would contract with Solvay or Evonik to secure lower-priced PEEK and additional or alternate sources of supply. However, medical device makers locked into long-term exclusive contracts have been precluded from pursuing their preferred procurement strategy.

Analysis to Aid Public Comment

III. Legal Analysis

Monopolization is among the “unfair methods of competition” prohibited by Section 5 of the FTC Act.¹ A firm unlawfully maintains monopoly power when it “engage[s] in anti-competitive conduct that reasonably appears to be a significant contribution to maintaining monopoly power.”²

Exclusive dealing by a monopolist may be condemned when it “allows [the] monopolist to maintain its monopoly power by raising its rivals’ costs sufficiently to prevent them from growing into effective competitors.”³ Of particular relevance is whether an exclusive dealing policy has “foreclose[d] competition in such a substantial share of the relevant market so as to adversely affect competition.”⁴ To be unlawful, exclusive dealing need not have foreclosed all competition from the market.⁵

1 See, e.g., *McWane, Inc. v. FTC*, 783 F.3d 814, 827 n.10 (11th Cir. 2015), cert. denied 577 U.S. --- (Mar. 21, 2016).

2 *McWane*, 783 F.3d at 833 (internal quotation marks and citations omitted); accord *United States v. Dentsply Int’l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005); *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (*en banc*) (citing 3 PHILIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 651c, at 78 (1996)).

3 *McWane*, 783 F.3d at 832 (citing XI PHILIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1804a, at 116–17 (2011)); accord *Dentsply*, 399 F.3d at 191; *Microsoft*, 253 F.3d at 69–71; see also *In re McWane, Inc.*, No. 9351, 2014 WL 556261 at *19, *28 (F.T.C. Jan. 30, 2014) (exclusive dealing by a monopolist may be unlawful where it “impair[s] the ability of rivals to grow into effective competitors that might erode the firm’s dominant position” or “denie[s] its customers the ability to make a meaningful choice”) (internal quotation marks and citations omitted), *aff’d*, *McWane, Inc. v. FTC*, 783 F.3d 814 (11th Cir. 2015).

4 *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 271 (3d Cir. 2012); see also *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961) (“In practical application, even though a contract is found to be an exclusive-dealing arrangement, it does not violate the section unless the court believes it probable that performance of the contract will foreclose competition in a substantial share of the line of commerce affected.”).

5 *Dentsply*, 399 F.3d at 191.

Analysis to Aid Public Comment

The factual allegations in the complaint support a finding of monopolization. Invibio's exclusivity strategy has not prevented entry entirely. But its exclusivity terms—whether full exclusivity terms or terms that apply at the product or product category level across a wide range of products—have foreclosed its rivals from a substantial portion of available sales opportunities in the relevant market and prevented those rivals from competing effectively. Among the foreclosed sales opportunities are key customers that would validate the reputations of Solvay and Evonik as legitimate rivals of Invibio, notwithstanding their more recent entry into the market. Invibio's exclusionary conduct has also reduced incentives to innovate and prevented PEEK consumers from exercising a meaningful choice among suppliers.

A monopolist may rebut a showing of competitive harm by demonstrating that the challenged conduct is reasonably necessary to achieve a procompetitive benefit.⁶ Any proffered justification, if proven, must be balanced against the harm caused by the challenged conduct.⁷ Here, no procompetitive efficiencies justify the scope of Invibio's exclusionary and anticompetitive conduct. Any procompetitive benefit could have been achieved through less restrictive means.

IV. The Proposed Order

The proposed order remedies Invibio's anticompetitive conduct and imposes certain fencing-in requirements in order to prevent *de facto* exclusivity between Invibio and its customers.

Paragraph I of the proposed order defines the key terms used throughout the rest of the order.

Paragraph II addresses the core of Invibio's anticompetitive conduct. Paragraph II.A prohibits Invibio from adopting or implementing any agreement or policy that results in "exclusivity" with customers. "Exclusivity" is defined to include any limit or prohibition by Invibio on its customers dealing with a competing implant-grade PEEK supplier or any requirement by

⁶ See, e.g., *Microsoft*, 253 F.3d at 59.

⁷ *Id.*

Analysis to Aid Public Comment

Invibio that a customer use only Invibio PEEK in (1) all of its devices, (2) in any group of devices, or (3) in any one device. The order thus applies to all forms of exclusivity that appear in Invibio's contracts.

Under Paragraph II.A, Invibio may not require exclusivity for any new contract, except in the limited circumstances set forth in Paragraph II.E (described below). Further, Invibio may not enforce exclusivity terms in an existing contract with any medical device maker that chooses to use an alternate implant-grade PEEK supplier instead of Invibio for any or all future devices. In addition, Paragraph II.A, in conjunction with Paragraph II.F (described below), prohibits Invibio from enforcing provisions in an existing contract that would prevent a medical device maker from using other suppliers of implant-grade PEEK for any device, or from switching suppliers for any current device, provided that the device maker agrees to the tracking requirements contained in Exhibit C of the order. The tracking requirements are designed to accommodate Invibio's concerns, related to potential product liability actions, about maintaining the ability to identify devices that use Invibio PEEK and are generally consistent with industry practice.

Paragraph II.B prohibits Invibio from retaliating against customers for using or preparing to use an alternate PEEK supplier. Prohibited retaliation includes cutting off PEEK sales or withholding access to regulatory support.

Paragraph II.C contains provisions designed to prevent *de facto* exclusivity in the future. For all new contracts, Invibio may not require minimum purchases, either as a condition of sale or as a condition for receiving important contract terms or services, other than as described in Paragraph II.D. Invibio may not offer volume discounts that are applied retroactively once a customer reaches a specified threshold. For example, Invibio may provide a discount on sales beyond 100 units but it may not lower the price of the first 99 units if and when the customer buys the 100th unit. Invibio may, however, provide certain discounts and non-price incentives designed to meet competition.

Analysis to Aid Public Comment

Paragraph II.D allows Invibio to condition its provision of certain types of extraordinary support to a customer for new devices on minimum purchase requirements for three years after the date of FDA clearance for such devices, so long as the minimum purchase amounts to less than 30 percent of the customer's implant-grade PEEK requirements for the device(s) that received the support. Extraordinary support excludes routine services such as maintaining and granting access to Invibio's FDA master file.

Paragraph II.E contains provisions designed to allow for procompetitive collaboration with a customer and preserve Invibio's incentives to innovate, including through investments that may be susceptible to free-riding by competitors. The paragraph allows Invibio to enter into a mutually exclusive contract with a customer when Invibio and the customer have engaged in the joint development of a new product that has required the contribution of significant capital, intellectual property rights, or labor by both Invibio and the customer, or when a customer asks that Invibio manufacture a custom component to the customer's specifications. Current PEEK sales subject to such contracts represent a small portion of the relevant market. Nonetheless, several limitations apply under this paragraph. The contracts must be: in writing, time-limited, applicable only to the jointly developed or custom product, and notified to the Commission. Invibio may not tie the availability of other forms, grades, or types of PEEK to a customer's willingness or agreement to enter into this type of contract. Further, sales resulting from these exclusive contracts may not account for more than 30 percent of Invibio's total annual sales.

Paragraph II.F allows Invibio to maintain limited exclusivity in existing contracts if customers do not agree to certain tracking requirements. Specifically, Invibio may enforce specified product-level exclusivity terms in existing contracts if the customer does not accept the terms set forth in Exhibit C to the proposed order, thereby agreeing: (1) not to mix (commingle) PEEK from different suppliers in a single unit of a device; (2) to maintain records that identify which supplier's PEEK is used in any batch of devices that are dual-sourced; and (3) to notify Invibio in the event of an adverse event related to Invibio's PEEK. These

Analysis to Aid Public Comment

tracking requirements are generally consistent with existing industry practice.

Paragraph III requires Invibio to implement an antitrust compliance program, which includes providing notice of the order to Invibio's customers. Paragraphs IV-VI impose reporting and other compliance requirements.

The proposed order would expire in 20 years.

Complaint

IN THE MATTER OF

AMERICAN AIR LIQUIDE HOLDINGS, INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT

Docket No. C-4574; File No. 161 0045
Complaint, May 12, 2016 – Decision, July 15, 2016

This consent order addresses the \$13.4 billion acquisition by American Air Liquide Holdings, Inc., of certain assets of Airgas, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by substantially lessening competition in various geographic markets for bulk oxygen, bulk nitrogen, bulk argon, bulk nitrous oxide, bulk liquid carbon dioxide, dry ice, and retail packaged welding gases. The consent order requires Air Liquide to divest sixteen air separation units (“ASUs”), four vertically integrated dry ice and liquid carbon dioxide plants, two separate liquid carbon dioxide plants, two nitrous oxide plants, and three retail packaged welding gas and hardgoods stores.

Participants

For the *Commission*: Jeffrey Dahnke, Jonathan. Ripa, Christine Tasso, and Sarah Wohl.

For the *Respondent*: Bryan Byrne, Cleary Gottlieb Steen & Hamilton LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent American Air Liquide Holdings, Inc. (“Air Liquide”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Airgas, Inc. (“Airgas”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect