

**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-**

**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 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 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.

- 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 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 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) 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 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.

## 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
    - (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
    - (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;
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 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:
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 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.

### 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 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 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 Respondents 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 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;
- 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 twenty years following the date of this Order.

By the Commission.

Donald S. Clark  
Secretary

[SEAL]

ISSUED:

**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].

## 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.



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.

## 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 “Commingling” 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

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]

**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]**