Analysis of Agreement Containing Consent Order to Aid Public Comment
In the Matter of Victrex, plc; Invibio, Limited; and Invibio, Inc., File No. 141-0042

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.

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.

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-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.

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

[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)).

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]

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.

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[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.

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

[7] *Id*.

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 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 100^{th} unit. Invibio may, however, provide certain discounts and non-price incentives designed to meet competition.

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 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.