

Analysis to Aid Public Comment Biovail Corporation and Elan Corporation, File No. 011 0132

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with Biovail Corporation (“Biovail”) and Elan Corporation, plc (“Elan”), settling charges that the two companies illegally agreed to restrain competition in the market for generic Adalat CC. The Commission has placed the proposed consent order on the public record for thirty days to receive comments by interested persons. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by either Biovail or Elan that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

Background

Biovail is a Canadian manufacturer of branded and generic pharmaceutical products. Elan is an Irish manufacturer of branded and generic pharmaceutical products. Biovail and Elan are the only two sellers of generic forms of Adalat CC (“generic Adalat”), a once-a-day anti-hypertension medication. No other company has even sought Food and Drug Administration (“FDA”) approval to sell a 30 mg or a 60 mg dosage form of generic Adalat. Bayer AG (“Bayer”) manufactures branded Adalat CC. In 1999, before the entry of generic equivalents to Adalat CC, Bayer’s United States sales of the 30 mg and 60 mg dosages of Adalat CC were in excess of \$270 million.

Biovail was the first to file an Abbreviated New Drug Application (“ANDA”) for FDA approval on the 60 mg dosage, and Elan was the first to file an ANDA for FDA approval on the 30 mg dosage. Thus, Elan had 180 days of exclusivity for the 30 mg product upon receiving final FDA approval, and Biovail had the 180-day exclusivity on the 60 mg product upon receiving final FDA approval. Each was the second to file on the other dosage.

In October 1999, after both Biovail and Elan (hereinafter sometimes referred to as “Respondents”) had filed for FDA approval of their 30 mg and 60 mg generic Adalat products, they entered into an agreement involving all four of their generic Adalat products. That agreement (the “Agreement”), and the Respondents’ conduct arising out of that Agreement, are the subject of the Commission’s complaint. The complaint alleges that, by entering the Agreement, Respondents illegally created market power in the United States market for sales of 30 mg and 60 mg dosages of generic Adalat. There is little prospect of new entry in the near future, because no other companies have applied for FDA approval of a 30 mg or a 60 mg generic Adalat product.

The Challenged Conduct

Under Respondents’ Agreement, Elan appointed Biovail as the exclusive distributor of Elan’s 30 mg and 60 mg generic Adalat products. At the time of the Agreement, neither Elan nor Biovail distributed its own generic drugs in the United States. Teva Pharmaceuticals, Inc. (“Teva”), a distributor of some of Biovail’s products, participated in the negotiations leading up to the Agreement. The Agreement provided that Biovail appoint Teva to sub-distribute Elan’s 30 mg generic Adalat product in the United States. With

respect to Elan's 60 mg product, the Agreement provided that, upon notice from Elan that Elan's 60 mg product was ready for commercial launch, Biovail would appoint either Teva or another company as a sub-distributor of that product. The Agreement has a minimum term of 15 years.

The FDA approved Elan's 30 mg generic Adalat product in March 2000 and its 60 mg product in October 2001. It approved Biovail's 30 mg and 60 mg generic Adalat products in December 2000. Biovail began selling Elan's 30 mg product immediately after receiving final FDA approval. Biovail began selling its own 60 mg product through Teva immediately after the FDA gave final approval to that product. Neither Elan's 60 mg product nor Biovail's 30 mg product, however, has ever been launched commercially. Thus, although two 30 mg generic Adalat products and two 60 mg generic Adalat products have had FDA approval for many months, consumers can purchase only one product at each strength.

The complaint alleges that, in exchange for the right to distribute Elan's products and share in the profits of those products, Biovail agreed to make specified payments to Elan. To date, Biovail has paid Elan approximately \$33 million in connection with its distribution of Elan's 30 mg generic Adalat product, and \$12.75 million in connection with the right to distribute Elan's 60 mg generic Adalat product.

As the complaint alleges, the Agreement gave Biovail substantial incentives not to launch its own 30 mg product. Although Biovail has had final FDA approval to market its 30 mg product for over one year, and the Agreement purports to require Biovail to use "reasonable commercial endeavors" to launch that product "with reasonable dispatch," Biovail has not yet launched that product. Biovail's launch of its own 30 mg product could be expected to cause a significant reduction in the price of Elan's incumbent 30 mg product, and generate for Elan's product lower total profits, which Biovail shares with Elan. For the same reasons, the Agreement diminished Biovail's incentives to exercise maximum efforts at eliminating the technological obstacles, if any, that Biovail asserts have impeded its ability to launch a self-manufactured 30 mg product. Elan also does not have any incentive to enforce the Agreement's provision requiring that Biovail use reasonable efforts to launch its 30 mg product in competition with Elan's product.

Similarly, the complaint alleges that the Agreement gave Elan substantial incentives not to launch its 60 mg product. Under the Agreement, in exchange for receiving a large up-front payment, Elan, in effect, stood to receive no royalties upon launch of its 60 mg product, until that product generated certain profits for Biovail. It would take several years of sales before Elan's 60 mg product would generate such profits, and once that triggering event happened, Elan's royalty was to be only 6% of profits. Accordingly, the complaint alleges that the Agreement compensated Elan for its 60 mg product up-front and pre-entry, while substantially diminishing that product's value to Elan thereafter. The Agreement also diminished Elan's incentives to exercise maximum efforts at eliminating any technological obstacles to launching its 60 mg product, if any, that Elan has asserted to exist. Moreover, neither Elan nor Biovail had any financial incentives to enforce the provision requiring launch of Elan's 60 mg product. As with the launch of Biovail's 30 mg product, Respondents knew that Elan's launch of its own 60 mg product could be expected to cause a reduction in the price of Biovail's incumbent 60 mg product by a significant amount and generate lower total profits for Biovail's product. It was in Biovail's strategic interest, therefore, for Elan not to launch its 60 mg product.

The complaint further alleges that even if Biovail had launched its 30 mg product and Elan had launched its 60 mg product, the Agreement allows Biovail to control or influence pricing and other competitive features of both its and Elan's 30 mg and 60 mg generic Adalat products. Biovail was thus in a position to profit by suppressing competition between its and Elan's products.

For the above reasons, the complaint alleges that Respondents' Agreement is an agreement not to compete between the only two producers of the 30 mg and 60 mg generic Adalat products. As a result, Teva, Biovail's distributor, is the only firm selling generic Adalat to consumers in the United States, and consumers have had access to only one of two approved generic Adalat products at each strength. Moreover, the Agreement is not justified by any countervailing efficiency.

The Proposed Order

The proposed order remedies the Respondents' anticompetitive conduct by requiring them to end their anticompetitive Agreement and barring them from engaging in similar conduct in the future. It maintains supply of the incumbent generic Adalat products while Respondents unwind their anticompetitive Agreement and eliminates the anticompetitive obstacles to entry of a second 30 mg and a second 60 mg generic Adalat product.

Paragraph I of the proposed order contains definitions, one of which defines the "Adalat CC Agreement" as the "License, Distribution & Supply Agreement" covering generic Adalat that Biovail and Elan executed on October 4, 1999, and all modifications and amendments thereto. We discuss other definitions below, as needed to explain the substantive provisions of the proposed order.

Paragraph II of the proposed order is a core provision, prohibiting Biovail or Elan from repeating the instant conduct by entering anticompetitive price, output, or distribution agreements with other generic drug companies. This provision targets agreements between either Respondent and other persons concerning a generic drug for which both parties to the agreement have filed for FDA approval of an ANDA referencing the same pioneer drug product. It aims to prohibit agreements between competing generic drug manufacturers that restrict the marketing of competing generic drugs.

Paragraph III of the proposed order requires Biovail and Elan to terminate their agreement on generic Adalat no later than the date on which the order becomes final. Paragraph 13 of the Agreement Containing Consent Order required them to start the termination process upon their execution of that document. The proviso to Paragraph III allows Biovail and Elan to resolve financial issues connected to the termination of their agreement on generic Adalat on mutually agreeable terms; however, they cannot resolve those financial issues by using sales, revenues, or profits generated by generic Adalat or any other drug product, or by transferring rights connected to any drug product. This limitation is intended to ensure that, in resolving the financial issues, Respondents do not perpetuate the anticompetitive effects of the Agreement by continuing the entanglements between them on generic Adalat or on other drug products.

Paragraph IV of the proposed order prohibits Elan from distributing its generic Adalat products through Teva. This prohibition is necessary because Biovail and Teva have a long-standing commercial relationship, whereby Teva distributes some of Biovail's products. Forbidding Elan from distributing its generic Adalat products through Teva will minimize the risk of inappropriate information exchanges among Biovail, Elan, and Teva regarding generic Adalat, by eliminating any legitimate reason for all three companies to discuss their marketing of the products. Thus, it will help ensure that the termination of the Agreement fully restores the proper competitive incentives for each company.

The proviso to Paragraph IV requires Elan to supply Teva, through Biovail, with Elan's 30 mg product, until the earlier of Biovail's launch of its own 30 mg product or May 31, 2003 (the "Interim Supply Agreement"). This provision eliminates any disruption of supply of the 30 mg product to consumers while Elan makes alternate arrangements for the distribution of its products. Once Elan begins to distribute its own product through an independent distributor, the Interim Supply Agreement will assure that consumers have access to two generic 30 mg Adalat products. The Interim Supply Agreement may continue for up to a year, to give consumers the continued benefit of two 30 mg generic Adalat products while Biovail solves its purported manufacturing difficulty. Biovail has assured the Commission that it expects to overcome any manufacturing problems it has and launch its 30 mg generic Adalat product within a year. (Paragraph V further addresses Biovail's launch of its own 30 mg product, as we discuss below.)

Paragraph IV prohibits Elan from charging Biovail more than Elan's "Cost" for the product. Paragraph I of the proposed order defines "Cost" to mean Elan's actual manufacturing cost. The cost definition is narrow, to minimize Elan's ability to profit from the Interim Supply Agreement through manipulation of the definition. Preventing Elan from profiting by supplying Biovail with the Elan 30 mg generic Adalat product gives Elan a strong incentive to launch its own 30 mg product through an independent distributor as quickly as possible. Only through that launch will Elan begin to earn a profit on its 30 mg product. Because, under the Interim Supply Agreement, Biovail will receive Elan's 30 mg product at Elan's manufacturing cost, Biovail will be in the same competitive position with respect to the cost of the 30 mg product as will Elan. In addition, Biovail will have to compete with Elan's new distributor to gain and maintain market share. Thus, the narrow cost definition will also give consumers the benefit of immediate price competition between the 30 mg product marketed by Teva and the 30 mg product marketed by Elan's independent distributor.

Paragraph V of the proposed order requires Elan to use best efforts to launch its 30 mg and 60 mg generic Adalat products as promptly as possible through a distributor other than Teva. It also requires Biovail to use best efforts to manufacture and distribute its 30 mg generic Adalat product, and to use best efforts to continue to manufacture and distribute its 60 mg generic Adalat product through a distributor other than Elan's generic Adalat distributor. Paragraph V.C states that the purpose of these requirements is to restore competitive incentives in the market for generic Adalat, and to remedy the lessening of competition resulting from the anticompetitive practices alleged in the Commission's complaint. This provision covers all four generic Adalat products, to ensure that Biovail and Elan market their 30 mg and 60 mg products through separate distributors. The proposed order defines "Launch" to require Biovail and Elan to deliver commercial quantities of their generic Adalat products to a viable pharmaceutical distributor pursuant to a

commercially reasonable, multi-year contract. This definition will ensure that the launch of Elan's 60 mg product and of Biovail's 30 mg product is on a competitive scale.

The Commission will closely monitor Respondents' efforts to market their products. To facilitate this, the proposed order includes reporting requirements. Paragraph VIII requires Biovail and Elan to submit to the Commission verified written reports detailing each of their efforts to comply with the proposed order. Biovail and Elan must submit these reports every thirty days until they have complied with the proposed order.

Paragraph VI of the proposed order requires Biovail and Elan to give the Commission notice of two types of agreements with other pharmaceutical manufacturers. First, Paragraph VI.A requires Biovail and Elan to give notice of agreements where, at the time of the agreement, the parties to the agreement each own, control, or license another product that is in the same "Therapeutic Class" as the product covered by the agreement. (The proposed order defines "Therapeutic Class" as a class of drugs categorized by the Unified System of Classification contained in the most recent version of the IMS Health Incorporated publication *Market Research Database: Product Directory*.) A proviso excepts from the reporting requirement agreements that only transfer "Drug Delivery Technology" in exchange for a commercially reasonable cash royalty not to exceed five per cent of revenue. (The proposed order defines "Drug Delivery Technology" to mean technology that controls the release rate, or enhances the absorption or utilization, of a pharmaceutical compound.)

Second, Paragraph VI.B requires Biovail and Elan to give notice of agreements involving a product for which one party to the agreement has an ANDA that references a New Drug Application ("NDA") that the other party owns, controls, or licenses. The notification provisions contained in Paragraph VI are necessary, because the core prohibition in Paragraph II only reaches agreements involving ANDAs that reference the same branded drug. Paragraph VI ensures that the Commission will receive notice of potentially anticompetitive agreements not covered by Paragraph II (*i.e.*, agreements involving potentially competitive branded products, and agreements regarding a brand product and its generic equivalent.)

Paragraphs VII, VIII, IX, and X of the proposed order contain reporting and other standard Commission order provisions designed to assist the Commission in monitoring compliance with the order. Paragraph XI provides that the order will expire in ten years.

Opportunity for Public Comment

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

By accepting the proposed order subject to final approval, the Commission anticipates that the competitive issues alleged in the complaint will be resolved. The purpose of this analysis is to facilitate public

comment on the agreement. It is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.