

Complaint

IN THE MATTER OF

BIOVAIL CORPORATION, ET AL.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4057; File No. 0110132*
Complaint, August 15, 2002--Decision, August 15, 2002

This consent order addresses practices used by Respondents Biovail Corporation and Elan Corporation – respectively Canadian and Irish manufacturers of branded and generic pharmaceutical products – which were the first firms to file Abbreviated New Drug Applications (“ANDAs”) to market generic versions (in different dosage levels) of Adalat CC, a once-a-day anti-hypertension medication. The order, among other things, requires the respondents to terminate an agreement executed in 1999 – involving all four of the respondents’ generic Adalat products – under which Elan appointed Biovail as the exclusive distributor of Elan’s two generic Adalat products. The order also prohibits the respondents from entering into certain price, output, or distribution agreements with other generic drug companies concerning any generic drug for which both parties to the agreement have filed for FDA approval of an ANDA referencing the same pioneer drug product. In addition, the order prohibits Elan from distributing its generic Adalat products – with certain exceptions – through Teva Pharmaceuticals, Inc., which distributes some of Biovail’s products under a long-standing commercial relationship. The order also requires the respondents to use best efforts to market their respective 30 mg and 60 mg versions of generic Adalat products through separate distributors. In addition, the order requires the respondents to give the Commission notice of two prescribed types of agreements with other pharmaceutical manufacturers.

Participants

For the Commission: *Randall David Marks, Garry R. Gibbs, Ellen Connelly, Dara J. Diomande, Emily Jones, Timothy Abbott, Michael Kades, David R. Pender, Jeffrey W. Brennan, Rendell A. Davis, Jr., Roberta S. Baruch, and David J. Balan.*

For the Respondents: *Steven Newborn, Clifford Chance Rogers & Wells LLP, Ken Cancellara, Biovail, Charles Gilman, Larry Sorkin and Kristen Emigholz, Cahill, Gordon & Reindel, Marc Schildkraut, Howrey Simon Arnold & White LLP, and Libby Murphy, Elan.*

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that an agreement between Biovail Corporation (“Biovail”) and Elan Corporation, plc (“Elan”), hereinafter sometimes referred to as Respondents, has violated and violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint, stating its charges in that respect as follows:

Respondents

1. Respondent Biovail is a corporation organized under the laws of the Province of Ontario, Canada, with its principal place of business at 2488 Dunwin Drive, Mississauga, Ontario, Canada. Biovail’s subsidiary, Biovail Technologies, Ltd., has offices in the United States located at 3701 Concorde Parkway, Chantilly, Virginia 20151. Biovail is a manufacturer of branded and generic pharmaceutical products, and it is engaged in all stages of pharmaceutical development, from research, through clinical testing and regulatory filings, to full-scale manufacturing. Biovail’s 2001 world-wide revenues were over \$583 million.

2. Respondent Elan is a corporation organized under the laws of Ireland, with its principal place of business at Lincoln House, Lincoln Place, Dublin 2, Ireland. Elan’s subsidiary, Elan Pharmaceutical Research Corporation, has offices in the United States located at 1300 Gould Drive, Gainesville, Georgia 30504. Elan is a manufacturer of branded and generic pharmaceutical products, and it is engaged in all stages of pharmaceutical development, from research, through clinical testing and regulatory filings, to full-scale manufacturing. Elan’s 2001 world-wide revenues were \$1.7 billion.

3. Respondents are, and at all relevant times herein have been, engaged in commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

Complaint

4. Respondents are, and at all relevant times herein have been, corporations, as “corporation” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

Respondents’ Market Power

5. Adalat CC (“Adalat”), a prescription drug used to treat hypertension, is marketed in the United States in 30 mg, 60 mg, and 90 mg dosage forms. Bayer AG (“Bayer”) launched Adalat as a branded pharmaceutical product in 1993. In 1999, before the first entry of generic equivalents to Adalat (“generic Adalat”) in 2000, Bayer’s United States sales of the 30 mg and 60 mg dosages of Adalat were approximately \$270 million.

6. The relevant product markets within which to assess the effects of Respondents’ conduct described herein are the sale of 30 mg dosages of generic Adalat and the sale of 60 mg dosages of generic Adalat.

7. The relevant geographic market within which to assess the effects of Respondents’ conduct described herein is the United States.

8. In April 1997, Elan was the first company to file an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”) for approval to market a 30 mg generic Adalat product. In December 1997, Biovail became the second company to file an ANDA for approval to market a 30 mg generic Adalat product. In March 2000, the FDA granted final approval to Elan’s 30 mg product. The same month, pursuant to the agreement described hereinafter, Elan entered the market with its 30 mg product. In December 2000, the FDA granted final approval to Biovail’s 30 mg product. Biovail has never entered the market with its own 30 mg product.

9. In April 1998, Biovail was the first company to file an ANDA for approval to market a 60 mg generic Adalat product. In June 1999, Elan became the second company to file an ANDA for

Complaint

approval to market a 60 mg generic Adalat product. In December 2000, the FDA granted final approval to Biovail's 60 mg product. The same month, Biovail entered the market with its 60 mg product. In October 2001, the FDA granted final approval to Elan's 60 mg product. Elan has never entered the market with its own 60 mg product.

10. Biovail and Elan are the only manufacturers with FDA approval to market 30 mg and 60 mg generic Adalat products. No other manufacturer has applied for FDA approval of either a 30 mg or 60 mg generic Adalat product.

11. Biovail and Elan have market power in the United States markets for sales of the 30 mg and 60 mg dosages of generic Adalat (collectively the "relevant markets").

Respondents' Agreement

12. Biovail and Elan entered into an agreement in October 1999 whereby Elan appointed Biovail the exclusive distributor of Elan's 30 mg and 60 mg generic Adalat products. In exchange, Biovail agreed to make specified payments to Elan. Biovail also shares with Elan in the profits on the two Elan products. The agreement has a minimum term of 15 years.

13. 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 Biovail products in the United States, participated in the negotiations leading up to the agreement. Respondents' agreement provided that Teva would become Biovail's sub-distributor of Elan's 30 mg generic Adalat product. The agreement further provided that, upon notice from Elan that Elan's 60 mg product was ready for commercial launch, Biovail would appoint either Teva or another firm as sub-distributor for that product. Respondents thus created an arrangement whereby Teva could distribute Elan's 30 mg and Biovail's 60 mg product, some other sub-distributor of Biovail

Complaint

could distribute Elan's 60 mg product and Biovail's 30 mg product, and Biovail would receive profits from all four products.

14. Respondents modified their agreement in December 2000 and June 2001, but these modifications did not lessen any of the agreement's anticompetitive features. The June 2001 modification affected only Elan's 60 mg product.

15. Pursuant to its agreement with Elan, Biovail has paid Elan approximately \$33 million in connection with Teva's 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. Under the agreement, Biovail will continue to make payments to Elan, and share in profits from sales of Elan's generic Adalat products, at least until the year 2014.

Respondents' Incentives Under Their Agreement

16. Respondents' agreement gave Biovail substantial incentives not to launch its own 30 mg product. Respondents knew that Elan, as the first ANDA filer for a 30 mg generic Adalat product, would be the first to enter the market with that product, and that Biovail, as the second and only other ANDA filer for that product, would be the second to enter. Biovail's launch of its own 30 mg product could be expected to cause a reduction in the price of Elan's incumbent 30 mg product by a significant amount and generate for Elan's product lower total profits, which Biovail shares with Elan. Biovail, therefore, had a substantially reduced commercial interest in launching its own 30 mg product. For the same reasons, the agreement also diminished Biovail's incentives to exercise maximum efforts at eliminating the technological obstacles, if any, that Biovail asserts impeded its ability to launch a self-manufactured 30 mg product.

17. Respondents knew that Biovail, as the first ANDA filer for a 60 mg generic Adalat product, would be the first to enter the market with that product, and that Elan, as the second and only other ANDA filer for that product, would be the second to enter.

Complaint

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.

18. Respondents' agreement gave Elan substantial incentives not to launch its own 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. Once that triggering event happened, moreover, Elan's royalty was only to be 6% of profits. Accordingly, the agreement compensated Elan for its 60 mg product up-front and pre-entry, while substantially diminishing that product's value to Elan thereafter. For the same reasons, the agreement also diminished Elan's incentives to exercise maximum efforts at eliminating the technological obstacles, if any, that Elan asserts impeded its ability to launch a self-manufactured 60 mg product.

19. Respondents' agreement contained provisions that purportedly compelled Biovail to exercise "reasonable commercial endeavors" to launch "with reasonable dispatch" a self-manufactured 30 mg product in competition with Elan's 30 mg product, and compelled Elan to launch, through Biovail and Biovail's sub-distributor, a 60 mg product in competition with Biovail's product of that dosage. These provisions are ineffective. Neither Biovail nor Elan has any incentive to enforce these provisions against the other and, in fact, neither has done so, because to do so would have the effect of forcing competing products onto the market against their respective incumbent products and lowering each Respondent's profits.

20. 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

Complaint

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.

Respondents' Implementation of Their Agreement

21. After the FDA approved Elan's 30 mg generic Adalat product in March 2000, Biovail, pursuant to its agreement with Elan, began selling that product through Teva. Although Biovail obtained FDA approval to market its 30 mg generic Adalat product in December 2000, it has not entered the relevant market with that product. Had Biovail entered, and had the agreement's anticompetitive provisions not existed, Biovail's 30 mg product would have competed freely with Elan's 30 mg product.

22. After the FDA approved Biovail's 60 mg generic Adalat product in December 2000, Biovail immediately began selling that product through Teva. Although Elan obtained FDA approval to market its 60 mg generic Adalat product in October 2001, it has not entered the relevant market with that product. Had Elan entered, and had the agreement's anticompetitive provisions not existed, Elan's 60 mg product would have competed freely with Biovail's 60 mg product.

23. As a result of Biovail's failure to launch its own 30 mg generic Adalat product and Elan's failure to launch its 60 mg generic Adalat product, Teva is the only firm selling generic Adalat to consumers in the United States.

Effects of Respondents' Agreement

24. Respondents' acts and practices herein alleged have had either the purpose or effect of restraining, or the tendency to restrain, competition unreasonably and injuring consumers in the following ways, among others:

- a. By denying consumers, pharmacies, hospitals, insurers, wholesalers, government agencies, managed care

Complaint

organizations, and others the benefits of having competing generic Adalat products on the market;

- b. By forcing pharmacies, hospitals, insurers, wholesalers, government agencies, managed care organizations, and others to pay artificially high prices for generic Adalat products; and
- c. By forcing individual consumers to pay artificially high prices for generic Adalat products or to forgo purchasing such products by reason of an inability to afford them.

Unfair Methods of Competition

25. Respondents have agreed not to compete and thereby unreasonably restrained competition between the only two producers of generic Adalat products.

26. Respondents' anticompetitive agreement is not justified by any countervailing efficiencies.

27. Respondents' agreement and related acts and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. The acts and practices, as herein alleged, are continuing and will continue in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this fifteenth day of August, 2002, issues its complaint against said respondents.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of certain acts and practices of Biovail Corporation ("Biovail") and Elan Corporation, plc ("Elan"), hereinafter sometimes referred to as Respondents, and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violation 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 the Respondents of all the jurisdictional facts set forth in the aforesaid draft of 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 determined that it had reason to believe that the 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 from interested persons pursuant to section 2.34 of its Rules, hereby issues its Complaint, makes the following jurisdictional findings, and issues the following Order:

1. Respondent Biovail is a corporation organized under the laws of the Province of Ontario, Canada, with its principal

Decision and Order

place of business at 2488 Dunwin Drive, Mississauga, Ontario, Canada. Biovail's subsidiary, Biovail Technologies, Ltd., has offices in the United States located at 3701 Concorde Parkway, Chantilly, Virginia 20151.

2. Respondent Elan is a corporation organized under the laws of Ireland, with its principal place of business at Lincoln House, Lincoln Place, Dublin 2, Ireland. Elan's subsidiary, Elan Pharmaceutical Research Corporation, has offices in the United States located at 1300 Gould Drive, Gainesville, Georgia 30504.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of 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:

- A. "Respondent Biovail" means Biovail Corporation and its officers, directors, employees, agents and representatives, successors, and assigns; subsidiaries, divisions, groups, and affiliates controlled by Biovail; and the officers, directors, employees, agents and representatives, successors, and assigns of each.
- B. "Respondent Elan" means Elan Corporation, plc, and its officers, directors, employees, agents and representatives, successors, and assigns; subsidiaries, divisions, groups, and affiliates controlled by Elan; and the officers, directors, employees, agents and representatives, successors, and assigns of each.

Decision and Order

- C. “Respondents” means Respondent Biovail and Respondent Elan.
- D. “Commission” means the Federal Trade Commission.
- E. “Adalat CC Agreement” means the “License, Distribution & Supply Agreement” covering generic Adalat CC that Biovail and Elan executed on October 4, 1999; the subsequently modified separate agreements executed on December 29, 2000, and titled “Amended and Restated Licensing and Supply Agreement (30 mg Nifedipine O.D.)” and “Amended and Restated Licensing and Supply Agreement (60 mg Nifedipine O.D.);” and all other agreements and understandings that relate to or modify the agreements executed on October 4, 1999, and December 29, 2000. The October 4, 1999, “License, Distribution & Supply Agreement” is attached to this Order as a Confidential Appendix.
- F. “Agreement” means anything that would constitute an agreement under Section 1 of the Sherman Act or Section 5 of the Federal Trade Commission Act.
- G. “ANDA” means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j), *et seq.*
- H. “Cost” means Elan’s actual manufacturing cost. In no case shall Cost exceed fully allocated cost, which is the sum total of all production-related costs, packaging, and labeling for the product (direct labor, direct materials, facility overhead, and other overhead and expenses, including manufacturing charges for material adjustments, handling losses, physical adjustments, salvage and start-up costs, quality assurance, quality control, analytical charges, packaging, and regulatory compliance costs for the product including stability and FDA fees), together with insurance costs accounted for in accordance with United States Generally Accepted Accounting Principles and in a manner consistent with expenses and overhead allocated to other products

Decision and Order

manufactured by Elan. “Cost” shall *not* include any costs associated with (a) Elan's or Biovail's litigation against Bayer (including, but not limited to, attorneys’ fees, court fees, and actual or expected financial settlements with or payments to Bayer) and (b) compliance with this Order (including, but not limited to, attorneys’ fees and allocations for time spent by Respondents’ employees in complying with this Order).

- I. “Drug Delivery Technology” means a technology that controls the release rate, or enhances the absorption or utilization, of a pharmaceutical compound. “Drug Delivery Technology” does not include a Drug Product.
- J. “Drug Product” means a finished dosage form (*e.g.*, tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients, as defined in 21 C.F.R. § 314.3(b).
- K. “FDA” means the United States Food and Drug Administration.
- L. “Generic Adalat CC” means the Drug Products that include Biovail ANDAs 75-269 and 75-359 and Elan ANDAs 75-128 and 75-659.
- M. “Launch” means the delivery of commercial quantities of Generic Adalat CC to a viable pharmaceutical distributor pursuant to a commercially reasonable multi-year contract.
- N. “NDA” means a New Drug Application, as defined under 21 U.S.C. § 355(b), *et seq.*
- O. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- P. “Teva” means Teva Pharmaceuticals, Inc.

Decision and Order

- Q. "Therapeutic Class" means a class of drugs categorized at the fourth-level (xxxx-0) or, if no fourth-level exists for such class of drugs, then at the third-level (xxx-00) in the Unified System of Classification (USC) contained in the most recent version of the IMS Health Incorporated publication *Market Research Database: Product Directory*.

II.

IT IS FURTHER ORDERED that each Respondent, directly or indirectly, or through any corporate or other device, in connection with the manufacture or sale of a Drug Product in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, forthwith cease and desist from entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or facilitating any Agreement with any other person on the price, production, volume, marketing, distribution, or sale of a Drug Product where the ANDAs for that Drug Product of Respondent and of the other person reference the same NDA.

III.

IT IS FURTHER ORDERED that no later than the date on which this Order becomes final, Respondents shall terminate all rights, under the Adalat CC Agreement, of Respondent Biovail to import, use, offer for sale, sell, or distribute Respondent Elan's Generic Adalat CC, and restore such rights to Respondent Elan. The purpose of the reallocation of rights is to restore competitive incentives to the Generic Adalat CC market and to remedy any lessening of competition resulting from the alleged anticompetitive practices stated in the Commission's complaint.

Decision and Order

PROVIDED that, without affecting the foregoing, Respondents may resolve financial issues, if any, connected with the termination of the Adalat CC Agreement on mutually agreeable terms. Such resolution shall not be measured directly or indirectly by sales, revenues, or profits generated by Generic Adalat CC or any other Drug Product, and shall not include compensation in the form of the United States rights relating to any Drug Product.

IV.

IT IS FURTHER ORDERED that Respondent Elan shall not sell, directly or indirectly, commercial quantities of Generic Adalat CC to Respondent Biovail or to Teva.

PROVIDED that Respondent Elan shall supply, to Respondent Biovail, Respondent Elan's 30 mg Generic Adalat CC for sale through Teva in the United States, subject to each of the following conditions:

- (1) Respondent Elan shall supply to Respondent Biovail amounts of 30 mg Generic Adalat CC requested by Respondent Biovail, up to the amounts to which Respondent Biovail would be entitled under Clause 7.6 of the October 4, 1999, Generic Adalat CC "License, Distribution & Supply Agreement," but in no event shall Respondent Elan, in any quarter, supply to Respondent Biovail more than 125 per cent of the quantity of 30 mg Generic Adalat CC than it supplied during the corresponding quarter of the previous year;
- (2) Respondents Biovail and Elan shall order and deliver, respectively, Respondent Elan's 30 mg Generic Adalat CC product in accordance with the procedures in the October 4, 1999, Generic Adalat CC "License, Distribution & Supply Agreement;"
- (3) Respondent Elan shall charge Respondent Biovail no more than Respondent Elan's Cost;

Decision and Order

- (4) On the day Respondent Biovail begins manufacturing sufficient commercial quantities of 30 mg Generic Adalat CC to supply Teva, Respondent Biovail shall notify Respondent Elan in writing of that fact;
- (5) Respondent Elan shall not fill any order from Respondent Biovail or Teva for 30 mg Generic Adalat CC more than thirty (30) days after it receives the notice pursuant to clause (4) above;
- (6) In no event shall Respondent Elan supply Respondent Biovail with 30 mg Generic Adalat CC later than May 31, 2003;
- (7) Respondent Elan shall permit Respondent Biovail to verify that it is charging Respondent Biovail no more than Respondent Elan's Cost, but only if Respondent Biovail uses an independent auditing firm that does not disclose to Respondent Biovail or any other person, confidential, proprietary information about Respondent Elan's costs; however, the independent auditing firm may reveal confidential, proprietary information only for the purpose of prosecuting a bona fide court or arbitration action regarding a dispute on the price charged Respondent Biovail for Respondent Elan's 30 mg Generic Adalat CC, and then only pursuant to a protective order or confidentiality agreement assuring that such information will be used only for the purpose of resolving the dispute; and
- (8) In the event that a Court of competent jurisdiction holds that Respondent Biovail's sale of Respondent Elan's 30 mg Generic Adalat CC infringes any patent, Respondents shall resolve issues of indemnification in accordance with the October 4, 1999, Generic Adalat CC "License, Distribution & Supply Agreement," unless Respondents

Decision and Order

mutually agree otherwise and so long as their agreement complies with all other provisions of this Order.

V.

IT IS FURTHER ORDERED that:

A. Respondent Elan shall use best efforts to manufacture and launch, as promptly as possible, its 30 mg and 60 mg Generic Adalat CC for sale and distribution in the United States through a distributor other than Respondent Biovail or Teva.

B. Respondent Biovail shall use best efforts to manufacture and launch, as promptly as possible, its 30 mg Generic Adalat CC for sale and distribution in the United States through a distributor other than Respondent Elan's Generic Adalat CC distributor. Respondent Biovail shall use best efforts to continue to manufacture and distribute its 60 mg Generic Adalat CC for sale and distribution in the United States through a distributor other than Respondent Elan's Generic Adalat CC distributor.

C. The purpose of Paragraphs V.A and V.B is to restore competitive incentives in the market for Generic Adalat CC and to remedy any lessening of competition resulting from the alleged anticompetitive practices stated in the Commission's complaint.

VI.

IT IS FURTHER ORDERED that:

A. Each Respondent shall notify the Commission of any agreement with another person relating to the price, production, volume, marketing, distribution, or sale of a Drug Product:

(1) Where, at the time of the agreement:

Decision and Order

- (a) Respondent and the other party to the agreement each own, control, or license a Drug Product that:
 - (i) Respondent knows, after diligent inquiry, is the subject of an NDA or ANDA pending with or approved by the FDA; and
 - (ii) Are in the same Therapeutic Class; and
- (b) The agreement covers one or both such Drug Products.
- (2) For which, at the time of the agreement, Respondent or the other party has an ANDA for the Drug Product that references an NDA that the other party owns, controls, or licenses.

PROVIDED that Paragraph VI.A.1 does not apply to any agreement that only transfers a Drug Delivery Technology solely in exchange for a commercially reasonable cash royalty not to exceed 5 per cent of revenue.

B. Such notice to the Commission shall occur no later than five (5) days after execution of said agreement.

C. Such notice to the Commission shall include:

- (1) The agreement;
- (2) The names of the parties to the agreement, including the name, address, and phone number of the chief executive officer of each party;
- (3) The name, address, and phone number of each person who has filed an ANDA with the FDA for any Drug Product to which the agreement relates and, to the extent known, the status of such ANDA; and

Decision and Order

- (4) The last two annual marketing plans for the Drug Product(s) that the agreement covers and any documents that Respondent's board of directors received concerning the agreement.

VII.

IT IS FURTHER ORDERED that:

- A. Each Respondent shall distribute a copy of this Order and the Complaint, within thirty (30) days after the date on which this Order becomes final, to each of its officers, members of its board of directors, and managers with responsibility for prescription drug business development, licensing, sales, and marketing.
- B. Respondent Biovail shall provide to Teva a copy of this Order and the Complaint, within five (5) days after the date on which this Order becomes final.
- C. Respondent Elan shall provide to each person Respondent Elan appoints as a distributor of its Generic Adalat CC a copy of this Order and the Complaint, within five (5) days of such appointment.
- D. Each Respondent shall distribute a copy of this Order and the Complaint, for a period of five (5) years after the date this Order becomes final, within five (5) days of appointment, to: (1) each new officer, member of its board of directors, and manager with responsibility for prescription drug business development, licensing, sales, or marketing; and (2) each person Respondent appoints as a United States distributor of its Generic Adalat CC.

Decision and Order

VIII.

IT IS FURTHER ORDERED that:

A. Within thirty (30) days after the date this Order becomes final, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with Paragraphs III, IV, and V of this Order. Each Respondent shall submit such a compliance report every thirty (30) days until it has complied fully with Paragraphs III, IV, and V of this Order. Each Respondent shall include in such compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with Paragraphs III, IV, and V of this Order.

B. As part of its obligation under Paragraph VIII.A:

- (1) Respondent Elan shall include in its compliance reports (a) a description of all substantive contacts or negotiations concerning the launches provided for in Paragraph V and the identity of all parties contacted, and (b) copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning the launches provided for in Paragraph V. Respondent Elan's final compliance report under Paragraph VIII.A shall include a statement that the launches provided for in Paragraph V have been accomplished and shall include the date they were accomplished.
- (2) Respondent Biovail shall include in its compliance reports (a) a description of all substantive contacts with suppliers and/or Teva regarding obstacles to launch, and (b) copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning obstacles to launch. Respondent Biovail's final compliance report under Paragraph VIII.A shall

Decision and Order

include a statement that the launch provided for in Paragraph V of this Order has been accomplished and shall include the date it was accomplished.

C. One year (1) from the date this Order becomes final, annually for the next four (4) years on the anniversary of the date this Order becomes final, and at other 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 this Order.

IX.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty days prior to (1) any dissolution, assignment, or sale resulting in the emergence of a successor corporation, or (2) the creation or dissolution of subsidiaries or any other change in the Respondent that may affect compliance obligations arising out of the Order.

X.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, each Respondent shall permit any duly authorized representative of the Commission, in the presence of Respondent's counsel:

A. Access, during office hours, to all facilities and to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of each Respondent relating to compliance with this Order; and

B. Without restraint or interference from each Respondent, to interview officers, directors, or employees of each Respondent relating to compliance with this Order.

Decision and Order

PROVIDED that each Respondent:

- (1) Shall receive five (5) days' written notice;
- (2) May assert any legally authorized privilege; and
- (3) May have counsel present during any inspection or interview.

XI.

IT IS FURTHER ORDERED that this Order shall terminate on August 15, 2012.

By the Commission.

Decision and Order

**Confidential Appendix Containing
October 4, 1999 “License, Distribution & Supply Agreement”**

[Redacted from Public Record Version]

Analysis

Analysis to Aid Public Comment

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

Analysis

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

Analysis

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

Analysis

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

Analysis

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.

Analysis

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

Analysis

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

Analysis

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

Analysis

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.

Complaint

IN THE MATTER OF

AMGEN INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT

Docket C-4056; File No. 0210059
Complaint, July 12, 2002--Decision, September 3, 2002

This consent order addresses the merger of Respondent Amgen Inc. and Respondent Immunex Corporation, two pharmaceutical manufacturers. The order, among other things, requires the respondents to divest all of Respondent Immunex's assets relating to Leukine – a neutrophil regeneration factor used to treat neutropenia (the suppression of production of certain white blood cells known as “neutrophils”), which often results from chemotherapy – to Schering AG. The order also requires the respondents to license certain Amgen patents relating to its tumor necrosis factor (“TNF”) receptor to Serono S.A. In addition, the order requires the respondents to license certain Amgen and Immunex patents relating to the development of Interleukin-1 (“IL-1”) receptors to Regeneron Pharmaceuticals Inc., thereby enabling Regeneron to continue to develop its IL-1 Trap product – an IL-1 inhibitor used to treat rheumatoid arthritis – in competition with the respondents.

Participants

For the Commission: *Elizabeth A. Jex, James J. Hegarty, Kari A. Wallace, David von Nirschl, Jennifer Lee, Kristen M. Gorzelany, Stephanie Richard, Ann Malester, Christina Sarris, Elizabeth A. Piotrowski, Hajime Hadeishi, and Michael G. Vita.*

For the Respondents: *John M. Nannes, Skadden, Arps, Slate, Meagher & Flom, and Daniel M. Wall and J. Thomas Rosch, Latham & Watkins.*