UNITED STATES OF AMERICA **011-0132**
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:
Timothy J. Muris, Chairman
Sheila F. Anthony
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary

In the Matter of BIOVAIL CORPORATION, a corporation, and ELAN CORPORATION, PLC, a corporation.	Docket No. ___

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.

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 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 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. 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 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 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 _____ day of _____, 2002, issues its complaint against said respondents.

By the Commission.

SEAL

Donald S. Clark
Secretary