

Complaint

IN THE MATTER OF
GENEVA PHARMACEUTICALS, ET AL.
CONSENT ORDER, ETC., IN REGARD TO ALLEGED
VIOLATIONS OF SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT

Docket C-3946; File No. 9810395
Complaint, May 22, 2000--Decision, May 22, 2000

This consent order prohibits Respondents Abbot Laboratories and Geneva Pharmaceuticals, Inc. from entering agreements in which the first company to file an ANDA agrees with the NDA holder not to relinquish its right to the 180-day exclusivity period established under the Hatch-Waxman Act, or agreements where the ANDA first filer from agrees not to develop or market a generic drug product that is not the subject of a patent infringement lawsuit. The order also prohibits agreements involving payments to keep a generic drug off the market during patent infringement litigation brought by an NDA holder, and respondents can only enter these arrangements if specific criteria are met. This prohibition includes agreements made in the context of an interim settlement of a patent infringement action, whereby the NDA holder pays the generic not to enter the market, unless the parties obtain court approval through a process that is designed to enhance the court's ability to assess the competitive implications of the agreement. In addition, the order requires that Respondents notify the Commission 30 days before entering into an agreement in which an ANDA first filer agrees with an NDA holder to refrain from going to market.

Participants

For the Commission: *Karen Bokat, Bradley S. Albert, Daniel Kotchen, Robin Moore, David Narrow, Martha Oppenheim, David Pender, Richard A. Feinstein, William K. Tom, Daniel Ducore, Alan A. Fisher, Roy B. Levy, and Gregory S. Vistnes.*

For the Respondents: *Jeffrey Weinberger, Munger Tolles & Olson, and Wayne Cross, Dewey Ballentine.*

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Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that respondents Abbott Laboratories and Geneva Pharmaceuticals, Inc., have engaged in conduct, as described herein, that violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

The Respondents

1. Respondent Abbott Laboratories ("Abbott") is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Illinois, with its office and principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott is engaged principally in the development, manufacture, and sale of a broad line of health care products and services. In 1998, Abbott had net sales of \$12.5 billion worldwide and \$7.7 billion domestically. Among other products, Abbott manufactures and sells the brand-name product Hytrin, a drug that accounts for over 20% of the net sales of Abbott's U.S. pharmaceutical products division.
2. At all relevant times herein, Abbott has been, and is now, a corporation as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
3. Respondent Geneva Pharmaceuticals, Inc. ("Geneva") is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 2555 W. Midway Blvd., Broomfield, Colorado 80020. Geneva, an indirect wholly-owned subsidiary of Novartis Corporation, is one of

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the leading generic drug manufacturers in the United States. Geneva sought and received approval from the United States Food and Drug Administration (“FDA”) to market a generic version of Hytrin.

4. At all relevant times herein, Geneva has been, and is now, a corporation as “corporation” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
5. Respondents’ acts and practices, including the acts and practices alleged herein, are in or affect commerce as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Federal Regulation of Pharmaceutical Products

6. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., approval by the United States Food & Drug Administration (“FDA”) is required before a company may market or sell a pharmaceutical product in the United States. Approval for a new or brand name drug is sought by filing a New Drug Application (“NDA”) with the FDA.
7. A generic drug is a product that the FDA has found to be bioequivalent to a brand name drug. Generic drugs are chemically identical to their branded counterparts, but typically are sold at substantial discounts from the branded price. Approval may be sought for a generic version of a brand name drug by filing an Abbreviated New Drug Application (“ANDA”) with the FDA.
8. The FDA maintains a book of Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the “FDA Orange Book”), which lists all patents that the brand name manufacturer asserts relate to each brand name drug. If

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an applicant intends to market a generic product before the expiration of one or more patents relating to a brand name drug, the applicant must certify to the FDA that the patent or patents listed in the FDA Orange Book are either invalid or not infringed by the generic version of the product (a "Paragraph IV Certification"), and must notify the holder of the approved NDA and the owner of the patent or patents of the filing of the ANDA. If neither the patent holder nor the NDA holder files a patent infringement suit against the ANDA filer within 45 days of receipt of notification of a Paragraph IV Certification, the FDA review and approval process may proceed and, upon FDA approval of the ANDA, the generic product may be marketed. If a patent infringement suit is filed against the ANDA filer within the 45-day period, however, FDA approval of the ANDA is automatically stayed until the earliest of: (i) patent expiration; (ii) a final judicial determination of non-infringement or invalidity in the lawsuit; or (iii) the expiration of a 30-month period from the time the patent holder receives Paragraph IV Certification.

9. The Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act"), as currently implemented by the FDA, provides that the first applicant to submit an ANDA with a Paragraph IV Certification for a generic version of a brand name drug ("ANDA first filer") is entitled to a 180-day period of marketing exclusivity ("180-day Exclusivity Period") before the FDA may grant final approval of any other generic manufacturer's ANDA regarding the same brand name drug. This period does not begin to run until either the generic is commercially marketed or a court enters final judgment that the patents subject to the Paragraph IV Certification are invalid or not infringed. No other generic manufacturer may obtain FDA approval to market its product until the ANDA first filer's 180-day Exclusivity Period has expired.

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Relevant Product and Geographic Market

10. The relevant product market for assessing respondents' anticompetitive conduct is terazosin hydrochloride ("terazosin HCL"). Terazosin HCL is used principally to treat benign prostatic hyperplasia ("BPH" or enlarged prostate) and hypertension. Both hypertension and BPH are chronic conditions that afflict millions of Americans, many of whom are senior citizens. BPH afflicts at least 50% of the men over 60, and results in 1.7 million men each year making office visits to their physicians. Total U.S. sales of terazosin HCL amount to approximately \$540 million per year.
11. Hytrin, which is manufactured and marketed by Abbott, is the pioneer brand name drug in the United States containing terazosin HCL. Hytrin was introduced in 1987. It was the only terazosin HCL product sold in the United States until Geneva introduced such a product on or around August 13, 1999.
12. Other drugs are not effective substitutes for terazosin HCL because they are different in terms of chemical composition, safety, efficacy, and side effects. In addition, there is little price sensitivity between terazosin HCL and non-terazosin HCL products.
13. The relevant geographic market is the United States.

Factual Background

14. Hytrin, which Abbott markets in tablet and capsule form, has been one of the company's most important products. Abbott introduced Hytrin tablets in 1987. In 1995, Abbott launched Hytrin capsules, which now account for over 90% of Hytrin sales. In 1998, Abbott's sales of Hytrin amounted to \$542

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million in the United States alone, accounting for 9.41 million prescriptions. For the first 6 months of 1999, Abbott reported \$292 million in U.S. sales of Hytrin, representing over 20% of the net sales of Abbott's pharmaceutical division.

15. Abbott currently holds at least seven patents that relate to terazosin HCL. Abbott's initial patent covering the chemical compound terazosin HCL expired in or around 1994.
16. Geneva filed ANDAs covering a tablet form and a capsule form of generic terazosin HCL. It was the first company to file an ANDA for each form. Geneva submitted its tablet ANDA to the FDA in or around January 1993, and its capsule ANDA was submitted in or around December 1995.
17. In early 1996, Abbott notified the FDA of a new patent ('207 patent) relating to its Hytrin product, and the FDA listed that patent in the FDA Orange Book. In April 1996, Geneva filed a Paragraph IV certification with the FDA, claiming that its generic terazosin HCL tablet and capsule products did not infringe any of Abbott's patents covering terazosin HCL, including Abbott's newly listed '207 patent, and notified Abbott of the Paragraph IV certification.
18. On June 4, 1996, Abbott sued Geneva in the Northern District of Illinois, claiming patent infringement by Geneva's terazosin HCL tablet product. Abbott made no infringement claim against Geneva's terazosin HCL capsule product, even though both of Geneva's products involved the same potential infringement issues.
19. Pursuant to the Hatch-Waxman Act, Abbott's lawsuit triggered a 30-month stay of final FDA approval of Geneva's terazosin HCL tablet ANDA, until December 1998. Because no infringement claim had been filed within the requisite 45-day period, the FDA review and approval process for Geneva's terazosin HCL capsule ANDA could proceed without delay.

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20. By early 1998, Geneva, including particularly its CEO, was confident that it ultimately would prevail in its patent infringement dispute with Abbott.
21. Accordingly, Geneva pushed ahead in early 1998 with plans to bring to market as soon as possible its generic terazosin HCL capsule product, which could have received FDA approval at any time. Preparations to launch this product were proceeding on all fronts: the manufacturing team sought to validate with the FDA its terazosin HCL capsule manufacturing process; the purchasing department instructed its product supplier to manufacture commercial quantities of terazosin HCL active ingredient; sales and marketing personnel were contacting customers to inform them of an impending launch and to enter into distribution contracts; and the legal staff was drafting papers to oppose any effort by Abbott to block Geneva's entry.
22. The FDA granted Geneva final approval to market generic terazosin HCL capsules on March 30, 1998.
23. As the first generic company to submit a Paragraph IV Certification for generic terazosin HCL, Geneva was entitled to the 180-day Exclusivity Period pursuant to the Hatch-Waxman Act, as currently interpreted. Unless and until Geneva's 180-day Exclusivity Period had been triggered and had expired, or Geneva relinquished its entitlement to this period of exclusivity, only Geneva would be approved by the FDA to market a generic terazosin HCL product.

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Anticompetitive Conduct

24. On March 30, 1998, the very day it was granted FDA approval to market its generic terazosin HCL capsules, Geneva contacted Abbott and announced that it would launch its generic terazosin HCL capsules unless it was paid by Abbott not to enter the market. From Abbott's perspective, a launch of Geneva's generic terazosin HCL product would have had a significant adverse impact on Abbott's financial performance. Abbott forecasted that entry of generic terazosin HCL on April 1, 1998 would have eliminated over \$185 million in Hytrin sales in just six months. Because Hytrin was highly profitable, Abbott sought to keep from the market Geneva and all other potential generic competition to Hytrin, until at least February 2000.
25. Over the course of two days, representatives of Abbott and Geneva negotiated the framework for an agreement, whereby Abbott would pay Geneva not to enter the market. Abbott estimated Geneva's revenues from launching generic terazosin HCL at \$1 million to \$1.5 million per month, but was willing to pay Geneva a "premium" over that not to compete.
26. On April 1, 1998, Abbott and Geneva entered into a written agreement ("Agreement"), pursuant to which Geneva agreed not to enter the market with any generic terazosin HCL capsule or tablet product until the earlier of: (1) the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, including review through the Supreme Court; or (2) entry of another generic terazosin HCL product. Geneva also agreed – at Abbott's insistence – not to transfer, assign, or relinquish its right to a 180-day Exclusivity Period.
27. In exchange, Abbott agreed to pay Geneva \$4.5 million per month in non-refundable payments until a district court judgment in the parties' patent infringement dispute. Respondents agreed that if the district court declared that

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Geneva's tablet product did not or would not infringe any valid and enforceable claim of the '207 patent, Abbott would thereafter pay the \$4.5 million monthly payments into an escrow fund until the final resolution of the litigation. Under the Agreement, the party prevailing in the litigation would receive the money in the escrow fund.

28. The court hearing the patent litigation was not made aware of the respondents' Agreement.
29. In the words of Geneva's CEO at the time the Agreement was signed, this Agreement represented to Geneva the "best of all worlds," because Geneva obtained a risk-free "monetary settlement on an ongoing basis until the litigation was resolved" and still could market its product exclusively for 180 days after the litigation was over.
30. In accordance with the terms of the Agreement, in April 1998, Geneva refrained from entering the market with its generic terazosin HCL capsules, and instead began receiving monthly payments of \$4.5 million from Abbott.
31. On September 1, 1998, the United States District Court for the Northern District of Illinois granted Geneva's motion for summary judgment in its patent tablet litigation with Abbott, invalidating Abbott's patent under the on-sale provision of 35 U.S.C. § 102(b).
32. The district court's decision invalidating Abbott's patent only strengthened Geneva's litigation position. Nonetheless, Geneva, in accordance with the terms of the Agreement, did not enter the generic terazosin HCL market even after the favorable district court decision.

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33. On July 1, 1999, the United States Court of Appeals for the Federal Circuit affirmed, without dissent, the summary judgment in favor of Geneva. Under the Agreement, Geneva still could not enter the generic terazosin HCL market until after the Supreme Court either denied Abbott's petition for certiorari or disposed of the patent infringement litigation. Nonetheless, in August 1999, aware of the Commission's investigation, the respondents canceled their Agreement, and on August 13, 1999, Geneva finally introduced its generic terazosin HCL capsule product to the marketplace. The Supreme Court denied certiorari on January 10, 2000.

The Effects of Respondents' Conduct

34. The acts and practices of the respondents as herein alleged have had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition by preventing or discouraging the entry of competition in the form of generic versions of Hytrin into the relevant market.
35. As a result of respondents' conduct as herein alleged, consumers were deprived of the benefits of new competition from Geneva and other generic competitors. Without this lower-priced generic competition, consumers, pharmacies, hospitals, insurers, wholesalers, government agencies, managed care organizations, and others were forced to purchase Abbott's more expensive Hytrin product.
36. Earlier entry of a generic terazosin HCL product would have had a significant procompetitive impact in the relevant market. Pharmacists generally are permitted, and in some instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, managed care plans and Medicaid programs) encourage or insist on the use of generic drugs wherever possible. A generic product can quickly and

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efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year. For example, Abbott's forecasts projected that generic terazosin HCL would capture roughly 70% of Hytrin sales within the first six months alone.

37. The purpose and effect of the \$4.5 million monthly payments from Abbott to Geneva during the term of the Agreement were to ensure that Geneva would not enter the relevant market, and would not take any steps, including giving up its right to a 180-day Exclusivity Period, to permit or facilitate the entry of any other generic manufacturer.
38. By prohibiting Geneva from transferring, assigning, or giving up its right to a 180-day Exclusivity Period until the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, the Agreement had the purpose and effect of preventing Geneva from relinquishing its eligibility for a 180-day Exclusivity Period under the Hatch-Waxman Act. As of February 1999, at least one other generic manufacturer had satisfied the FDA's requirements for approval and was barred from entering the market because Geneva's 180-day Exclusivity Period had not begun to run.
39. The Agreement is not justified by any countervailing efficiency.

Violations Alleged

40. The Abbott-Geneva Agreement as a whole, and particular provisions such as that described in Paragraphs 37 and 38 above, constitute an unreasonable restraint of trade in violation of Section 5 of the Federal Trade Commission Act, as amended.

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41. Abbott and Geneva acted with the specific intent that Abbott monopolize the relevant market, and engaged in overt acts described in Paragraphs 24-33 above in furtherance of a conspiracy to monopolize the relevant market, in violation of Section 5 of the Federal Trade Commission Act, as amended.
42. Abbott had monopoly power in the relevant market and monopolized that market in violation of Section 5 of the Federal Trade Commission Act, as amended.
43. The acts and practices described above are anticompetitive in nature and tendency and constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-second day of May, 2000, issues its complaint against said respondents.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of certain acts and practices of Abbott Laboratories ("Abbott") and Geneva Pharmaceuticals, Inc. (hereinafter referred to as "Respondent Geneva"), an indirect wholly-owned subsidiary of Novartis Corporation, and Respondent Geneva having been furnished thereafter with a copy of a draft complaint which the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent Geneva with violation of the Federal Trade Commission Act; and

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Respondent Geneva and counsel for the Commission having thereafter executed an Agreement Containing Consent Order, an admission by Respondent Geneva of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondent Geneva that the law has been violated as alleged in such complaint, 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 Respondent Geneva has violated the said Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed by interested persons pursuant to Section 2.34 of its Rules, now in further conformity with the procedure described in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Geneva Pharmaceuticals, Inc., an indirect wholly-owned subsidiary of Novartis Corporation, is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 2555 W. Midway Blvd., Broomfield, Colorado 80020.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent Geneva, and the proceeding is in the public interest.

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ORDER

I.

IT IS ORDERED that for the purposes of this order, the following definitions shall apply:

- A. "Respondent Geneva" means: (1) Geneva Pharmaceuticals, Inc., and its successors and assigns; (2) any entity that the parent of Geneva Pharmaceuticals, Inc. controls and that engages in the manufacture or sale of Drug Products in the United States for which it is, or becomes, an ANDA First Filer; (3) any predecessor, subsidiary, division, group and affiliate controlled by the entities described in subparagraphs (1) and (2) above that engages in the manufacture or sale of Drug Products in the United States for which it is, or becomes, an ANDA First Filer; (4) successors and assigns of the entities described in subparagraphs (2) and (3) above that are or become ANDA first filers; and (5) the respective directors, officers, employees, agents and representatives of each acting in their capacities as such.
- B. "Commission" means the Federal Trade Commission.
- C. "180-day Exclusivity Period" means the period of time established by Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j) *et seq.*).
- D. "Agreement" means anything that would constitute an agreement under Section 1 of the Sherman Act or Section 5 of the Federal Trade Commission Act.
- E. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j) *et seq.*

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- F. "ANDA First Filer" means the party whom the FDA determines is entitled to, or eligible for, a right to a 180-day Exclusivity Period which has not yet expired.
- G. "Control" has the same meaning as the definition of the term in 16 C.F.R. § 801.1(b).
- H. "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).
- I. "FDA" means the United States Food and Drug Administration.
- J. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b) *et seq.*
- K. "NDA Holder" means: (1) the party that received FDA approval to market a Drug Product pursuant to an NDA; (2) a party owning or controlling enforcement of the patent(s) listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the "FDA Orange Book") in connection with the NDA; or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by the entities described in subparagraphs (1) and (2) above, as well as the entities' licensees, successors and assigns.
- L. "Parent" has the same meaning as "ultimate parent entity" in 16 C.F.R. § 801.1(a).
- M. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

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- N. “Relinquishing” means transferring, selling, assigning, waiving, or relinquishing.

II.

IT IS FURTHER ORDERED that Respondent Geneva cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, from being a party to any Agreement in which one party is an NDA Holder for a Drug Product(s), any other party is the ANDA First Filer for the Drug Product(s), and:

- A. the ANDA First Filer is prohibited by such Agreement from relinquishing, or is subject to a penalty, forfeiture, or loss of benefit if it relinquishes, its right to the 180-Day Exclusivity Period; or
- B. the ANDA First Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that could be approved for sale by the FDA pursuant to the ANDA and that is not the subject of a court action alleging patent infringement.

Provided, however, that nothing in this Paragraph II shall prohibit Agreements involving the complete transfer of rights in a Drug Product.

III.

IT IS FURTHER ORDERED that, in any instance where Respondent Geneva is a party to a patent infringement action in which it is either the NDA Holder or the alleged infringer, it shall cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, from being a party to any

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Agreement in which the parties do not agree to dismiss the litigation, and in which the NDA Holder provides anything of value to the alleged infringer and the alleged infringer agrees to refrain during part or all of the course of the litigation from selling the Drug Product at issue, or any Drug Product containing the same chemical entity(ies) at issue. *Notwithstanding the above, however*, such an Agreement is permissible when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, if: (1) together with the stipulation for a preliminary injunction, Respondent Geneva provides the court with the proposed Agreement, as well as a copy of the Commission's complaint, order, and Analysis to Aid Public Comment in this matter; (2) Respondent Geneva has provided Notification, as described in Paragraph V below, to the Commission at least thirty (30) days prior to submitting the stipulation for a preliminary injunction; (3) Respondent Geneva does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court's consideration of any such action for preliminary relief; and (4) the court issues an order which incorporates the terms of the Agreement. Nothing in this Paragraph shall be interpreted to prohibit or restrict the right of Respondent Geneva to unilaterally seek relief from the court, without notice to the Commission, including, but not limited to, applying for preliminary injunctive relief or seeking to extend the 30-month stay pursuant to 21 U.S.C. § 355(j)(4)(B)(iii).

IV.

IT IS FURTHER ORDERED that Respondent Geneva shall provide Notification as described in Paragraph V below to the Commission at least thirty (30) days before entering into, enforcing, or otherwise participating in any Agreement made after the date the Agreement Containing Consent Order is signed whereby an ANDA First Filer agrees with an NDA Holder to

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refrain from selling any Drug Product under its ANDA for any period of time.IV.

V.

The Notification required by Paragraphs III and IV shall be filed with the Secretary of the Commission and shall include the following information, to the extent known, and not subject to any legally recognized privilege: (1) identification of the parties involved in the Agreement; (2) identification of all Drug Products involved in the Agreement; (3) identification of all persons who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the Agreement; (4) a copy of the proposed Agreement; (5) identification of the court, and copy of the docket sheet, for any legal action which involves either party to the Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and (6) all documents which were prepared by or for any officer(s) or director(s) of Respondent Geneva for the purpose of evaluating or analyzing the Agreement.

VI.

IT IS FURTHER ORDERED that, within ten (10) days of signing the Agreement Containing Consent Order in this matter, Respondent Geneva shall notify the FDA in writing that Respondent Geneva is relinquishing any and all eligibility for, and entitlement or right to, a 180-day Exclusivity Period for ANDA No. 74-315 (terazosin HCL tablets).

VII.

IT IS FURTHER ORDERED that Respondent Geneva shall file a verified written report within sixty (60) days after the date this order becomes final, annually thereafter for five (5) years on the anniversary of the date this order becomes final, and at such other times as the Commission may by written notice require,

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setting forth in detail the manner and form in which Respondent Geneva intends to comply, is complying, and has complied with this order. Respondent Geneva shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this order.

VIII.

IT IS FURTHER ORDERED that Respondent Geneva shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent Geneva such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in Respondent Geneva that may affect compliance obligations arising out of this order.

IX.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this order and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondent Geneva, Respondent Geneva shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities, and to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in its possession or under its control relating to compliance with this order; and

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- B. To interview officers, directors, employees, agents, and other representatives of Respondent Geneva, who may have counsel present, regarding such compliance issues.

X.

IT IS FURTHER ORDERED that this order shall terminate on May 22, 2010.

By the Commission.

**STATEMENT OF CHAIRMAN ROBERT PITOFSKY AND
COMMISSIONERS SHEILA F. ANTHONY, MOZELLE W.
THOMPSON, ORSON SWINDLE,
AND THOMAS B. LEARY**

The attached Analysis to Aid Public Comment, which accompanied our acceptance of consent agreements with Geneva Pharmaceuticals, Inc. and Abbott Laboratories, describes the conduct of those two companies in agreeing that Abbott would pay Geneva to refrain from selling a generic version of Hytrin, Abbott's branded version of terazosin hydrochloride. It also describes relevant provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), including particularly the provision that gives the first generic company to seek FDA approval a 180-day period during which it has the exclusive right to market the generic version of a brand name drug.

Pursuant to a private agreement not reviewed by any court, Abbott paid Geneva substantial sums not to enter the market with its generic version of Hytrin, and not to transfer, assign or relinquish its 180-day exclusive marketing right to any other producer of generic products that might compete with Abbott. By

Statement of the Commission

not selling its generic version, Geneva prevented the start of the 180-day exclusivity period, with the result that neither Geneva nor any other company could introduce a generic version of Hytrin into the market.

The consent orders that we issue today against Abbott and Geneva represent the first resolution of an antitrust challenge by the government to a private agreement whereby a brand name drug company paid the first generic company that sought FDA approval not to enter the market, and to retain its 180-day period of market exclusivity. Because the behavior occurred in the context of the complicated provisions of the Hatch-Waxman Act, and because this is the first government antitrust enforcement action in this area, we believe the public interest is satisfied with orders that regulate future conduct by the parties. We recognize that there may be market settings in which similar but less restrictive arrangements could be justified, and each case must be examined with respect to its particular facts.

In March we also issued an administrative complaint against two other pharmaceutical companies with respect to conduct that is in some ways similar to the conduct addressed by these consent orders. We anticipate that the development of a full factual record in the administrative proceeding will help to shape further the appropriate parameters of permissible conduct in this area and will guide other companies and their legal advisors.

Pharmaceutical firms should now be on notice, however, that arrangements comparable to those addressed in the present consent orders can raise serious antitrust issues, with a potential for serious consumer harm. Accordingly, in the future, the Commission will consider its entire range of remedies in connection with enforcement actions against such arrangements, including possibly seeking disgorgement of illegally obtained profits.

Analysis to Aid Public Comment

If firms are uncertain about the limits of permissible behavior under the Hatch-Waxman Act, they may, of course, seek advisory opinions from the staff of this agency.

Analysis to Aid Public Comment

The Federal Trade Commission has accepted for public comment agreements and proposed consent orders with Geneva Pharmaceuticals, Inc. and Abbott Laboratories. The proposed consent orders settle charges that these parties unlawfully agreed that Geneva would refrain from selling its generic version of one of Abbott's drugs, in exchange for payments from Abbott. The proposed consent orders have been placed on the public record for 30 days to receive comments by interested persons. The proposed consent orders have been entered into for settlement purposes only and do not constitute an admission by Abbott or Geneva that they violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

Background

Abbott Laboratories develops, manufactures, and sells a variety of health care products and services. Based in Abbott Park, Illinois, Abbott's 1998 net sales worldwide were approximately \$ 12.5 billion. Over 20% of Abbott's net sales of pharmaceutical products in the U.S. are for a drug called Hytrin. Hytrin is used to treat two chronic conditions that affect millions of Americans, particularly senior citizens: hypertension (high blood pressure) and benign prostatic hyperplasia (enlarged prostate).

Geneva is one of the leading generic drug manufacturers in the United States. An indirect wholly-owned subsidiary of

Analysis to Aid Public Comment

Novartis Corp., Geneva is based in Broomfield, Colorado. Geneva developed a generic version of Hytrin, and in March 1998 received approval from the U.S. Food and Drug Administration (“FDA”) to market that generic product.

A generic drug is a product that the FDA has found to be bioequivalent to a brand name drug. A company seeking FDA approval to market a new drug must file a New Drug Application (“NDA”). In order to market a generic version of a brand name drug, a company must file an Abbreviated New Drug Application (“ANDA”) and receive approval from the FDA.

Generic drugs are chemically identical to their branded counterparts, but typically are sold at substantial discounts from the branded price. A Congressional Budget Office Report estimates that purchasers saved an estimated \$8-\$10 billion on prescriptions at retail pharmacies in 1994 by purchasing generic drugs instead of the brand name product.¹

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as “the Hatch-Waxman Act,” to facilitate the entry of generic drugs while maintaining incentives to invest in new drug development. In particular, the Hatch-Waxman Act establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic product prior to the expiration of a patent or patents relating to a brand name drug upon which the generic is based. In such cases, the applicant must: (1) certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a “paragraph IV certification”); and (2) notify the patent holder of the filing of the certification. If the

¹ Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* at xiii, 13 (July 1998).

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holder of patent rights files a patent infringement suit within 45 days, FDA approval to market the generic drug is automatically stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed. This automatic 30-month stay allows the patent holder time to seek judicial protection of its patent rights before a generic competitor is permitted to market its product.

In addition, the Hatch-Waxman Act provides an incentive for generic drug companies to bear the cost of patent litigation that may arise when they challenge invalid patents or design around valid ones. The Act grants the first company to file an ANDA in such cases a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. No other generic manufacturer may obtain FDA approval to market its product until the first filer's 180-day exclusivity period has expired.

Geneva was the first company to file an ANDA for terazosin hydrochloride ("terazosin HCL"), the generic version of Hytrin. It filed applications covering a tablet form and a capsule form of its generic terazosin HCL. Geneva filed a paragraph IV certification with the FDA stating that these products did not infringe any valid patent held by Abbott covering terazosin HCL. In June 1996, Abbott sued Geneva for patent infringement by Geneva's terazosin HCL tablet product, but due to an oversight failed to make an infringement claim against Geneva's capsule product, although both products raised the same potential infringement issues.

Abbott's lawsuit triggered a 30-month stay of final FDA approval of Geneva's terazosin HCL tablet ANDA, until December 1998. No stay applied to the FDA approval process for Geneva's terazosin HCL capsule ANDA, however, because no infringement claim was filed within the statutory time period required by the Hatch-Waxman Act. The FDA granted Geneva final approval to market generic terazosin HCL capsules on March 30, 1998.

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The Challenged Agreement

The complaint challenges an agreement whereby Abbott, following the FDA approval of Geneva's generic terazosin HCL capsule product, paid Geneva not to enter the market during their ongoing patent litigation over the tablet product. According to the complaint, on the day it was granted approval to market its generic terazosin HCL capsules, Geneva contacted Abbott and announced that it would launch its generic terazosin HCL capsules unless it was paid by Abbott not to enter. Two days later, on April 1, 1998, Abbott and Geneva entered into an agreement, pursuant to which Geneva agreed not to enter the market with any generic terazosin HCL capsule or tablet product until the earlier of: (1) the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, including review through the Supreme Court; or (2) entry of another generic terazosin HCL product.

Geneva also agreed – at Abbott's insistence – not to transfer, assign, or relinquish its 180-day exclusivity right. The effect of this provision was to ensure that no other company's generic terazosin HCL product could obtain FDA approval and enter the market during the term of the agreement, because Geneva's agreement not to launch its product meant that the 180-day exclusivity period would not expire.

In exchange, Abbott agreed to pay Geneva \$4.5 million per month until a district court judgment in the parties' patent infringement dispute, and then (assuming Geneva won in the district court) to pay the \$4.5 million monthly payments into an escrow fund until the final resolution of the litigation, which Geneva would then receive if its district court victory was upheld.

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Abbott's payment to Geneva of \$4.5 million a month was well over the \$1 to \$1.5 million per month that, the complaint states, Abbott believed Geneva would forego by staying off the market. The complaint alleges that Abbott was willing to pay Geneva a "premium" to refrain from competing because of the substantial impact that launch of a generic version of Hytrin would have on Abbott's overall financial situation. Abbott forecasted that entry of generic terazosin HCL on April 1, 1998 would eliminate over \$185 million in Hytrin sales in just six months. Accordingly, the complaint charges, Abbott sought to forestall Geneva -- and all other potential generic competition to Hytrin -- from entering the market because of the threat they represented to the high profits it was making from Hytrin.

The complaint further charges that, in accordance with the terms of the agreement, Geneva did not enter the market with its generic terazosin HCL capsules, even after the district court and the court of appeals upheld Geneva's position that Abbott's patent was invalid. In August 1999, Abbott and Geneva -- aware of the Commission's investigation -- terminated their agreement (which by its terms would not have ended until disposition of the litigation by the Supreme Court). Geneva finally brought its generic terazosin HCL capsule product to market on August 13, 1999.

Competitive Analysis

The complaint charges that the challenged agreement prevented competition that Abbott's Hytrin product would otherwise have faced from generic products of Geneva and other potential generic competitors. Generic drugs can have a swift marketplace impact, because pharmacists generally are permitted, and in some instances are required, to substitute lower-priced generic drugs for their branded counterparts, unless the prescribing physician directs otherwise. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, state Medicaid programs and many private health plans) encourage or insist on the use of

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generic drugs wherever possible. Abbott's forecasts, the complaint states, projected that generic terazosin HCL would capture roughly 70% of Hytrin sales within the first six months following its launch. The agreement, however, ensured that Geneva would not offer generic terazosin HCL in competition with Hytrin, and would not take action – such as relinquishing exclusivity rights – that would have permitted the entry of any other generic manufacturer.

These restraints on generic competition had direct and substantial effects on consumers. Without a lower-priced generic alternative, consumers, government agencies, health plans, pharmacies, hospitals, wholesalers, and others were forced to purchase Abbott's more expensive Hytrin product. Other drugs, the complaint states, are not effective substitutes for terazosin HCL because they are different in terms of chemical composition, safety, efficacy, and side effects. There is little price sensitivity between terazosin HCL and other products. Thus, the complaint alleges that the sale of terazosin HCL in the United States is the relevant market within which to assess the effects of the challenged agreement.

The challenged conduct represents an agreement not to compete between potential horizontal competitors. A firm is a potential competitor if there is evidence that entry by that firm is reasonably probable in the absence of the agreement at issue.² Geneva certified to the FDA that its entry with generic HCL would not infringe a valid patent, and was confident that it ultimately would prevail in its patent infringement dispute with Abbott, the complaint states. In early 1998, Geneva was making preparations to launch its generic terazosin HCL capsule product

² Federal Trade Commission and United States Department of Justice, *Antitrust Guidelines for the Licensing of Intellectual Property* at § 1.1 n.6 (1995).

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as soon as possible. After receiving FDA approval for the capsule product, Geneva threatened to launch that product unless Abbott paid it not to do so. The challenged agreement directly restrained competition between these potential competitors.

In addition, the agreement created a bottleneck that prevented any other potential competitors from entering the market, because no other ANDA filer could obtain FDA approval until Geneva's 180 day exclusivity period expired. Other companies were developing generic terazosin HCL products, and at least one other generic manufacturer had satisfied the FDA's requirements for approval by February 1999, but was barred from entering the market because Geneva's failure to launch its product meant its 180-day exclusivity right had not even begun to run.

The complaint states that the challenged agreement is not justified by any countervailing efficiency. Although the agreement between Abbott and Geneva provided substantial private benefits to both parties, the facts in this matter demonstrate that the broad restraints were not justified by any benefits to competition and consumer welfare. The Commission considered whether the agreement could be considered a procompetitive effort to effectuate a temporary settlement of a patent dispute, akin to a court-ordered preliminary injunction. However, it finds that any legitimate interest in resolving patent disputes cannot justify the harm to consumers imposed by the agreement in this case. The restraint imposed exceeds what likely would be available to the parties under a court-ordered preliminary injunction. For example, it: (1) barred Geneva's entry beyond the pendency of the district court litigation; (2) provided large up-front payments that could be expected to create disincentives for Geneva to enter (in contrast to a court-ordered bond to cover damages actually incurred as a result of the court's injunction); (3) barred Geneva from relinquishing its exclusivity rights; (4) prohibited Geneva from developing or marketing non-infringing generic products. Moreover, the restraints contained in the agreement were entered into without any judicial finding that Abbott was likely to succeed on the merits of its infringement

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suit, without any consideration of whether Abbott would suffer irreparable injury, and without any weighing of the equities, including any consideration of the public interest.

The complaint also charges that Abbott had a monopoly in the market for terazosin HCL, and, by entering into the agreement with Geneva, Abbott sought to preserve its dominance by delaying the entry of Geneva and other generic companies into the market. As detailed above, there were no countervailing justifications for Abbott's conduct. In addition, the complaint alleges that Abbott and Geneva conspired to monopolize the market for terazosin HCL. As stated in the complaint, Abbott and Geneva acted with specific intent that Abbott monopolize the market for terazosin HCL, and entered into a conspiracy to achieve that goal. Finally, the parties' agreement otherwise amounts to an unfair method of competition in violation of Section 5 of the FTC Act.

The Proposed Orders

The proposed orders are designed to remedy the unlawful conduct charged in the complaint. Although the particular agreement challenged in the complaint has been terminated, prospective relief is necessary to prevent a recurrence of similar agreements with respect to other drugs. Private agreements in which the brand name drug company (the NDA holder) pays the first generic to seek FDA approval (the first filer) not to enter the market can substantially delay generic competition and raise serious antitrust issues. Moreover, the FDA, which has expressed concern about such private agreements, has observed that the incentives for companies to enter into such arrangements are becoming greater, as the returns to the brand name company from extending its monopoly increasingly exceed the potential

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economic gains to the generic applicant from its 180 days of market exclusivity.³

In essence, the proposed orders:

- bar two particular types of agreements between brand name drug companies and potential generic competitors -- restrictions on giving up Hatch-Waxman 180-day exclusivity rights and on entering the market with a non-infringing product;
- require that agreements involving payments to the generic company to stay off the market be approved by the court when undertaken in the context of an interim settlement of patent litigation, with notice to the Commission to allow it time to present its views to the court;
- require respondents to give the Commission written notice 30 days before entering into such agreements in other contexts; and
- require that Geneva waive its right to 180-day marketing exclusivity for its generic terazosin HCL tablet product, so that other generic tablet producers can immediately enter the market.

Paragraph II prohibits two kinds of agreements between “an NDA Holder” and “the ANDA First Filer” (that is, the party possessing an unexpired right to Hatch-Waxman 180-day exclusivity). Paragraph II.A. bars agreements in which the first company to file an ANDA agrees with the NDA holder not to relinquish its right to the 180-day exclusivity period established under the Hatch-Waxman Act. Paragraph II.B. prohibits the ANDA first filer from agreeing not to develop or market a generic

³ FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed.Reg. 42873, 42882-83 (August 6, 1999).

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drug product that is not the subject of a patent infringement lawsuit. The order prohibits restrictions on giving up exclusivity rights and on competing with a non-infringing product because under the circumstances of this case these restraints are not justified.

Paragraph II's focus on agreements between an NDA holder and the ANDA first filer does not mean that the Commission believes that there is no risk of competitive harm in other contexts. In particular, Abbott or Geneva's participation in an agreement in which a generic company that is not the ANDA first filer is paid by the NDA holder not to market a non-infringing product could raise substantial competitive concerns. Given the variety of circumstances in which the restraints may arise, however, and the possibility that some legitimate justifications might exist in some other contexts, the Commission believes that it is appropriate at this time to limit the flat bans in Paragraph II to agreements between NDA holders and ANDA first filers.

Paragraph III bans private agreements involving payments to keep a generic drug off the market during patent infringement litigation brought by an NDA holder. Abbott and Geneva can enter into such arrangements only if (a) they are presented to the court and embodied in a court-ordered preliminary injunction, and (b) the following other conditions are met: (i) along with any stipulation for preliminary injunction, they provide the court with a copy of the Commission's complaint, order, and this Analysis to Aid Public Comment in this matter, as well as the proposed agreement between the parties; (ii) at least 30 days before submitting the stipulation to the court, they provide written notice to the Commission; and (iii) they do not oppose Commission participation in the court's consideration of the request for preliminary relief.

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Thus, the proposed orders bar agreements made in the context of an interim settlement of a patent infringement action, whereby the NDA holder pays the generic not to enter the market, unless the parties obtain court approval through a process that is designed to enhance the court's ability to assess the competitive implications of the agreement. This remedy, in addition to facilitating the court's access to information about the Commission's views, also makes the process public and thereby may prompt other generic drug manufacturers (or other interested parties) to alert the court to potential anticompetitive provisions that could delay their entry into the market. Furthermore, the Commission believes that the requirement that the agreement be filed on the public record with the court will deter Abbott and Geneva from entering into anticompetitive agreements.

Paragraph IV addresses certain agreements to stay off the market that are not covered by Paragraph III because they do not involve interim relief in a litigated matter. Such situations would include agreements that are part of a final settlement of the litigation, and situations in which no litigation has been brought. In these circumstances, there is no judicial role in ordering relief agreed to by the parties. The Commission is concerned about such private agreements in which the first filer is paid by the NDA holder not to enter the market, because of the substantial risk of competitive harm that they may create. Thus, the order requires that Abbott and Geneva notify the Commission 30 days before entering into an agreement in which an ANDA first filer agrees with an NDA holder to refrain from going to market. Such notice will assist the Commission in detecting anticompetitive agreements before they have caused substantial injury to consumers. Absent the order, there is no mechanism for the antitrust enforcement agencies to find out about such agreements.

The form of notice that Abbott and Geneva must provide to the Commission under Paragraphs III and IV of the orders is set forth in Paragraph V. In addition to supplying a copy of the proposed agreement, they are required to provide certain other information to assist the Commission in assessing the potential

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competitive impact of the agreement. Accordingly, the orders require them to identify, among other things, all others who have filed an ANDA for a product containing the same chemical entities as the product at issue, and the court that is hearing any relevant legal proceedings involving either party. In addition, they must provide the Commission with all documents that evaluate the proposed agreement.

In addition, the proposed order against Geneva requires that it waive its 180-day marketing exclusivity period for its generic terazosin HCL tablet product. Although Geneva's exclusivity right with respect to the terazosin capsules product has expired, its exclusivity period for the tablet product still remains as a barrier to entry. This provision of the order will therefore open the market to greater generic competition in terazosin HCL products.

The proposed orders also contain certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The orders will expire in 10 years.

Opportunity for Public Comment

The proposed orders have 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 agreements and the comments received and will decide whether it should withdraw from the agreements or make the proposed orders final.

Analysis to Aid Public Comment

The purpose of this analysis is to facilitate public comment on the agreements. The analysis is not intended to constitute an official interpretation of the agreements, the proposed complaint, or the proposed consent orders, or to modify their terms in any way.

Complaint

IN THE MATTER OF
ELLERY COLEMAN

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

*Docket C-3948; File No. 0023053
Complaint, June 5, 2000--Decision, June 5, 2000*

This consent order requires Respondent Ellery Coleman to have a reasonable basis substantiating any representation that the users of his S&P futures trading programs can reasonably expect to achieve substantial profits on a consistent basis, that specific trades or investments were actually made and resulted in substantial profits, about the amount of earnings, income, profit, or rate of return that a prospective user of the trading program could reasonably expect to attain, about the percentage, ratio, or number of trades that a prospective user of Respondent's programs could reasonably expect to be profitable, or about any financial or other benefit from any trading programs offered by the Respondent. The order also prohibits Respondent from misrepresenting that users of his trading programs can expect to profit with very little financial risk, that Respondent uses his program on his own behalf, whether trade suggested were actually made or only hypothetical, whether any testimonial or endorsement of the Respondent's program represents the testimonialist's or endorser's actual experience and current opinions, findings, beliefs, or experiences, or from misrepresenting the risk to which users of the trading program are exposed. In addition, the order requires Respondent to disclose, clearly and conspicuously, "FUTURES [or STOCK, CURRENCY, OPTIONS, ETC., as applicable] TRADING involves high risks and YOU can LOSE a lot of money," in close proximity to any representation he makes about the financial benefits of any trading program. Respondent is also prohibited from representing without a reasonable basis that the experience represented by any user, testimonial or endorsement of any trading program represents the typical or ordinary experience of members of the public who use the program; or respondent must disclose either what the generally expected results would be for users of the trading program, or the limited applicability of the endorser's experience to what users may generally expect to achieve, that is, that users should not expect to experience similar results.