

**UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION**

COMMISSIONERS: **William E. Kovacic, Chairman**
 Pamela Jones Harbour
 Jon Leibowitz
 J. Thomas Rosch

In the Matter of

INVERNESS MEDICAL INNOVATIONS, INC.

a corporation.

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) **Docket No. C- 4244**
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COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 et seq., and by virtue of the authority vested in it by said Act, the Federal Trade Commission (“Commission”), having reason to believe that respondent Inverness Medical Innovations, Inc. (“Inverness”) has violated Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint, stating its charges as follows:

1. This action challenges Inverness’s unlawful maintenance of its monopoly power in the market for the research, development, manufacture, and sale of consumer pregnancy tests through its acquisition of certain assets of ACON Laboratories, Inc. (“ACON”), a rival manufacturer of consumer pregnancy tests. Inverness’s conduct threatened to stifle future competition from digital consumer pregnancy test products and from a potentially competing consumer pregnancy test based on water-soluble dye technology.

RESPONDENT

2. Inverness is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453.
3. Inverness is the leader in the research, development, manufacture, and sale of consumer pregnancy tests. Inverness manufactures and sells consumer pregnancy tests under several brand names, including Clearblue, Accu-Clear, and FactPlus. Inverness is also

the leader in the research, development, manufacture, and sale of digital consumer pregnancy tests.

4. Inverness is, and at all relevant times has been, a person, partnership, or corporation within the meaning of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and at all times relevant herein, Inverness has been, and is now, engaged in commerce as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

INDUSTRY BACKGROUND

5. Consumer pregnancy tests rely on immunoassay-based “lateral flow” technology, which tests a urine sample for the presence of a hormone (called human chorionic gonadotropin (“hCG”)) produced by pregnant women.
6. Consumer pregnancy tests typically include a test strip that contains an agent that reacts when exposed to any hCG present in the sample. The agent itself is bound to a colored label, typically a small gold or latex particle, in a complex called a “conjugate.” If hCG is present, the agent in the conjugate binds to the hCG, and a second antibody or antigen immobilized in the test strip then captures the complex. The test strip is imbedded inside a plastic handheld stick device that has an indicator window. If the test is positive, a colored line develops within the indicator window.
7. There are no viable substitutes for consumer pregnancy tests based on lateral flow technology. Lateral flow pregnancy tests are more accurate, easier to use, and less costly than other pregnancy tests, which resemble laboratory test kits.
8. “Digital” consumer pregnancy tests use and improve upon lateral flow technology. Rather than a colored line indicator, a digital pregnancy test indicates results through a digital display of words, such as “PREGNANT” or “NOT PREGNANT.”
9. Digital consumer pregnancy tests have been a growing segment of the consumer pregnancy test market.
10. Digital consumer pregnancy tests are more difficult to develop and manufacture than standard consumer pregnancy tests. They require more extensive know-how and more exacting manufacturing tolerances than analog tests.

RELEVANT MARKET & MARKET STRUCTURE

11. A relevant product market is the research, development, manufacture, and sale of consumer pregnancy tests. A relevant geographic market is the United States.
12. Intellectual property, know-how, and advertising are barriers to entry into the consumer pregnancy test market.
13. Inverness is the dominant player in the market for consumer pregnancy tests. Inverness maintains an approximately 70% share of the U.S. consumer pregnancy test market.
14. Inverness also is the dominant player in the digital consumer pregnancy test segment. At the time of the acquisition, Inverness also was one of only three independent firms manufacturing or marketing digital consumer pregnancy tests. The other firms exited the market in 2006.

COMPETITION BETWEEN INVERNESS AND ACON

15. ACON Laboratories, Inc. (“ACON”) developed, manufactured, and sold rapid diagnostic tests in competition with Inverness.
16. Before the acquisition, ACON was developing digital consumer pregnancy tests in a joint venture with Church & Dwight Co., Inc. (“Church & Dwight”), Inverness’s leading competitor. The collaboration with Church & Dwight envisioned that ACON would manufacture and supply the resulting digital consumer pregnancy test products on Church & Dwight’s behalf.
17. Before the acquisition, ACON had invested in the development of a new lateral flow consumer pregnancy test, which used a water-soluble dye as the label in the conjugate on the test strip. ACON had completed prototypes of the product, and supplied sample quantities to U.S. customers.
18. ACON also was one of the only, if not the only, firm involved in the development of consumer pregnancy tests that used water soluble dye technology.

INVERNESS’S ANTI-COMPETITIVE CONDUCT AND ITS EFFECTS

19. In 2006, Inverness acquired several assets from ACON, including its water-soluble dye product and assets relating to its digital consumer pregnancy test joint venture with Church & Dwight.

20. Inverness's 2006 acquisition made a significant contribution to maintaining its power in this market. As outlined below, the acquisition of the ACON assets enabled Inverness to maintain its monopoly power by jeopardizing the development of consumer pregnancy test products that could pose future competition to Inverness.
21. At the time of the acquisition, Inverness's actions reasonably appeared capable of making a significant contribution to maintaining its monopoly power by restricting competition from new consumer pregnancy tests.

DIGITAL CONSUMER PREGNANCY TESTS

22. Inverness's acquisition of the ACON assets interfered with ACON's ability and incentive to develop and manufacture digital consumer pregnancy tests. Among other things:
 - a. Inverness imposed a substantial covenant not to compete on ACON, which limited the term and scope of ACON's digital joint venture with Church & Dwight;
 - b. Inverness required ACON to remit to Inverness any profits from its digital consumer pregnancy test venture with Church & Dwight; and
 - c. Inverness acquired certain rights to intellectual property developed by ACON and Church & Dwight during their joint venture.
23. Inverness's acquisition of the ACON assets protected Inverness's monopoly power in consumer pregnancy tests by weakening future competition from digital consumer pregnancy test products. Inverness's acquisition of the ACON assets impaired ACON's ability and incentive to serve as an independent developer and supplier of digital consumer pregnancy tests. Inverness's acquisition of the ACON assets also hampered Church & Dwight's ability and incentive to develop and introduce competing digital consumer pregnancy test products.

WATER SOLUBLE DYE CONSUMER PREGNANCY TESTS

24. Inverness's acquisition of the ACON assets eliminated competition from ACON's water-soluble dye consumer pregnancy test product.
25. After Inverness acquired the rights to ACON's water-soluble dye consumer pregnancy test product, Inverness made no use of the test and ceased development and marketing efforts for it.

26. Inverness's acquisition protected Inverness's monopoly power in consumer pregnancy tests by weakening potential competition from competing water-soluble dye consumer pregnancy tests.

VIOLATIONS ALLEGED

27. The acts and practices of Inverness, as described in Paragraphs 1-26 above, incorporated herein by reference, constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.
28. The conduct at issue in this action caused or threatens to cause substantial harm to competition and to consumers, absent the issuance of appropriate relief in the manner set forth below.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-third day of January, 2009, issues its complaint against Inverness.

By the Commission, Commissioner Harbour recused.

Donald S. Clark
Secretary

SEAL: