

Analysis of the Agreement Containing Consent Order to Aid Public Comment
In the Matter of Inverness Medical Innovations, Inc.,
File No. 061-0123

I. Introduction

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Inverness Medical Innovations, Inc. (“Inverness”).

The proposed Consent Agreement is designed to remedy the harm to competition from Inverness’ conduct in acquiring certain assets of ACON Laboratories, Inc. (“ACON”). It would settle charges that Inverness engaged in an unlawful course of conduct to maintain its monopoly power in the lateral flow consumer pregnancy test market and hamper the development of future competition in that market, by restricting ACON’s digital consumer pregnancy test supply and development joint venture with Church & Dwight Co., Inc. (“Church & Dwight”), and by acquiring ACON’s competing water-soluble dye consumer pregnancy test technology.

Under the terms of the proposed Decision and Order, Inverness will divest ACON’s water-soluble dye consumer pregnancy test product assets. In addition, Inverness will remove barriers to ACON’s continued supply of digital tests to Church & Dwight during the remaining term of their joint venture. The proposed Decision and Order also limits Inverness’ ability to interfere with the unwinding of the ACON/Church & Dwight joint venture by, among other things, requiring Inverness to disclaim ownership of intellectual property developed by ACON and Church & Dwight during their joint venture.

II. Background

Inverness is a leader in the research, development, manufacture, and sale of consumer pregnancy tests in the United States. Nearly all retail consumer pregnancy tests use immunoassay-based “lateral flow” technology, which tests a urine sample for the presence of the human chorionic gonadotropin (“hCG”) hormone produced by pregnant women. Consumer pregnancy tests consist of a plastic handheld stick device, which contains a test strip embedded beneath an indicator window. The test strip contains chemical agents that react to the presence of hCG in the urine sample. If the test is positive for hCG, a colored line will develop within the indicator window.

Lateral flow consumer pregnancy tests are more accurate, easier to use, and less costly than other pregnancy tests, which resemble laboratory test kits. There are no viable substitutes for consumer pregnancy tests based on lateral flow technology.

“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.” Digital consumer pregnancy tests are more difficult to develop and manufacture than standard consumer pregnancy tests,

because they require more extensive know-how and more exacting manufacturing tolerances. Digital consumer pregnancy tests are a growing segment of the consumer pregnancy test market.

Inverness is the dominant firm in the market for consumer pregnancy tests. Inverness maintains an approximately 70% share of the U.S. consumer pregnancy test market. At the time of Inverness' acquisition of ACON, Inverness was one of only three independent companies marketing or manufacturing digital consumer pregnancy tests. The other firms exited the market in 2006.

ACON developed, manufactured, and sold consumer pregnancy tests in competition with Inverness. Before Inverness' acquisition of the ACON assets, ACON was developing digital consumer pregnancy tests in a joint venture with Church & Dwight, Inverness' 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.

ACON also had invested in the development of new lateral flow tests that used water-soluble dyes, rather than colored particles, as the reactive agents in the test strip. ACON was one of the only, if not the only, firm involved in the development of consumer pregnancy tests that used water-soluble dye technology. Before the acquisition, ACON had completed prototypes of the product, and supplied sample quantities to U.S. customers.

In 2006, Inverness acquired certain assets from ACON, which included assets relating to ACON's water-soluble dye technology and assets relating to ACON's digital consumer pregnancy test joint venture with Church & Dwight.

III. The Proposed Complaint

The proposed complaint alleges that relevant market in which to analyze Inverness' conduct is the research, development, manufacture, and sale of consumer pregnancy tests in the United States. Inverness is the dominant player in the market for consumer pregnancy tests. Barriers to entry into the consumer pregnancy test market include intellectual property, know-how, and advertising.

The proposed complaint alleges that Inverness engaged in a course of conduct to maintain its monopoly power in this market by threatening to hamper or stifle future competition from two emerging alternative consumer pregnancy test technologies.

First, the proposed complaint alleges that Inverness' acquisition of the ACON assets weakened future competition from digital consumer pregnancy test products. The proposed complaint alleges that, through its acquisition of the ACON assets, Inverness: (a) imposed a covenant not to compete on ACON, which limited the scope and duration of the ACON's digital consumer pregnancy test joint venture with Church & Dwight; (b) required ACON to surrender to Inverness any profits from ACON's joint venture with Church & Dwight; and (c) acquired rights to the intellectual property developed by ACON and Church & Dwight in their joint

venture. Through these actions, Inverness interfered with ACON's ability and incentive to develop and manufacture digital consumer pregnancy tests in its joint venture with Church & Dwight. Inverness' conduct also injured competition that might arise after the unwinding of the joint venture between ACON and Church & Dwight, by interfering with ACON's ability and incentive to serve as an independent developer and supplier of digital consumer pregnancy tests, and by hampering Church & Dwight's ability and incentive to introduce competing digital consumer pregnancy test products manufactured by another developer.

Second, the proposed complaint alleges that Inverness' acquisition of the ACON assets eliminated future competition from water-soluble dye lateral flow consumer pregnancy tests. 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. Inverness' acquisition of the ACON assets further entrenched Inverness' monopoly power in consumer pregnancy tests by preventing future competition from competing water-soluble dye consumer pregnancy tests.

IV. The Proposed Order

The proposed order will remedy the Commission's competitive concerns about Inverness' conduct in maintaining its consumer pregnancy test product monopoly power.

First, the proposed order contains provisions to prevent Inverness from interfering with the digital consumer pregnancy test product joint venture between ACON and Church & Dwight, and to enable ACON and Church & Dwight to maintain their competitive viability after the joint venture ends. These provisions include a requirement that Inverness disclaim any ownership rights on intellectual property developed during the joint venture. The proposed order further requires that Inverness will not interfere with ACON's transfer or licensing of digital consumer pregnancy test technology to Church & Dwight, and that Inverness not interfere with ACON's ability to manufacture digital consumer pregnancy tests for Church & Dwight during their collaboration.

Second, to prevent Inverness from harming emerging competition from water-soluble dye consumer pregnancy test products, the proposed order requires Inverness to divest, to Aemoh Products, LLC, a fully-paid perpetual exclusive sublicense to Inverness' water-soluble dye intellectual property. The proposed order seeks to ensure that water-soluble dye products can be developed without risk of infringing Inverness' intellectual property, by requiring Inverness to covenant not to assert intellectual property infringement claims against certain lateral flow products that use Inverness' water-soluble dye technology. These provisions, among others, will give Aemoh – a start-up run by a successful and experienced health products entrepreneur – the ability to complete the commercialization of water-soluble dye based consumer pregnancy tests.

V. Opportunity for Public Comment

The proposed consent order has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed consent order and the comments received and will decide whether it should withdraw from the agreement or make the proposed consent order final.

By accepting the proposed Consent Agreement subject to final approval, the Commission anticipates that the competitive problems alleged in the complaint will be resolved. The purpose of this analysis is to invite public comment on the proposed Consent Agreement, in order to aid the Commission in its determination of whether to make the proposed order final. This analysis is not intended to constitute an official interpretation of the proposed order nor is it intended to modify the terms of the proposed order in any way.