



HOW THE FDA, BATTELLE
MEMORIAL INSTITUTE, AND THE
GROCERY MANUFACTURER'S
ASSOCIATION ARE VIOLATING
ANTITRUST LAWS

ABSTRACT

IN JUNE AND JULY OF 2015, ACTING
COMMISSIONER OF THE FDA STEPHEN
OSTROFF, PRESIDENT OF BATTELLE
MEMORIAL INSTITUTE JEFFREY
WADSWORTH, AND PRESIDENT OF
THE GROCERY MANUFACTURERS
ASSOCIATION PAMELA BAILEY ALL
CONCEDED TO PREDATORY AND
ANTICOMPETITIVE CONDUCT. THIS IS
THE STORY OF HOW THE U.S.
GOVERNMENT AND THEIR
CONTRACTORS ARE ENGAGING IN
MONOPOLISTIC PRACTICES THAT
HARM EVERY AMERICAN CONSUMER.

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HOW THE FOOD AND DRUG ADMINISTRATION (FDA), BATTELLE MEMORIAL INSTITUTE (BMI) AND THE GROCERY MANUFACTURER'S ASSOCIATION (GMA) ARE VIOLATING ANTITRUST LAWS

The Sherman Anti-Trust Act, was the first Federal law to outlaw monopolistic business practices. The Sherman Act authorized the Federal Government to dissolve “trusts” engaged in anticompetitive conduct that harmed the consumer.

The Sherman Act also declared that any actions “in the form of trust or otherwise that was in restraint of trade or commerce among the several states, or with foreign nations” was now against the law. Persons engaging in anticompetitive conduct were subject to fines and possible incarceration. Individuals and companies suffering economic losses because of anticompetitive conduct could now sue in Federal court for treble damages.

The broadly worded nature of the Sherman Act, however, left much room for subsequent interpretation by the Courts. Just five years after the Sherman Act was passed the Supreme Court, in the case of the United States v. E. C. Knight Company (1895), ruled that the American Sugar Refining Company was not in violation of the law even though the

The story of Samuel Dodd, Esq.

Samuel Dodd, an attorney for Standard Oil, first came up with the idea of a “trust.”

In 1882, Dodd worked to establish a single Board of Trustees to govern all of Standard Oils' properties and holdings. Every Standard of Ohio stockholder received 20 trust certificates for each share of stock they owned.

Nine trustees were appointed to receive and pool all of the profits from each of the Standard Oil owned companies that were brought together to form the new and massive economic enterprise.

The trustees were given the power to determine dividends and elect the directors and officers of each component company. This allowed Standard Oil to eliminate the competition that was necessary to keep prices at fair market value for the consumer.

company controlled about 98 percent of all sugar refining in the United States. The Court reasoned that the company's control of manufacture did not necessarily constitute "a control of trade."

THERE ARE FIVE PRINCIPAL ACTIVITIES THAT CONSTITUTE ANTICOMPETITIVE CONDUCT UNDER THE CLAYTON ACT:

1. Price discrimination that substantially lessens competition or tends to create a monopoly.
2. Sales on the condition that the buyer agrees not to deal with competitors of the seller, i.e., "exclusive dealings".
3. Sales on the condition that the buyer also purchase another different product to substantially lessen competition, i.e., "tying."
4. Mergers and acquisitions that substantially lessen competition.
5. Any person that becomes a director of two or more competing corporations, if those corporations would violate anti-trust criteria by merging.

However, other decisions by the courts have resulted in the dissolution of monopolistic giants like the Northern Securities Company of Minnesota, Standard Oil and the American Tobacco Company. In more recent years, the Federal Government has relied on the Sherman Act to stop predatory anticompetitive conduct by the software super-giant Microsoft.ⁱ

In 1914, in an attempt to clarify and supplement the Sherman Act Congress passed the Clayton Antitrust Act. The Clayton Act made significant modifications to federal antitrust law. The focus of the Clayton Act was to deter and prevent anticompetitive practices in their embryonic stages. Significantly, the Act seeks to stop anticompetitive practices by prohibiting particular types of conduct, not deemed in the best interest of a competitive market.ⁱⁱ

Undergirding all antitrust law in the United States is the fundamental principle that the Federal Government will serve as the honest

broker by abiding by the principles of antitrust law and enforcing it as necessary to preserve open and fair competition in the marketplace.

Today, however, the expanding role of the Federal Government has grown to include the production of goods and services in direct competition with the private sector where the Federal Government has placed itself in the awkward position of engaging in anticompetitive conduct in collusion with groups of their own preferred contractors. Nowhere is this more evident than Federal Government agencies that exercise regulatory oversight over the different critical infrastructures of our society including energy, healthcare, pharmaceuticals, transportation, food and agricultural and others.

By way of example, let us consider a case involving the actions of the Food and Drug Administration (FDA) and a small high technology business. The FDA has regulatory responsibility for approximately 80% of the U.S. food supply. What is most interesting in this case, however, is

FDA, BMI AND GMA ADMISSIONS OF GUILT

The Uniform Commercial Code (UCC) sets forth rules and processes that companies use to mediate disputes. The UCC contains a provision for what is called a constructive notice. A constructive notice is a legal document that contains the sworn statement of the facts as set forth by one of the aggrieved parties to the dispute.

The recipient of a constructive notice is given 30 days under the law to rebut the facts as stated in the sworn statement. If the recipient does not rebut the facts within the allotted time frame the facts as presented by the aggrieved party are accepted by the courts as true and a concession of guilt by the offending party.

In this case, the small high technology company sent constructive notices setting forth the facts of their case to Dr. Stephen Ostroff, Acting Commissioner of the FDA, Dr. Jeffrey Wadsworth, President of Battelle Memorial Institute and Ms. Pamela G. Bailey, President of the Grocery Manufacturer's Association.

By failing to rebut the facts Dr. Ostroff, Dr. Wadsworth and Ms. Bailey have all conceded their guilt to the facts as presented to them. You can review the constructive notices as served on the FDA, Battelle and the Grocery Manufacturers Association at <http://www.jgpis.org>

that the FDA, Battelle Memorial Institute (BMI) and the Grocery Manufacturers Association have all conceded guilt.

In this example, the FDA misappropriated the patented ideas and trade secrets of a small high technology start-up company. The technology involved what is called predictive analytics. Predictive analytics is the collection and mathematical treatment of massive amounts of data, i.e., big data, to help determine what may and what may not happen in the future as complex systems evolve.ⁱⁱⁱ In 2014, the major investment broker Gartner estimated that the move to big data including predictive analytics will drive a \$212 billion investment in information technology (IT) through the year 2016.^{iv}

WHAT HAPPENED?

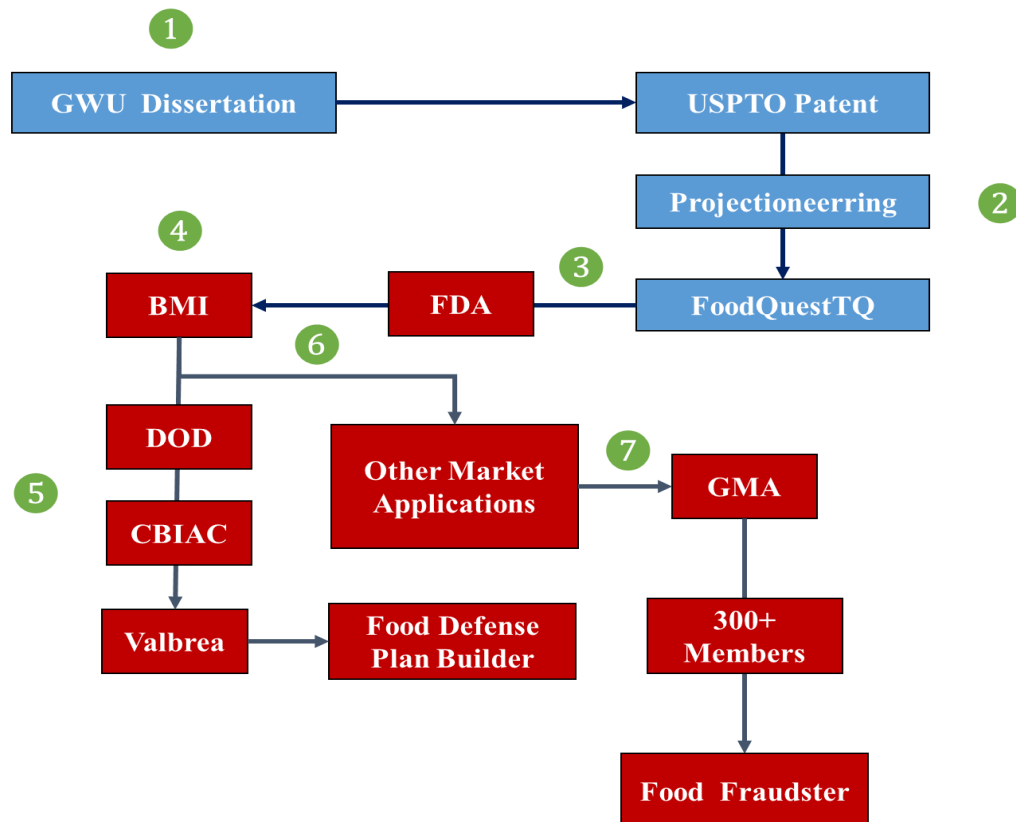


Figure 1: What Happened?

1 The story begins at The George Washington University when a doctoral student conducted some of the first research on applying the science of predictive analytics to the behavior of complex systems including energy production and distribution, water availability and distribution, cyber networks, transportation, healthcare, food and agriculture and all of the other critical infrastructures on which our society depends.^v

2 After he graduated, the new doctor got a patent^{vi} on his inventions and started two companies. The first company called Projectioneering LLC was established to serve as an intellectual property holding company for applying his patents across all of the critical infrastructures of our society. He also started up a company called FoodQuestTQ LLC to specifically apply his patented ideas and trade secrets across the food and agricultural vertical. One of the principal goals of FoodQuestTQ's predictive analytics was to prevent food emergencies and the deaths and illnesses associated with intentional or accidental food poisoning—the types of things that cost the food industry hundreds of millions of dollars each year and cut sharply into their profits because of the low profit margins that characterize sales in the food industry.

3 In developing their new line of predictive analytic food safety risk management tools FoodQuestTQ LLC met with FDA officials and even submitted a proprietary proposal to the FDA's Joint Institute for Food and Nutrition (JIFSAN) and the Center for Food Safety and Applied Nutrition (CFSAN). The proposal was rejected and the FDA simply misappropriated the patented ideas and trade secrets contained in the proposal.^{vii}

4 Battelle Memorial Institute (BMI), one of the world's largest non-profit scientific research and applied engineering organizations, is one of FDA's principal contractors.

5 Coincidentally, BMI also serves as a principal contractor to the Department of Defense (DOD). BMI in collusion with their FDA contract

suitor and DOD facilitated an illegal “pass through” noncompetitive subcontract via DOD’s Chemical and Biological Information Assurance Center (CBIAC) to duplicate FoodQuestTQ’s products. The non-competitive subcontract went to a small technology company called Valbrea Technologies. Valbrea Technologies was paid by the U.S. Government to duplicate FoodQuestTQ’s food defense planning software. FDA then copyrighted the duplicated software as the property of the U.S. Government and provided it to the food industry free of any charge.

6 Meanwhile, BMI diverted the predictive analytic technology they misappropriated from FoodQuestTQ LLC in collusion with the FDA to increase the profitability of their own line of commercial predictive analytic tools for food safety and across other industry verticals. A sampling of these BMI commercial tools include PRIA™, Smart Vision™, Way Finder, EluciData™ and many others. (<http://www.battelle.org/our-work/consumer-industrial/consumer-products/food-beverage>).

7 With the help of the FDA, and as part of BMI’s efforts to expand their own foothold in the predictive analytics food safety risk management market, BMI colluded with the Grocery Manufacturer’s Association (GMA) to use FoodQuestTQ’s patented ideas and trade secrets to duplicate their Food Fraudster tool.

BID RIGGING BY FDA, DOD AND BATTELLE

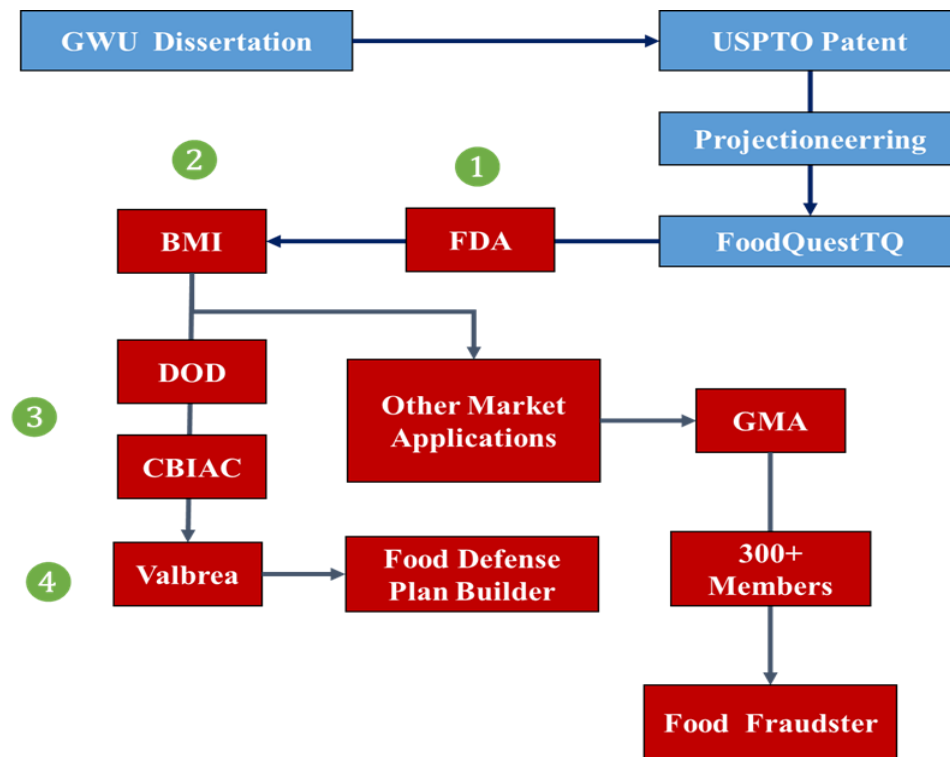


Figure: FDA, BMI and DOD Engage in Bid Rigging

① Bid rigging is a form of fraud in which a commercial contract is promised to only one party. In the case of FoodQuestTQ, the first predatory and anticompetitive conduct occurred when FDA saw a technology that they wanted—in this case predictive analytic tools that would allow them to prevent food emergencies before they happen. FDA desperately needed the technology in response to public and Congressional criticism about their slow response to improve the safety of the food supply.

② The FDA rather than following procurement laws to lawfully acquire the technology simply misappropriated it. They faced the possibility of public embarrassment if they did not “come up with the “goods” because of their own promises to Congress in the National Food Protection Plan in which the FDA itself proclaimed that they would be internally

PROCUREMENT LAWS THAT ARE INTENDED TO PREVENT THE U.S. GOVERNMENT FROM ENGAGING IN BID RIGGING:

- 1. The fair and open competition provisions of the Competition in Contracting Act (CICA) of 1984 (41 U.S.C. 253);**
- 2. The Federal Acquisition Streamlining Act (FASA) of 1994;**
- 3. The Federal Acquisition Reform Act (FARA) of 1996, as amended;**
- 4. Federal Activities Inventory Reform Act (FAIR), P.L. 105-270;**
- 5. Implementing Office of Management and Budget Circular A-76;**
- 6. The Federal Acquisition Regulations (FARS);**
- 7. 5 C.F.R. Part 2635--endorsements, Subpart E—impartiality; G—misuse of authority, and;**
- 8. P.L. 96-303—violations of public trust.**

building advanced computer software tools for the food industry.^{viii} The FDA could not afford to be publicly trumped by a little company like FoodQuestTQ as the source of predictive analytic tools that could prevent food emergencies. The agency's future budget allocations from Congress depended on their ability to deliver on their promises. The FDA considered FoodQuestTQ as nothing more than collateral damage.

③ BMI then colluded with two of their most important contract suitors, i.e., the FDA and DOD, to bypass a huge body of federal procurement and procurement integrity law specifically designed to prevent the U.S. Government itself from violating the Sherman and Clayton Acts.

④ In this example, BMI facilitated a non-competitive “directed by-pass” contract via DOD’s Biological and Chemical Information Assurance Center (CBIAC) to a single pre-selected contractor, i.e., Valbrea Technologies, to duplicate the predictive analytics technology FDA and BMI originally misappropriated from FoodQuestTQ.^{ix}

PRICE FIXING BY FDA, BMI AND GMA

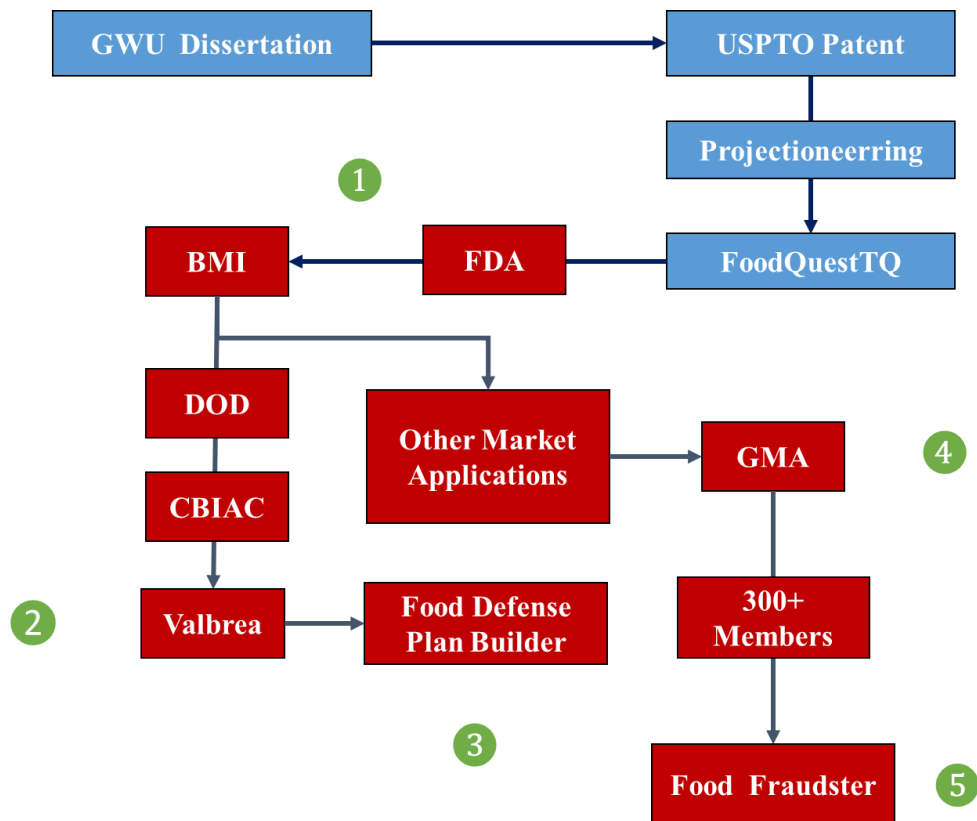


Figure: Price Fixing by FDA, BMI and GMA

① Price fixing is an agreement between participants in the same market to buy, sell, or maintain the price of a product at an artificially fixed price. In the case of FoodQuestTQ, the first step in fixing the price of their food risk management predictive analytic software took the form of collusion between FDA and their support contractor, BMI, to avoid procurement laws that preclude the U.S. Government from engaging in bid rigging or price fixing.

② Step two consisted of FDA, BMI and DOD colluding to let an unlawful non-competitive contract to one of DOD's preferred subcontractors, Valbrea Technologies. Valbrea was paid under a U.S. Government contract to use the misappropriated predictive analytic

technology to duplicate FoodQuestTQ's already existing food defense planning tools.

3 Soon thereafter, FDA publicly announced the release of their own Food Defense Plan Builder tool that duplicated the FoodQuestTQ software. FDA immediately claimed copyright ownership of the duplicated software and began to provide it to the food industry free of charge. The result of the FDA, BMI and DOD collusion served to fix the price of the new predictive analytic software tool at \$0 cost to the food industry. It also served to transform the originally patented predictive analytic technology licensed by Projectioneering LLC to FoodQuestTQ into a \$0 cost generic enabling technology solution for use across all other industry verticals.

4 BMI, seeking to expand its own competitive foothold in the burgeoning multi-billion dollar market for predictive analytics, colluded with FDA and GMA to duplicate another FoodQuestTQ software tool that uses predictive analytics to prevent food fraud. This time, a member company of GMA, Cargill Inc., gave a public briefing that BMI and GMA were working together to develop a new predictive analytic tool to combat food fraud. The briefing contained the same misappropriated predictive analytic technology originally stolen by the FDA and BMI from FoodQuestTQ. In this case GMA was pooling the resources of its member companies to duplicate FoodQuestTQ's already existing Food Fraudster predictive analytic software to produce an artificially low cost software solution for use by their GMA member companies.^x

HARM TO THE CONSUMER

It would be easy to mistakenly conclude that the actions of the FDA, DOD, BMI and GMA are not that significant. After all, the fact that computer software tools for preventing food poisoning are being made broadly available to the food industry at low cost can only be good for the public safety and the consumer. Right?

Well, unfortunately the answer is not as simple as that. Innovation by small companies is at the heart of practical solutions. For every problem we solve today there are nothing but equally vexing problems to solve tomorrow. An economic system that rewards entrepreneurs for their creativity in solving new problems is at the heart of a safe food supply.

The government has a poor track record of innovation. In our system we rely on entrepreneurs to do this heavy lifting for the government. By their predatory and anticompetitive actions FDA, DOD, BMI and GMA are compromising our ability to find the innovative solutions we are surely going to need to solve the next intractable problems that threaten the safety of the food supply. Government misappropriation of technology from entrepreneurs only serves to stifle innovation by eliminating the rewards system that stimulates problem solving. In the end, consumers rely on this rewards system to keep the food they eat safe.

The entire story of FoodQuestTQ LLC and the concessions of guilt by the FDA, Battelle memorial Institute and the Grocery Manufacturer's Association can be found at the John Galt Program for Investigative studies website at <http://www.jgpis.org>

ⁱ Sherman Anti-Trust Act, July 2, 1890; Enrolled Acts and Resolutions of Congress, 1789-1992; General Records of the United States Government; Record Group 11; National Archives. Retrieved from the World Wide Web on August 1, 2015 at: <http://www.ourdocuments.gov/doc.php?flash=true&doc=51>

ⁱⁱ Clayton Anti-Trust Act of 1914 (P.L. 63-212, 38 Stat. 730, enacted October 15, 1914, codified at 15 U.S.C. §§ 12-27, 29 U.S.C. §§ 52-53). See: <http://www.infoplease.com/encyclopedia/history/clayton-antitrust-act.html>

ⁱⁱⁱ John Galt Program for Investigative Studies (November 2014). The case of FoodQuestTQ: The Food and Drug Administration is implementing a criminal scheme to destroy small business. Retrieved from the World Wide Web on August 1, 2015, at:

<http://jgpis.org/the-story-of-foodquesttq/foodquesttq-fbi-report/>

^{iv} Alpine Data Labs (January 2014). *Market stats: What's the "True" size of the predictive analytics market?* Retrieved from the World Wide Web on August 1, 2015, at: <https://alpinenow.com/blog/market-stats-whats-the-true-size-of-the-predictive-analytics-market/>

^v Hnatio, J. (2006) "The complexity systems management method: A next generation decision support tool for the management of complex challenges at institutions of higher education," (dissertation). Washington, DC: The George Washington University.

^{vi} Hnatio, J. (2012). Complexity systems management method. USPTO patent no. US 20110173146 A1. Retrieved from the World Wide Web on August 1, 2015, at: <http://www.google.com/patents/US20110173146>

^{vii} John Galt Program for Investigative Studies (November 2014). The case of FoodQuestTQ: The Food and Drug Administration is implementing a criminal scheme to destroy small business. Retrieved from the World Wide Web on August 1, 2015, at:

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^{viii} Food and Drug Administration (2007). The national food protection plan. Retrieved from the World Wide Web on August 1, 2015, at: <http://www.fda.gov/Food/GuidanceRegulation/FoodProtectionPlan2007/ucm132565.htm>

^{ix} John Galt Program for Investigative Studies (November 2014). The case of FoodQuestTQ: The Food and Drug Administration is implementing a criminal scheme to destroy small business. Retrieved from the World Wide Web on August 1, 2015, at:

<http://jgpris.org/the-story-of-foodquesttq/foodquesttq-fbi-report/>

^x Ibid.