STATEMENT

OF

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BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

HEARING ON

COMPETITION IN THE PHARMACEUTICAL MARKETPLACE:
ANTITRUST IMPLICATIONS OF PATENT SETTLEMENTS

PRESENTED ON

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Good afternoon, Mr. Chairman and members of the Committee. I appreciate being invited here to testify.

The issues raised by today’s hearing on the antitrust implications of patent settlements in the pharmaceutical marketplace are currently the subject of investigations being conducted by the Federal Trade Commission (“FTC”). As a starting point I thought it would be helpful to the Committee if I were to describe in general the division of labor between the Antitrust Division and the FTC in the enforcement of the antitrust laws.

The Department of Justice and the FTC share federal responsibility for antitrust enforcement, but that shared responsibility is limited to civil antitrust enforcement, including merger enforcement. The Department of Justice has exclusive responsibility for criminal antitrust enforcement.

Because criminal investigations are highly sensitive, I cannot comment on any specific investigation. However, I can describe generally what distinguishes conduct subject to criminal prosecution from conduct subject to a civil enforcement action.

Section 1 of the Sherman Act prohibits contracts, combinations, and conspiracies in restraint of trade. Criminal prosecution is generally confined to a class of agreements that have been found to be unambiguously harmful and are considered *per se* unlawful. Examples of such conduct include naked agreements...
among competitors to fix prices, rig bids, or allocate customers, territories, or sales. Such agreements are generally secret, and businesses and consumers are defrauded and misled because the conspirators continue to hold themselves out as competitors.

I should note, however, that there are some situations in which criminal investigation or prosecution may not be considered appropriate, even though the conduct may appear to be a *per se* violation of law. Such situations may include cases in which (1) there is confusion in the law; (2) there are truly novel issues of law or fact presented; (3) confusion reasonably may have been caused by past prosecutorial decisions; or (4) there is clear evidence that the subjects of the investigation were not aware of, or did not appreciate, the consequences of their action. In these instances, as well as in other cases where the conduct does not rise to the level of a criminal violation of Section 1, the conduct may be subject to civil antitrust enforcement.

Individuals criminally convicted of violating the Sherman Act are subject to fines up to $350,000 and prison sentences up to three years, and corporations are subject to fines up to $10 million. Under the alternative sentencing provision found in 18 U.S.C. § 3571, a convicted defendant is subject to higher fines equaling twice the gain resulting from the violation, or twice the loss caused to the victims, whichever is higher.
The Antitrust Division places a high priority on criminal antitrust enforcement. In recent years, the Division has aggressively pursued price-fixing, bid-rigging, and market- and customer-allocation conspiracies in both international and domestic markets.

On the international side, the Division has prosecuted international cartels operating in a broad spectrum of commerce, including: products found in household goods, such as vitamins and food preservatives; products used in the manufacturing sector, such as graphite electrodes used in steel making; products used in the agricultural sector, such as animal and livestock feed additives; and a variety of services, ranging from auctioning fine art to marine transportation and construction. The Division estimates that the international cartels it has prosecuted over the last few years affected well over $10 billion in U.S. commerce. More importantly, the cartel activity in these cases cheated U.S. businesses and consumers of many hundreds of millions of dollars annually.

On the domestic side, the Division recently has prosecuted bid-rigging cartels affecting hundreds of millions of dollars in contracts to supply food to schools, hospitals, and other public institutions; typhoon relief projects; real estate foreclosure auctions; and contracts for the construction of water treatment plants, as
well as price-fixing conspiracies involving metal building insulation and numerous anticompetitive schemes in the graphics display industry.

Because we share federal antitrust enforcement responsibility for civil violations with the FTC, we have a clearance protocol with the FTC to determine which agency will investigate a particular civil matter. That determination is based primarily on which agency has the greater expertise in the product market as a result of recent antitrust investigations conducted by that agency. The clearance protocol enables the two agencies to make the most effective use of enforcement resources, as well as to avoid duplicative investigatory requests on private parties. Under this clearance protocol, the FTC has handled recent civil investigations involving patent disputes and the delay of generic competition in the pharmaceutical industry.

However, because the Division has sole responsibility for criminal antitrust enforcement, if the FTC were to uncover evidence of a potential criminal violation relating to the pharmaceutical industry, under our clearance protocol the FTC would be required to refer that evidence to us for criminal investigation. Likewise, if at the outset of an investigation, the evidence suggested a potential criminal violation, the Division would investigate the matter, regardless of which agency had greater expertise in the product market.
In fact, in the pharmaceutical market, the Division recently prosecuted the largest criminal antitrust conspiracy ever uncovered -- the international vitamin cartel. To date, we have prosecuted eleven companies, headquartered in the United States, Switzerland, Germany, Canada, and Japan, and thirteen individuals for cartel activity in ten vitamin markets. We have obtained nearly $1 billion in fines, including the $500 million fine imposed against F. Hoffmann-La Roche, the largest fine ever imposed in a U.S. criminal prosecution of any kind. In addition, we obtained the first jail sentences ever imposed against European business executives for violating U.S. antitrust laws. The investigation is continuing.

Mr. Chairman, I hope this information is helpful to the Committee. I would be happy to answer questions if I can.