

**American Antitrust Institute**  
**Private Antitrust Enforcement Conference**  
**National Press Club, Washington, D.C.**  
**December 2, 2014**  
**Remarks of Commissioner Terrell McSweeney**

Good evening. Thank you, Rick, for that kind introduction. Thank you to Bert and to the American Antitrust Institute for the invitation to join you this evening. Congratulations, Diana, on being selected as AAI's next President. As you know all too well, you have big shoes to fill. Bert, thank you also for your vision in founding AAI and your leadership of it for the last 16 years.

I also want to acknowledge the lawyers and economists being recognized tonight for their achievements in antitrust litigation. Having worked with a few of the finalists on matters while I was at the Antitrust Division, I can personally attest to their excellent work.

As Rick mentioned, I joined the FTC as a Commissioner earlier this year. And from day one I learned this important disclaimer: The views I express tonight are my own and do not reflect the views of the FTC or any other Commissioner.

My arrival at the FTC coincided with a very special time for the Commission – its 100<sup>th</sup> birthday. We've spent a good bit of time this year both celebrating and, importantly, reflecting on the FTC's history and accomplishments. It is also the centennial of another landmark piece of antitrust legislation: the Clayton Act.

It is not a historical accident that Congress passed the Federal Trade Commission Act and the Clayton Act in the same year. As most of you know, Congress initially passed the Sherman Act in 1890, in order to safeguard competition and prevent the consolidation of economic power.

But, by the second decade of the 20<sup>th</sup> century, there was growing recognition that legislation supplementing the Sherman Act was necessary to – as Woodrow Wilson put in his New Freedom campaign speeches – “open again the fields of competition, so that new men with brains, new men with capital, new men with energy in their veins, may build up enterprises in America.”<sup>1</sup>

It was Wilson – partly goaded by Theodore Roosevelt – who threw down the gauntlet against trusts in the 1912 election, proposing to “prevent private monopoly by law, to see to it that the methods by which monopolies have been built up are legally made impossible.”<sup>2</sup> Shortly after assuming office in 1913, President Wilson delivered a special address on trusts and monopolies to a joint session of Congress, in which he called for two things: (1) a “more explicit legislative definition of the policy and meaning of the existing antitrust law;” and (2) an

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<sup>1</sup> Woodrow Wilson, Campaign Speech in Indianapolis, Indiana (Oct. 3, 1912).

<sup>2</sup> Woodrow Wilson, Campaign Speech, *The New Freedom* (1913).

“interstate trade commission.”<sup>3</sup> Congress answered Wilson’s first call by passing the Clayton Act and his second by passing the FTC Act.

Importantly, with Sections 4 and 16 of the Clayton Act, Congress explicitly introduced a private right of action for damages and injunctive relief, respectively.<sup>4</sup> This expanded the private right of action within the Sherman Act to include all of the antitrust laws.<sup>5</sup> The legislative history of the Clayton Act suggests that Congress intended to open “the door of Justice to every man, whenever he may be injured by those who violate the antitrust laws.”<sup>6</sup>

So you could say that both the FTC and the plaintiffs’ bar are celebrating important antitrust milestones this year. I’d like to reflect this evening on how Congress’s vision of public and private enforcement working together to deter anticompetitive conduct and to protect consumers is alive and well today.

For example, *St. Luke’s* is a recent case of government and private enforcement challenging an anticompetitive health provider transaction. This particular case involved the acquisition of the largest primary care physician practice in Nampa, Idaho, Saltzer Medical Group, by the second largest practice, St. Luke’s Health System.<sup>7</sup> The acquisition resulted in a combined entity with 80% of the primary care physicians in the market, making St. Luke’s the dominant provider of those services and giving it enhanced bargaining leverage over area health insurance plans.<sup>8</sup>

Competing area health care providers, Saint Alphonsus and Treasure Valley Hospital, first sued as private plaintiffs, seeking to block the transaction between St. Luke’s and Saltzer.<sup>9</sup> The private plaintiffs claimed they substantially relied upon referrals and services performed by the Saltzer physicians and they feared that post-transaction, Saltzer would no longer provide these services at their facilities, harming not only them, but also their patients. Shortly thereafter, the FTC and the State of Idaho also sued to block the deal because of the likely harm to consumers in the form of higher prices and lower quality of care.<sup>10</sup>

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<sup>3</sup> Woodrow Wilson, Address Before a Joint Session of Congress on Additional Legislation for the Control of Trusts and Monopolies, Jan. 20, 1914, *reprinted at* 51 Cong. Rec. 1962-64, 1978-79 (1914).

<sup>4</sup> See 15 U.S.C. §§ 15(a), 26.

<sup>5</sup> Treble damages were originally provided for by Section 7 of the Sherman Act (1890), and then incorporated into Section 4 of the Clayton Act (1914). Congress repealed Section 7 of the Sherman Act as “superfluous” in 1955. Act of July 7, 1955, ch. 283, Pub. L. No. 137, 69 Stat. 282-83 (1955).

<sup>6</sup> 51 Cong. Rec. 9073 (1914) (remarks of Rep. Webb).

<sup>7</sup> *FTC v. St. Luke’s Health Sys., Ltd.*, No. 1:12-CV-00560, No. 1:13-CV-00116, 2014 U.S. Dist. LEXIS 9264 (D. Idaho Jan. 24, 2014).

<sup>8</sup> *Id.* at \*6.

<sup>9</sup> See generally Compl., *Saint Alphonsus Med. Ctr. v. St. Luke’s Health Sys., Ltd.*, No. 1:12-CV-00560 (D. Idaho filed Nov. 12, 2012).

<sup>10</sup> See generally Compl., *FTC v. St. Luke’s Health Sys., Ltd.*, No. 1:13-CV-00116 (D. Idaho filed Mar. 26, 2013), available at

<http://www.ftc.gov/sites/default/files/documents/cases/2013/03/130312stlukescmpt.pdf>.

Given the similarities in the cases, the district court consolidated the private and government actions.<sup>11</sup> After a 19-day bench trial, the district court agreed with the plaintiffs and found that the transaction violated Section 7 of the Clayton Act and the Idaho Competition Act.<sup>12</sup> The matter is currently on appeal to the Ninth Circuit, so stay tuned.

As today's conference discussed in detail, I recognize that private plaintiffs are facing increasingly tightened pleading standards, changes to class certification, and other limitations imposed by courts. These changes pose new challenges to private plaintiffs, but the *St. Luke's* case demonstrates how private plaintiffs, the FTC, and states can work together to challenge an anticompetitive transaction and protect consumers.

The Commission also has other tools – research, advocacy, and guidance – that can help courts and private plaintiffs shape antitrust law. One area where the FTC has utilized all of its tools involves reverse payment settlements. Both the FTC and private litigation have played – and will continue to play – a vital role in the evolution of the law around these settlements, which are also sometimes called “pay-for-delay” agreements.

The settlement of a Hatch-Waxman patent infringement suit has the potential to cause competitive harm – if the generic manufacturer agrees to delay its entry into the market in exchange for some sort of compensation from the brand name manufacturer that the generic could not have obtained even if it prevailed in the infringement litigation. In this situation, the brand and generic each make more money by sharing in the brand's monopoly profits instead of competing – and consumers foot the bill by paying higher prices for prescription drugs.

This harm is all too real. An FTC study in 2010 found that reverse payment settlements cost U.S. consumers \$3.5 billion a year.<sup>13</sup> In addition, agreements with compensation to generics restrict entry an average of 17 months longer than agreements without those restrictions.<sup>14</sup>

The FTC is actively engaged in stopping anticompetitive reverse payment settlements through a combination of developing its expertise through study and bringing that expertise to bear in enforcement efforts. Private plaintiffs have been alongside, including opting to file “follow-on” litigation. From 1999 through 2004, the FTC's investigations and enforcement efforts kept anticompetitive reverse payment settlements largely at bay.<sup>15</sup> Beginning around 2005, some appellate courts began to uphold these agreements and their number began to rise substantially.<sup>16</sup> As more courts heard these cases, a circuit split ultimately resulted. Some circuits found that reverse payment settlements were presumptively legal under the “scope of the

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<sup>11</sup> Order of Consolidation, No. 1:12-CV-00560 (D. Idaho Mar. 19, 2013), available at <http://www.ftc.gov/sites/default/files/documents/cases/2013/03/130319stlukeorder.pdf>.

<sup>12</sup> *FTC v. St. Luke's Health Sys., Ltd.*, No. 1:12-CV-00560, No. 1:13-CV-00116, 2014 U.S. Dist. LEXIS 9264, at \*7-8 (D. Idaho Jan. 24, 2014).

<sup>13</sup> Fed. Trade Comm'n, *Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010) at 2, available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.* at 1.

<sup>16</sup> *Id.*

patent” test, while others held that they were presumptively anticompetitive, prompting a “quick look” review.

This backdrop set the stage for the Supreme Court’s review of *FTC v. Actavis* last year. The Supreme Court’s *Actavis* decision was significant in confirming the harm to competition from reverse payment agreements.<sup>17</sup> But it left it to the lower courts to structure the rule-of-reason analysis in these cases.<sup>18</sup>

Going forward, the FTC, state enforcers, and private plaintiffs will all help lower courts interpret what *Actavis* means for litigants. For example, the issue of what constitutes a payment subject to antitrust scrutiny is currently playing out in a number of private actions across many different jurisdictions. The *Actavis* opinion only refers to “payments” and “money” but, in my view, nothing in the opinion suggests that the Supreme Court meant to limit its ruling to strictly cash, as opposed to in-kind compensation.

In fact, the Commission recently filed an amicus brief on this issue and participated in argument in the Lamictal direct purchaser litigation pending before the Third Circuit.<sup>19</sup> Weighing in in support of the private plaintiffs, the FTC noted that the in-kind payment at issue – a “no authorized generic” commitment whereby a brand refrains from marketing its own authorized generic in return for delayed generic entry – is a type of reverse payment subject to scrutiny under the Supreme Court’s analysis in *Actavis*.<sup>20</sup>

No AG commitments and other non-cash consideration appear to be increasingly common ways to delay generic entry. In September, the Commission filed its first post-*Actavis* lawsuit, charging pharmaceutical companies with illegally blocking consumers’ access to less expensive versions of the testosterone replacement drug AndroGel.<sup>21</sup> AndroGel has annual U.S. sales of over \$1 billion. In our complaint, we allege that branded drug manufacturer AbbVie and its partner Besins filed sham patent litigation suits against potential generic competitors in order to delay introduction of lower-priced versions of AndroGel. While the lawsuits were pending, the complaint alleges that AbbVie then entered into an anticompetitive reverse payment agreement with generic drug manufacturer Teva to further delay generic drug competition. Teva agreed to abandon its countersuit against AbbVie and refrain from launching its lower-cost AndroGel alternative. In return, AbbVie paid Teva in the form of an authorized generic deal on an unrelated cholesterol drug, TriCor. The Commission is seeking not only injunctive relief in this case, but also disgorgement of the defendants’ ill-gotten gains.

Another health care issue that is getting the attention of not only the FTC, but also private plaintiffs involves branded pharmaceuticals’ use of FDA-mandated restricted distribution systems known as risk evaluation and mitigation strategies, or “REMS.” REMS serve an

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<sup>17</sup> See generally *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

<sup>18</sup> *Id.* at 2238.

<sup>19</sup> Br. of Fed. Trade Comm’n as *Amicus Curiae* in Supp. of Pl.-Appellants, *King Drug Co. of Florence, Inc. v. SmithKlineBeecham Corp.*, No. 14-1243 (3d Cir. filed Apr. 28, 2014), available at [http://www.ftc.gov/system/files/documents/amicus\\_briefs/re-lamictal-direct-purchaser-antitrust-litigation/140428lamictalbrief.pdf](http://www.ftc.gov/system/files/documents/amicus_briefs/re-lamictal-direct-purchaser-antitrust-litigation/140428lamictalbrief.pdf).

<sup>20</sup> *Id.*

<sup>21</sup> See generally Compl., *FTC v. AbbVie, Inc.*, No. 14-CV-5151 (E.D. Pa. filed Sept. 8, 2014), available at <http://www.ftc.gov/system/files/documents/cases/140908abbviecmpt1.pdf>.

important and legitimate safety function, but they also have the potential to foreclose less expensive alternatives for customers by blocking access to samples needed by generic manufacturers to meet FDA requirements for approval. Congress included language in the 2007 FDA Amendments Act that stated that brand name drug manufacturers should not utilize the REMS program to impede generic competition,<sup>22</sup> but it appears this conduct nevertheless continues.

Although the Commission has yet to file an enforcement action challenging this type of conduct, the agency recently submitted an amicus brief in a private action, *Mylan v. Celgene*, which is pending in the District of New Jersey.<sup>23</sup> While the Commission did not take a position on the merits in the case, we did note that the case has broader implications for consumers because improper use of restricted distribution programs may impede generic competition in violation of the antitrust laws.

These are just a few examples of the Commission and private plaintiffs working alongside each other to shape the contours of antitrust law. Going forward, I expect there to be more – not only in the health care space, but perhaps also in sectors where our understanding is evolving, such as the role patent assertion entities are playing in markets.

I doubt Woodrow Wilson, Louis Brandeis, Henry Clayton, and others who helped form the FTC and strengthen the antitrust laws 100 years ago could have even imagined all the innovation and complexities of our modern economy – what would they have made of FDA-mandated restricted distribution systems and generic drugs? But they clearly recognized something that is as true today as it was in 1914 – that robust government and private antitrust enforcement are essential to protect competition, markets, and consumers.

Thank you again to AAI for having me here tonight.

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<sup>22</sup> See 21 U.S.C. § 355-1(f)(8).

<sup>23</sup> Fed. Trade Comm'n Br. as *Amicus Curiae*, *Mylan Pharm., Inc. v. Celgene Corp.*, No. 2:14-CV-2094 (D. N.J. filed Jun. 17, 2014), available at [http://www.ftc.gov/system/files/documents/amicus\\_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf](http://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf).