

# United States of America Federal Trade Commission

## A Pragmatist's Approach to Navigating the Intersection of IP and Antitrust

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### **December 4, 2013**

Good afternoon. I am pleased to be here today and to update you on the recent work of my agency, the Federal Trade Commission, at the intersection of the intellectual property and antitrust laws in the United States. The FTC's activities include research, market education, advocacy, as well as enforcement, and I will address three controversial areas: first, whether seeking an injunction on a FRAND-encumbered standard essential patent (SEP) is a competition law violation; second whether "patent assertion entities" (PAEs) are harming competition, innovation, and the economy; and, third, how "reverse-payment" settlements should be treated after the U.S. Supreme Court's ruling for the FTC in Actavis<sup>2</sup> earlier this year.

Each of these three issues arise from the intersection, or perhaps it would be better to say "collision," of the intellectual property and antitrust laws. Each issue presents complex questions about fundamental rights of property and of access to the courts, the relative scope of competition and intellectual property laws and, from a policy perspective, how best to balance the short and long-run consumer welfare trade-offs between favoring one set of laws over the

<sup>&</sup>lt;sup>1</sup> The views expressed in this speech are solely those of Commissioner Ohlhausen and are not intended to reflect the views of the Commission or any other Commissioner.

<sup>&</sup>lt;sup>2</sup> FTC v. Actavis, Inc., 133 S.Ct. 2223 (2013).

other. Reasonable minds can, and do, disagree on each of these subjects. Ultimately, however, our goal at the FTC is a simple one: to protect consumer welfare by using all of our tools. I think some of our efforts at the intersection of the antitrust and intellectual property laws have served this mandate well, like our successful decade-long campaign of research, advocacy, and litigation to combat anticompetitive reverse payment settlements in the pharmaceutical industry. But, as I will explain today, I have serious concerns about the Commission's handling of several other issues at this legal crossroads, in particular the majority's sometimes one-sided approach to patent hold-up in the context of SEPs and PAEs.

## I. <u>Wealth Creation Requires Both Innovation and Commercialization; The</u> Economy Therefore Also Needs Both Antitrust and Intellectual Property Law.

Let me begin with some observations on the FTC's goal of consumer welfare. The pursuit of ever-greater consumer welfare, or, put another way, the pursuit of wealth, requires a finding this balance between innovation and commercialization; between our goals for today and the others just over the horizon.

Nations with the legal and economic heritage of the United States and the United Kingdom historically have designed their intellectual property laws as the main way to promote innovative risk-taking for the common good. The Constitution wisely provides that "Congress shall have power . . . To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."4 The U.S. Court of Appeals for the Federal Circuit, which handles patent matters, has noted that if one were to eliminate the right to exclude from the basket of rights attached to patents that "the express purpose of the Constitution and Congress, to promote the progress of the useful arts, would be seriously undermined."<sup>5</sup> Note the inclusion of "useful" arts among the drafters' goals – their intent clearly was to entice inventors with the lure of "exclusive" rights, rights that may well lead to monopoly profits in commercial enterprises. The Supreme Court in 1974 recognized the important role of this system to provide "an incentive to inventors to risk the often enormous costs in terms of time, research and development. The productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy .....<sup>6</sup> In exchange for this "reward for inventions" the patent laws require the inventor to disclose his or her idea, so that after the period of exclusivity expires, "the knowledge of the invention enures [sic] to the people, who are thus enabled without

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competition law can work together to bring new and better products, technologies, and services to consumers more efficiently and at lower prices."

Knowing at a theoretical level that our competition and intellectual property laws must coexist to promote consumer welfare is important and, frankly, took all of us in the bar probably a bit too long to recognize. But the nagging question for enforcers is how to handle specific situations in which we see a competition problem rooted directly in a facet of the patent regime. This question is at the heart of the discussion today over SEPs, PAEs, and reverse payment drug settlements. And there is no easy answer. Before I give you an overview of the FTC's attempts to solve this problem, let me offer you what I consider to be the next best thing to an answer – a framework of leading priorities that guides my analysis of these problems. This will illuminate how I examine these issues and why I have dissented from several recent FTC actions.

#### II. <u>Taking the Pragmatic Road to Navigating the Intersection of IP and Antitrust.</u>

barriers to entry or permit other conduct that risks failure for disruptive innovators trying to break into industries and challenge incumbents. My tendency, though, is to err on the side of allowing the market to self-correct.

Third, although it is true that the intellectual property and antitrust laws are largely consonant in their overall aim of improving consumer welfare, it is important to recognize the natural tension between them; between pursuing mainly long-term social gains under the

think Judge Posner was incorrect in his assessment on this point last year in Apple v. Motorolato proposals to change the rights associated with a patent simply depending upon who owns it.

The conventional wisdom today seems to be that competition means cheap products; cheap products require cheap patents; and cheap patents are those with fewer rights – so let's start pruning away those rights. Supporters of this world view point to patent litigation as a drag on the economy. But patent litigation is only a drag if it is not upholding valid patent rights and a patented product is only truly more expensive if the higher price does not reflect what is needed to subsidize the development of future products. Making these decisions requires policy judgments about the value of ideas and the nature of intellectual property that, in my opinion, are beyond the scope of the competition laws. But recognizing the inherent tension between these two bodies of law animates my search for the proper balance of incentives that will propel innovation and dynamic efficiency while keeping markets efficient today.

Fourth, the world's most innovative economies tend to be those with strong intellectual property protections, like the United States and the nations of Europe. And, in case you hadn't guessed it by now, I do not believe that our leadership in innovative technologies is merely a happy coincidence. Although this success has many ingredients, chief among them is a strong patent system, which gives patent holders a basket of rights, including the right to exclude others from practicing, a presumption of patent validity, and the ability to pursue potential infringers in court. This system offers fair reward for insight and hard work and the right incentives to take

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wants its routers to interoperate with other wireless devices must license the patents essential to the relevant 802.11 WiFi standards, which are agreed on by the Institute of Electrical and Electronics Engineers, or IEEE, the relevant SSO. There are many SSOs out there, each with its own focus, terms and membership.

The FTC has done a lot of research and advocacy work related to SEPs, including a workshop and related report with DOJ in 2007, a 2010 hearing with the DOJ and the Patent and Trademark Office (PTO), and a comprehensive 2011 report on competition policy. The agency acknowledges the important pro-competitive value of SSOs and has said that "industry standards are widely acknowledged to be one of the engines of the modern economy." We also recently told the Senate that "standards can create enormous value for consumers by increasing competition, innovation, product quality, and choice. Standards lower costs by increasing manufacturing volume, and they increase competition by eliminating switching costs for consumers who want to switch between products manufactured by different companies."

The possible competition issue the FTC and others have identified after studying the SSO process is that SEP holders can use the bargaining power they may gain after having a patent designated "standard essential" either to charge higher royalties for the SEPs or to refuse a license to competitors. Many refer to these practices as forms of "patent hold-up." That is, once an SSO has adopted a standard, implementers across the industry invest to comply with the standard, increasing their switching costs and nearly ensuring industry lock-in to the standardized technology. This lock-in theoretically enhances the bargaining ability of SEP holders, allowing them to charge more in royalties than they could have before the patent was designated essential, in an amount reflecting the increased cost for implementers to switch to another technology. The FTC for years has focused on patent hold-up as a possible competition

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problem, summarizing its concerns in testimony to Congress in 2012 as follows: "Simply put, the FTC is concerned that a patent holder may use the threat of an [International Trade Commission (ITC)] exclusion order, or an injunction issued in district court, to 'hold up' or demand higher royalties or other more costly licensing terms after the standard is implemented than could have been obtained before its [intellectual property] was included in the standard."

Although I agree with my fellow Commissioners that patent hold-up is a theoretical possibility that the FTC, the ITC or a court should consider, I am not convinced that we have made the case yet that merely seeking an injunction, without more, is a competition law violation. In keeping with my philosophy of strong protection for intellectual property rights, transparency, predictability, and fairness, and my reluctance to have government inject itself into free markets needlessly, I have spent my tenure advocating for a more detailed examination of the facts surrounding possible hold-up and for a more balanced treatment of the issue that includes analysis of the several market-based factors that could mitigate hold-up.<sup>10</sup>

This advocacy is finally having some effect. This year, the Commission delivered testimony to the House of Representatives refining its position on patent hold-up and SEPs by explaining that the "Commission acknowledges that several market-based factors may mitigate the risk of hold-up, and this understanding informs our enforcement activity in this complex field." Thus, for example, the Commission now expressly recognizes that "patent holders that are frequent participants in standard-setting activities may incur reputational and business costs that could be sufficiently large to deter fraudulent behavior. Patent holders may also enjoy a first-mover advantage if [their] technology is adopted as the standard. As a result, patent holders

<sup>&</sup>lt;sup>10</sup> For a critical analysis of the potential risks and downsides to minimizing patent rights in an effort to mitigate

GmbH (Bosch)<sup>1</sup> the agency investigated a proposed acquisition by Bosch that raised competitive concerns in the market for certain automotive air conditioning repair equipment. During the course of the investigation, FTC staff uncovered evidence indicating that the acquired company, SPX Service Solutions (SPX), had sought injunctive relief against competitor firms that were interested in licensing certain SPX patents that may have been standard-essential and that SPX allegedly had offered to license on reasonable and non-discriminatory (RAND) terms.<sup>12</sup> The FTC settled this matter with Bosch, requiring Bosch to divest certain assets to address the proposed merger.<sup>13</sup> To address the alleged patent-related conduct, the FTC required Bosch, first, to agree not to seek injunctions on its standard-essential patents against parties that are willing to license such patents, and, second, to license those patents on a royalty-free basis.<sup>14</sup>

In the second matter, the FTC investigated and ultimately entered a settlement with Google and its recently acquired subsidiary, Motorola Mobility.<sup>15</sup> As in Bosch the FTC alleged that Google and Motorola violated Section 5 of the FTC Act – but not the antitrust laws – by seeking injunctive relief against competitors that were willing to license certain standard-essential patents that Motorola had agreed to license on RAND terms through its participation in several standard-setting organizations.<sup>16</sup> In Google the remedy imposed by the FTC was more complex than the flat prohibition on seeking injunctive relief imposed in Bosch Rather, the

<sup>&</sup>lt;sup>11</sup> In re Robert Bosch GmbH, FTC File No. 121-0081.

<sup>&</sup>lt;sup>12</sup> Id., Analysis of Agreement Containing Consent Orders to Aid Public Comment, at 4 (Nov. 26, 2012), available at <a href="http://www.ftc.gov/os/caselist/1210081/121126boschanalysis.pdf">http://www.ftc.gov/os/caselist/1210081/121126boschanalysis.pdf</a>.

<sup>&</sup>lt;sup>13</sup> See idat 3-4.

<sup>&</sup>lt;sup>14</sup> See idat 4-5.

<sup>&</sup>lt;sup>15</sup> In re Motorola Mobility LLC and Google Inc., FTC File No. 121-0120.

<sup>&</sup>lt;sup>16</sup> See id. Analysis of Proposed Consent Order to Aid Public Comment, at 3-6 (Jan. 3, 2013), available at <u>http://ftc.gov/os/caselist/1210120/130103googlemotorolaanalysis.pdf</u>.

FTC's consent order established a multi-step process that Google must undertake before it is permitted to seek injunctive relief on its standard-essential patents.<sup>17</sup>

In my dissents in the Boschand Googlematters, I took issue with, among other things, the lack of transparency and guidance that the FTC's decisions provided to patent holders and others subject to our jurisdiction.<sup>18</sup> In particular, I raised concerns about the FTC enforcing Section 5 without providing sufficient information about the relationship between that statutory provision and the antitrust laws, including the Sherman and Clayton Acts. Without such information, it is unclear what the term "unfair method of competition" means or how the Commission will use its enforcement discretion under Section 5. The inherent ambiguity in the FTC Act makes it all the more important that the agency provide meaningful limiting principles to application of Section 5. I proposed a set of principles this summer and have been advocating for dialogue on this point.<sup>19</sup>

A related point I raised in my Boschand Googledissents is that one of the effects of those decisions was to create conflict between the FTC and other U.S. government institutions.<sup>20</sup> The first such conflict arises between the FTC on the one hand and the ITC and the federal courts on the other as a result of our prohibiting holders of standard-essential patents from seeking injunctive relief before these institutions. Our decisions effectively tell holders of standard-essential patents that they cannot go to the ITC, where the only available relief is an exclusion

<sup>&</sup>lt;sup>17</sup> See idat 6-8.

<sup>&</sup>lt;sup>18</sup> Seeln re Robert Bosch GmbH, FTC File No. 121-0081, Statement of Commissioner Maureen K. Ohlhausen, at 3-4 (Nov. 26, 2012) [hereinafter Ohlhausen BoschStatement], available at <a href="http://www.ftc.gov/os/caselist/1210081/121126boschohlhausenstatement.pdf">http://www.ftc.gov/os/caselist/1210081/121126boschohlhausenstatement.pdf</a>; In re Motorola Mobility LLC and Google Inc., FTC File No. 121-0120, Dissenting Statement of Commissioner Maureen K. Ohlhausen, at 1-3 (Jan. 3, 2013) [hereinafter Ohlhausen GoogleDissent], available at <a href="http://ftc.gov/os/caselist/121020/130103googlemotorolaohlhausenstmt.pdf">http://ftc.gov/os/caselist/121020/130103googlemotorolaohlhausenstmt.pdf</a>.

<sup>&</sup>lt;sup>19</sup> Maureen K. Ohlhausen, Commissioner, Fed. Trade Comm'n, Remarks at the U.S. Chamber of Commerce, Section 5: Principles of Navigation (July 25, 2013), available at <a href="http://ftc.gov/speeches/ohlhausen/130725section5speech.pdf">http://ftc.gov/speeches/ohlhausen/130725section5speech.pdf</a>.

<sup>&</sup>lt;sup>20</sup> SeeOhlhausen BoschStatement, supranote 18, at 1-2; Ohlhausen GoogleDissent, supranote 18, at 5-6.

order. I would note that I am not saying that competition policy should take a secondary position to other industrial policy concerns. Quite the contrary, the FTC has correctly advocated for a greater role for competition in U.S. industrial policy decisions. However, as I have noted, I

#### **B.** Patent Assertion Entities.

Let me turn now for a few minutes to another major topic implicating patent hold-up, the conduct of patent assertion entities. A patent assertion entity, or PAE, is typically understood to mean a firm that owns patents but does not practice them, and that did not contribute to the research and development of those patents. The business model for many PAEs is to broadly assert and litigate the patent claims and thereby derive licensing and other revenues from entities already practicing the patented technology. Here are a few facts for context:

- x Nearly 5,000 patent lawsuits were filed in 2012; this is up from roughly 2500 in 2010.<sup>24</sup>
- X It has been estimated that PAE-generated revenue cost defendants and licensees \$29
  billion in 2011 400% more than in 2005.<sup>25</sup>
- x As of December 1, 2012, PAEs brought roughly 60% of patent infringement lawsuits for the year. This is up from 45% in 2011 and just 19% in 2006.<sup>26</sup>
- x PAEs make 100 or more demands for each lawsuit filed.<sup>27</sup>
- x Studies show that NPE/PAEs buy and litigate the patents of small companies (50%) and individual inventors (28%) more than the patents of others.<sup>28</sup> This means they may serve a pro-competitive benefit of protecting the little guy in monetizing patents. Other studies

<sup>&</sup>lt;sup>24</sup> Executive Office of the President, Patent Assertion and U.S. Innovation, June 2013, at 5 [hereinafter PAE Report].

<sup>&</sup>lt;sup>25</sup> James Bessen and Michael J. Meurer, The Direct Costs from NPE Disput@Boston Univ. School of Law and Economics Research Paper No. 12-34, 2012); Jon Leibowitz, Chairman, Fed. Trade Comm'n, Opening Remarks at Patent Assertion Entity Workshop (Dec. 10, 2012) at 3, available at http://www.ftc.gov/speeches/leibowitz/121210paeworkshop.pdf.

show, however, that the targets of PAE lawsuits are more often than not small companies on whom the impact is potentially more harmful.<sup>29</sup>

- x Studies also have shown that the legal costs exceed the settlement 90% of the time.<sup>30</sup>
- x Finally, another recent study showed that PAEs lose 92% of the time when litigated to trial on the merits.<sup>31</sup>

Many people are sounding the alarm on PAEs and calling for swift and far-reaching action in this area, including President Obama, whose office issued a report in June, claiming that PAE activity "significantly retard[s] innovation in the United States and result[s] in economic 'dead weight loss' in the form of reduced innovation, income, and jobs for the American economy."<sup>32</sup> The report calls for three action items: (1) "clearer patents with a high standard of novelty and non-obvious

One of the earliest bills garnering attention that is still being discussed is the SHIELD Act ("Saving High-tech Innovators from Egregious Legal Disputes"). This bill, one of the narrowest in its scope but most severe in its treatment of PAEs, calls for specifically increasing the cost for PAEs to litigate by shifting the fees of litigation to the losing party if it is a PAE and requiring PAEs to post bond.<sup>34</sup>

Another leading bill, perhaps the one with the most support right now, is the "Innovation Act," which was introduced in October by House Judiciary Chairman Bob Goodlatte of Virginia.<sup>35</sup> This bill offers sweeping changes to our patent litigation system in the hopes of reducing patent abuse. For example, it would impose tougher pleading requirements, require courts to shift fees to the losing party, except where the party was "reasonably justified" in bringing its case, allow lawsuits against customers to be stayed where a manufacturer intervenes and the customer agrees, and limit discovery to certain core materials until after claim construction. In addition, the bill provides for changes to the patent laws, including better recordation of patents and other changes more technical in nature. Recent amendments to the bill provide that sending purposely evasive demand letters to end users of patented products is an abuse of the patent system and call for a study of bad faith demand letters.<sup>36</sup> This bill, which initially received praise from the head of the PTO and enjoys bipartisan support, is now raising concerns because of the potential implications for non-PAE patent litigation, as well as for the

There are companion bills in the Senate, including the Patent Transparency and Improvements Act, introduced in late November and sponsored by Senators from both parties, including Senate Judiciary Chairman Patrick Leahy of Vermont, Senator Mike Lee of Utah, and Senator Sheldon Whitehouse of Rhode Island. This Senate bill contains several litigation and patent law reform provisions similar to the House's Innovation Act, but goes a step further by expanding the authority of my agency, the FTC, to pursue any demand letters issued in bad faith by PAEs. The bill characterizes these demand letters as unfair or deceptive acts and practices in violation of the FTC Act, so long as the letters would be likely to mislead a reasonable recipient.

Although I see possible value in these proposals, like recordation of parties in interest, and I believe that a patent litigation issue may exist, I am concerned we may be acting precipitously with these bills and with the general call to action against PAEs from so many influential people. I would counsel caution before making any sweeping changes, because, if you look closely, you will find mixed and incomplete evidence on the economic effects of PAE activity and on the causes of the recent surge in patent litigation.

For example, although several studies point to a rise in patent litigation brought by PAEs, like those I cited earlier, others seem to indicate just the opposite. The U.S. Government Accountability Office (GAO) in August issued the results of its in-depth study into patent infringement litigation, just a couple of months after the President's report.<sup>38</sup> The GAO report revealed that in many respects the conventional wisdom out there about PAEs, including much of what was cited to by the President in his June report, may be off base. Let me read you a portion of what they concluded: "Operating companies [which they define as those that produce products] brought most of the patent infringement lawsuits from 2007 to 2011. According to our

<sup>&</sup>lt;sup>38</sup> GAO, Intellectual Property: Assessing Factors That Aff

analysis of data for this period, operating companies and related entities brought an estimated 68 percent of all lawsuits. PMEs [GAO's term for PAEs, which stands for Patent Monetization Entities] and likely PMEs brought 19 percent of the lawsuits. PMEs and likely PMEs brought 17 percent of all lawsuits in 2007 and 24 percent in 2011, although this increase was not statistically significant. In contrast, operating companies and related entities filed 76 percent of the lawsuits in 2007 and 59 percent in 2011, a statistically significant decrease."<sup>39</sup>

Moreover, PAEs actually have some fans – and I'm not just referring to the PAEs themselves. Those supporting PAEs contend they help promote innovation and resolve inefficiencies in the patent system. PAEs offer a means for small companies and individual inventors to more efficiently protect and monetize their inventions. This sounds like a not unreasonable contention and, if it is correct, some PAEs actually could be addressing a market inefficiency – large companies with deep pockets infringing the patents of smaller companies with little independent recourse.

The key question is whether PAEs are distorting competitive dynamics in technology markets and chilling innovation by buying patents and asserting them on unsuspecting victims. The FTC has acknowledged the potential issues created by PAEs, but I believe we cannot yet answer this question conclusively. There are many types of PAEs with many different business plans of varying levels of success and no one can say for certain what net effect these businesses are having on the economy. We must therefore take steps to understand whether there is a problem with PAEs and, if so, the nature and scope of the problem. Otherwise, other policymakers could be wasting time and resources solving the wrong problem. And, worse, in the process they could end up doing more harm than good by chilling legitimate infringement litigation and diminishing the basket of rights that have successfully fueled our innovative economy for so many years.

The FTC, answering calls to action by members of Congress, announced this Fall a proposed comprehensive study of PAEs.<sup>42</sup> The agency has as part of its statutory mandate under Section 6(b) of the FTC Act the authority to conduct such industry studies, including through the issuance of subpoenas to market participants for their confidential information. The agency

<sup>&</sup>lt;sup>42</sup> Fed. Trade Comm'n, Notice and Request for Public Comment on PAE Activity, 78 Fed. Reg. 61,352 (Sep. 27, 2013), available athttp://www.gpo.gov/fdsys/pkg/FR-2013-10-03/pdf/2013-24230.pdf

plans to use its unique power to address questions that others have been unable to answer thus far, including:

- 1. How do PAEs organize their corporate legal structure, including parent and subsidiary entities?
- 2. What types of patents do PAEs hold, and how do they organize their holdings?
- 3. How do PAEs acquire patents, and how do they compensate prior patent owners?
- 4. How do PAEs engage in assertion activity (i.e. demand, litigation, and licensing behavior)?
- 5. What does assertion activity cost PAEs?
- 6. What do PAEs earn through assertion activity?<sup>43</sup>

This will likely be the most comprehensive and in-depth analysis of this issue, with more than 25 PAEs operating across a variety of industries likely to receive information requests. We also are planning a benchmarking exercise in which we will be sending out information requests to another 15 entities that assert patents.<sup>44</sup> This latter group will be concentrated in the wireless telecommunication sector and include manufacturers, patent pools, and other entities in this space that license and assert patent rights. In keeping with my philosophy of transparent, predictable, and well-informed government action, I would urge any interested parties to send in your comments – we recently extended the comment period until December 16th – and I would counsel anyone pushing for strong

Personally, I support the FTC's efforts to examine the PAE issues and advocate for greater clarity and certainty in the patent system. But given the absence of concrete evidence out there of harm, I have serious questions about whether this is a competition law problem or whether it is an issue in the patent system itself. One recent study indicates 82% of PAE defendants were sued for infringing software patents.<sup>45</sup> Another study estimates that it is five times more likely a software patent will be the subject of a lawsuit as a chemical patent.<sup>46</sup> It is even worse for business method patents, which are roughly fourteen times as likely to end up in litigation.<sup>47</sup> This suggests to me that we may be experiencing a problem in how to adequately define strong patents in terms of their nonobviousness, novelty, or other characteristics, which may not necessarily be a competition law problem. I hope the agency's 6(b) study will better help us understand this matter and inform people on all sides, before Congress passes legislation or the White House and other federal agencies take actions that may have unintended consequences.

As is probably obvious from what I have said about the agency's enforcement actions relating to patent hold-up in Google/SEPand Bosch as well as my philosophy of transparency, predictability, and fairness, I would be very cautious about expanding Section 5 unfair methods of competition liability to attach to basic claims of infringement by PAEs. Only where there is some evidence of additional conduct by a PAE that tends for instance to undermine the patent process or that falls within a recognized exception to the basic right to seek relief in court, like sham or repetitive litigation, would I be compelled to intervene. But, as with SEPs and other issues at the frontier of the intellectual property laws and competition policy, I am still evaluating

- <sup>46</sup> Id.
- <sup>47</sup> Id.

<sup>&</sup>lt;sup>45</sup> PAE Report, supranote 24, at 5.

these issues and will continue to refine my position on the nature of this problem and the appropriate remedy as we get more insight into the roots and scope of the problem.

#### C. Reverse Payment Settlements.

The last issue I would like to present involves so-called reverse payment patent settlements among pharmaceutical companies – also referred to as pay-for-delay agreements.

In a typical pay-for-delay agreement, the branded manufacturer pays the potential generic entrant to delay its entry into the market. An FTC staff study has estimated that a ban on such agreements would result in approximately \$3.5 billion in annual savings to drug purchasers.<sup>48</sup> It is important to note that the number of these patent settlements continues to rise year after year.

After more than a decade of FTC challenges to these agreements in the courts, last year the Third Circuit Court of Appeals, in the K-Dur decision, found that pay-for-delay payments are presumptively unlawful, adopting the position that, when compensation flows from the brand to the generic and the generic delays entry, the burden shifts to the parties to show that the compensation was not paid in exchange for that delay.<sup>49</sup>

The K-Dur decision created a split among circuit court decisions in pay-for-delay matters, and set the stage for the Supreme Court's review of the FTC v. Actavis, Inomatter. At issue in this case was the validity of the legal standard applied by the Eleventh Circuit Court of Appeals to reverse payment settlements. That standard, which is often referred to as the "scope of the patent" test, holds that "absent sham litig

within the scope of the exclusionary potential of the patent." The FTC strongly disagreed with the Eleventh Circuit's view.

As some of you may know, the Supreme Court issued its decision this year ruling that the FTC should be allowed to proceed with its case – under the rule of reason. The Court held that, although there is support for a legal policy that favors the settlement of private disputes, this factor alone cannot override other antitrust policy considerations. According to the Court, those considerations include, among others, that reverse payments have the potential for genuine adverse effects on competition, large payments may be indicative of market power, and branded and generic companies can still settle on terms that do not involve reverse payments – for example, by agreeing to an earlier generic entry date.

Nonetheless, the Court rejected the FTC's argument that reverse payments should be reviewed under a so-called quick look approach, finding that the courts must apply a standard rule of reason analysis.

The dissent in this matter, authored by Chief Justice Roberts, would have upheld the Eleventh Circuit's scope of patent test. Among other things, the dissent argued that taking the prospect of settlements off the negotiating table may very well dampen the incentives for generic manufacturers to challenge pharmaceutical patents in the first place.

Looking ahead, as Chairwoman Ramirez mentioned in a recent statement, the FTC is moving forward with the Actavis litigation itself. The Commission is also studying the Court's opinion and assessing how best to protect consumers' interests in other pay-for-delay cases. The Commission recently submitted an amicus brief in a reverse payment case involving the drug

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pharmaceutical company not to introduce its own generic drug to compete with the third party generic, should be treated as reverse payment settlements subject to the analysis under Actavis.<sup>50</sup>

## IV. Conclusion.

As you can see, the FTC is actively mapping the terrain at the intersection of the intellectual property and antitrust laws. We are developing a nuanced approach to analyzing and enforcing patent hold-up issues related to SEPs and PAEs, including consideration of mitigating factors, as well as pushing forward to challenge anticompetitive agreements involving patents. We will continue to pursue a deeper understanding of how we can work within our mandate to balance the innovation investments we need for tomorrow with the efficiency demands of the dynamic and increasingly cost-conscious economy of today. Thank you for your time.

<sup>&</sup>lt;sup>50</sup> FTC, Amicus Brief, In re Effexor XR Antitrust Litig. (D. N.J., Aug. 14, 2013), available at<u>http://www.ftc.gov/os</u>/2013/08/130816effexoramicusbrief.pdf.