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## “PAY-FOR-DELAY” SETTLEMENTS IN PHARMACEUTICAL LITIGATION: DRAWING A FINE LINE BETWEEN PATENT ZONE AND ANTITRUST ZONE

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### ABSTRACT

Congress has identified the recent trend of pharmaceutical companies to settle patent litigation under “pay-for-delay” settlements or reverse payment settlements. Under these agreements, a generic maker receives a payment from a brand-name company in exchange for withdrawing the patent challenge and refraining from entering the market until an agreed date. Most courts have rejected antitrust challenges to this practice in view of exclusive rights of patent holders and general benefits from settlements. As part of the health care reform, Congress now proposes to treat “pay-for-delay” settlements as *per se* illegal and entirely ban the practice. The proposal, however, limits the ability to end uncertain and costly litigation and is thus likely to discourage patent challenges and eventually harm the consumer. Congress should replace the *per se* illegal treatment with a quick look balancing approach to permit settlements if an antitrust analysis reveals its pro-competitive effects.

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# “PAY-FOR-DELAY” SETTLEMENTS IN PHARMACEUTICAL LITIGATION: DRAWING A FINE LINE BETWEEN PATENT ZONE AND ANTITRUST ZONE

YUKI ONOE\*

## INTRODUCTION

“In business, as in life, there’s no such thing as a perfect plan.”<sup>1</sup> Behind the blockbuster antidepressant Prozac, there is a bitter story that explains the common strategy of pharmaceutical companies to settle patent litigation.<sup>2</sup> Eli Lilly, the patent holder, first gained the high ground when a district court upheld the patent’s validity.<sup>3</sup> The company was confident of a victory on appeal and refused a \$200 million settlement.<sup>4</sup> The appellate court, however, invalidated the patent claim covering Prozac, and Eli Lilly lost \$2.6 billion in annual sales.<sup>5</sup>

Recently, in lieu of risking invalidation, pharmaceutical patent holders have often tried to settle litigation under a “pay-for-delay” agreement.<sup>6</sup> Under this type of settlement, the brand-name company pays the generic firm to stay off the market until a specified date, such as the patent expiration date.<sup>7</sup> Often called reverse payment settlements<sup>8</sup> or “pay-for-delay” settlements,<sup>9</sup> these agreements are highly

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<sup>1</sup> John Simons, *Lilly Goes Off Prozac*, FORTUNE, June 28, 2004, at 179.

<sup>2</sup> See Bethany McLean, *A Bitter Pill*, FORTUNE, Aug. 13, 2001, at 122, 126.

<sup>3</sup> *Eli Lilly & Co. v. Barr Labs., Inc.*, 100 F. Supp. 2d 917, 934 (S.D. Ind. 1999); McLean, *supra* note 2, at 126.

<sup>4</sup> McLean, *supra* note 2, at 126.

<sup>5</sup> *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 972 (Fed. Cir. 2001); Simons, *supra* note 1, at 180.

<sup>6</sup> See James F. Ponsoldt & W. Hennen Ehrenclou, *The Antitrust Legality of Pharmaceutical Patent Litigation Settlements*, 2006 J.L. TECH. & POLY 37, 41 (2006) (“Rather than incur the risks of its ‘probabilistic’ patent rights, the pioneer manufacturer may opt to pay the generic manufacturer to refrain from the challenge and to stay out of the market.”); Maureen A. O’Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 MINN. L. REV. 1767, 1773–74 (2003).

<sup>7</sup> See 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST, § 7.4e (Supp. 2007) [hereinafter HOVENKAMP ET AL., IP AND ANTITRUST] (“Insofar as antitrust is concerned, among the most problematic settlement agreements are those in which the infringement plaintiff pays the infringement defendant for the latter’s abandonment of the market.”).

<sup>8</sup> See MICHAEL A. CARRIER, INNOVATION FOR THE 21ST CENTURY: HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST LAW 364 (Oxford Univ. Press 2009) (“[R]everse payment agreements are not typical settlements. They are agreements that dispose of the validity and infringement challenges central to the Hatch-Waxman scheme. Any general preference in the law for settlement was displaced by the Act’s specific framework.”).

<sup>9</sup> See *Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs: Hearing Before the Subcomm. on Courts and Competition Policy*, 111th Cong. 2 (2009) (statement of the Federal Trade Commission), available at [http://judiciary.house.gov/hearings/pdf/Feinstein\\_090603.pdf](http://judiciary.house.gov/hearings/pdf/Feinstein_090603.pdf) (stating “pay-for-delay” settlements are those in which “the brand-name drug firm pays its

controversial and have antitrust implications because, under this system, a potentially invalid patent can remain in effect and restrain competition.<sup>10</sup> Opponents argue such settlements impair consumer access to generic drugs, but this contention is likely to fail in court.<sup>11</sup> Courts generally allow the settlements if their anti-competitive effects are within the “exclusionary zone of the patent” provided by patent law.<sup>12</sup> Although the patent zone and antitrust zone are “complementary,” the line between the two zones is not always clear.<sup>13</sup>

This comment addresses the antitrust implications of “pay-for-delay” settlements. Part I describes three regulations relating to “pay-for-delay” settlements, the role of patent protection in the pharmaceutical industry, and the regulatory framework that promotes generic competition. Part I then introduces antitrust laws and pending bills aimed at preventing anti-competitive conduct. Part II describes the inconsistent standards applied in court to “pay-for-delay” settlements and explains the potential effects of the pending legislation on the pharmaceutical industry. Part III proposes changes to the pending legislation to apply a standard more suitable for “pay-for-delay” settlements, allowing for a more fact-specific but relatively quick analysis. This modified approach will effectively reduce anti-competitive settlements that block consumer access to generic products.

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potential generic competitor to abandon a patent challenge and delay entering the market with a lower cost, generic product”).

<sup>10</sup> See CARRIER, *supra* note 8, at 370 (taking the position that reverse-payment settlements should be presumptively illegal); see also 12 HERBERT HOVENKAMP, ANTITRUST LAW 307 (2d ed. 2005) (“[A]t least some settlement agreements raise significant antitrust issues and some would be illegal per se if created in the absence of a genuine intellectual property dispute.”). *But see In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008) (“[T]here is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation.”), *cert. denied*, 129 S. Ct. 2828 (2009); Marc G. Schildkraut, *Patent-splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1034 (2004) (“There are many circumstances where a reverse payment is necessary to resolve a patent litigation and that resolution is better for consumers than continued litigation.”).

<sup>11</sup> See, e.g., *Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F.3d 1056, 1076 (11th Cir. 2003).

<sup>12</sup> *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1341; see *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981) (“The patentee is entitled to exact the full value of his invention.”); see also Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Dispute*, 87 MINN. L. REV. 1719, 1762 (2003) (“[C]ourts ordinarily should not object to a delayed-entry settlement, because it is likely to be an estimate of the expected outcome by the parties with the best information about the outcome.”).

<sup>13</sup> See, e.g., *Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990) (“[T]he aims and objectives of patent and antitrust laws may seem . . . wholly at odds. However, the two bodies of law are actually complementary, as both are aimed at encouraging innovation, industry and competition”); see also SECTION OF ANTITRUST LAW, AM. BAR ASSOC., INTELLECTUAL PROPERTY AND ANTITRUST HANDBOOK 58 (2007) [hereinafter SECTION OF ANTITRUST LAW, INTELLECTUAL PROPERTY AND ANTITRUST HANDBOOK] (“[T]he Department of Justice and Federal Trade Commission formally recognized that the intellectual property and antitrust laws are complements.”).

## I. BACKGROUND

“Pay-for-delay” settlements relate to three regulations that affect the pharmaceutical business.<sup>14</sup> The regulations on patents and pharmaceutical products control essential parts of innovators’ businesses and require them to make large investments while developing products and obtaining patents.<sup>15</sup> Generic firms monitor the patents, develop their products, and try to invalidate the patents so they can enter the market.<sup>16</sup> Innovators then face a high risk of losing the product’s value through litigation and generic competition.<sup>17</sup> “Pay-for-delay” settlements occur in this unique context where companies try to recoup the investments and reduce the risk of losing to the competition.<sup>18</sup> This risk-avoiding practice, however, triggers scrutiny under the antitrust regulation that prohibits anti-competitive conduct.<sup>19</sup> Concerned with an adverse impact of the settlements on consumer access to affordable generics, Congress is now considering whether to amend the regulatory framework to prohibit this practice.<sup>20</sup>

### A. Regulatory Schemes Relating to “Pay-for-Delay” Settlements

The antitrust implications of “pay-for-delay” settlements involve three regulatory schemes—patent laws, food and drug laws, and antitrust laws.<sup>21</sup> Patent laws shape the patent landscape and define which territory in the market is exclusive to an innovator.<sup>22</sup> Food and drug laws, however, allow a generic firm to seek an approval for marketing its product in that territory by claiming invalidity and/or non-infringement of the patent.<sup>23</sup> Soon after the matter goes to a court, and the parties dispute the validity and the scope of the patent. Antitrust laws become involved when the parties settle the litigation to avoid the gamble of receiving unfavorable judgments such as patent invalidity.<sup>24</sup> The laws intended to promote

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<sup>14</sup> See MICHAEL E. CLARK & CAROL A. POINDEXTER, PHARMACEUTICAL LAW 626 (Michael E. Clark ed., Am. Bar Assoc. 2007).

<sup>15</sup> See *id.* at 625.

<sup>16</sup> See CARRIER, *supra* note 8, at 351–52; JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 14–16 (Bureau of Nat’l Affairs, Inc. 2005).

<sup>17</sup> See CLARK & POINDEXTER, *supra* note 14, at 625; *Over a Dozen Fight on US Lamotrigine*, GENERICS BULLETIN, Feb. 13, 2009, at 16 (describing intense competition among more than a dozen pharmaceutical companies).

<sup>18</sup> See O’Rourke & Brodley, *supra* note 6, at 1773–74 (“Without settlement, the alleged infringer risks entry of a permanent injunction restraining it from marketing its product . . . until the patent’s expiration, and a judgment ordering payment of damages in the amount of the patentee’s profits plus interest and costs.”).

<sup>19</sup> See CLARK & POINDEXTER, *supra* note 14, at 626.

<sup>20</sup> See *generally* Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009) (proposing legislation to assist generic drug makers enter the market); Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009) (same).

<sup>21</sup> See CLARK & POINDEXTER, *supra* note 14, at 626.

<sup>22</sup> See 35 U.S.C. §§ 1–376 (2006); THOMAS, *supra* note 16, at 5–6.

<sup>23</sup> See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006); THOMAS, *supra* note 16, at 14–16.

<sup>24</sup> See HOVENKAMP ET AL., IP AND ANTITRUST, *supra* note 7, § 7.4e1 (“[T]he problem of exclusion payments can arise whenever the patentee has an incentive to postpone determination of the validity of its patent.”); see also Alden F. Abbott & Suzanne T. Michel, *The Right Balance of*

competition may prohibit certain settlement agreements as anti-competitive.<sup>25</sup> These three regulatory schemes thus largely affect the business of both innovators and generic firms.<sup>26</sup> For the innovators, securing effective patents to achieve market exclusivity in desired territories is crucial.<sup>27</sup>

### *B. Pharmaceutical Investment in Patent Protection*

Innovators must make large upfront investments in research because only one of about four thousand new drugs receives approval to enter the market.<sup>28</sup> As a result, the innovator funds a broad range of patents to protect its products from competitors and to recover their research costs.<sup>29</sup> Patent protection is therefore essential for the pharmaceutical business and “necessary to encourage innovation” in this field.<sup>30</sup>

#### *1. Investment and the Patent Strategy of Innovators*

One study shows that the overall cost of developing a marketable drug is over \$800 million.<sup>31</sup> Even if the drug finally becomes marketable, it may not produce sufficient profits to recoup development costs due to competition from inexpensive generics.<sup>32</sup> To maximize patent protection, innovators try to obtain patents on various matters such as novel drug substances and drug delivery methods.<sup>33</sup> A common strategy is to obtain “good” and “strong” patents, casting a wide net to catch

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*Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 24–25 (2005) (“[T]he brand firm and its generic rival are always better off eliminating their expected competition and sharing the brand’s monopoly profits.”).

<sup>25</sup> See CLARK & POINDEXTER, *supra* note 14, at 626.

<sup>26</sup> See *id.*

<sup>27</sup> See *id.* at 625; CARRIER, *supra* note 8, at 346.

<sup>28</sup> CLARK & POINDEXTER, *supra* note 14, at 625; see also PETER BARTON HUTT ET AL., FOOD AND DRUG LAW 624 (3d ed. 2007) (“It is often estimated that, for every 5,000 chemicals screened, five will proceed to clinical testing and one will survive to approval of [a new drug application].”).

<sup>29</sup> See HUTT ET AL., *supra* note 28, at 764 (stating a short patent life “may not be long enough for a drug’s sponsor to recoup the full research and development investment made in the drug other than by charging extremely high prices”).

<sup>30</sup> THOMAS, *supra* note 16, at 4 (“Pharmaceuticals stand among one of the few fields where experts agree that patent protection is necessary to encourage innovation.”).

<sup>31</sup> See CLARK & POINDEXTER, *supra* note 14, at 625–26; see also CARRIER, *supra* note 8, at 300 (“Pharmaceutical companies devote approximately 75 percent of their R&D to product innovation.”).

<sup>32</sup> See William Shieber, *One View from the Road: State Antitrust Enforcement in Pharmaceutical Cases*, in ANTITRUST 74, 75 (Spring 2004) (“Branded pharmaceuticals generally lose over 80 percent of their market share within two years of the onset of generic competition.”); see also *Tough Times for Big Pharma*, MED AD NEWS, September 2008, at 4 (“With 2007 as its first full year battling generic competition, sales for Merck’s cholesterol drug Zocor fell to \$877 million, less than a third of sales generated in 2006.”).

<sup>33</sup> See THOMAS, *supra* note 16, ch. 2.III–IV (describing various types of pharmaceutical patent claims including drug substances, formulations, chemical intermediates, metabolites, prodrugs, crystals, polymorphs, isomers, salts, methods of using a drug for combination therapies, methods of making a pharmaceutical, and methods of medical treatment).

potential infringers and protecting its commercial products from competition.<sup>34</sup> To obtain such patents, innovators select promising inventions for submission to the United States Patent and Trademark Office (“USPTO”).<sup>35</sup>

## 2. Patent Prosecution and Validity of Patents

Patent prosecution starts with filing an application in the USPTO and, if successful, ends with the grant of a patent.<sup>36</sup> Examiners at the USPTO evaluate whether the claimed subject matter is novel and non-obvious with respect to prior art.<sup>37</sup> After issuance, a patent is presumed to be valid unless a court decides otherwise.<sup>38</sup> Despite the presumption of validity, generic makers have invalidated many patents in court, which has allowed generic products to enter the market.<sup>39</sup> Noting the possibility of invalidation, some argue that the patent holder is entitled to only a “right to try to exclude.”<sup>40</sup> Under this view of “probabilistic” patent rights, patentees have rights to assert their patents, but their exclusionary power is not fully vested.<sup>41</sup> Rather, the power depends on court decisions regarding the patent validity.<sup>42</sup> This view of “partial property rights” leads to the contention that the patentee is not entitled to buying exclusion under “pay-for-delay” settlements.<sup>43</sup>

### C. Marketing Generic Drugs and Hatch-Waxman Act

Generic drugs<sup>44</sup> are priced lower than brand-name drugs “because their manufacturers do not incur the research, development, and promotional costs

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<sup>34</sup> See MARTIN A. VOET, *THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA & PHARMACEUTICAL LIFE-CYCLE MANAGEMENT* 82 (2d ed. 2008) (describing “good” patents as broad patents and “strong” patents as narrow patents).

<sup>35</sup> See 35 U.S.C. § 111 (2006); VOET, *supra* note 34, at 82–85.

<sup>36</sup> See 35 U.S.C. § 151.

<sup>37</sup> See *id.* § 102(b) (“A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States.”); *id.* § 103(a) (“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious.”).

<sup>38</sup> *Id.* § 282; see 6 DONALD S. CHISUM, *CHISUM ON PATENTS* § 19.02 (2008) (addressing the question of whether the presumption of patent validity is “primarily a procedural device, merely shifting the burden of proof on issues of fact that are pertinent to a legal conclusion on validity, or a rule of deference to the determination of patentability by the [USPTO]”).

<sup>39</sup> See CARRIER, *supra* note 8, at 346.

<sup>40</sup> See Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 *RAND. J. ECON.* 391, 395 (2003).

<sup>41</sup> *Id.* at 395; see *Petition for a Writ of Certiorari at 16, Fed. Trade Comm’n v. Schering-Plough Corp.* No. 05-273, 2005 WL 2105243 (U.S. Aug. 29, 2005).

<sup>42</sup> See Shapiro, *supra* note 40, at 395.

<sup>43</sup> See *id.* at 407–08.

<sup>44</sup> THOMAS, *supra* note 16, at 307, 310 (stating the term generic drug refers to drugs that contain “the same active ingredients as but not necessarily the same inactive ingredients as a ‘pioneer drug’ that is sold under a brand name” or those that contain a different active ingredient but are expected to have the same therapeutic effect).

normally associated with the creation and marketing of an original product.”<sup>45</sup> To facilitate consumer access to inexpensive generic drugs, Congress enacted the Drug Price Competition and Patent Term Restoration Act (“Hatch-Waxman Act”)<sup>46</sup> to amend the Federal Food, Drug, and Cosmetic Act (“FD&C Act”)<sup>47</sup> in 1984.<sup>48</sup>

The Hatch–Waxman Act provides “expedited marketing approval pathways” for generic firms that file an abbreviated new drug application (“ANDA”) with the FDA.<sup>49</sup> Consumers usually benefit from inexpensive alternatives and resulting competition that drives down the drug prices.<sup>50</sup> The Act also provides generic exclusivity for one hundred and eighty days, during which time the first ANDA filer can exclude other generic entrants.<sup>51</sup> This generic exclusivity is a reward for challenging the patent and opening the door for more generics.<sup>52</sup>

#### *D. Litigation and “Pay-for-Delay” Settlements*

In patent litigation, parties contest the scope of the patent claims in *Markman* hearings and discuss validity and infringement contentions at later stages.<sup>53</sup> One way generic firms can challenge validity is by presenting a previously published reference that discloses the patented invention.<sup>54</sup>

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<sup>45</sup> United States v. Generix Drug Corp., 460 U.S. 453, 455 n.1 (1983); *see also* CLARK & POINDEXTER, *supra* note 14, at 625–26 (stating the cost for bringing a generic drug to the market is about \$1 to \$2 million as compared to \$800 million for an innovator).

<sup>46</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §§ 355, 360c (2006); 35 U.S.C. §§ 156, 271, 282 (2006)).

<sup>47</sup> 21 U.S.C. §§ 301–399a (2006).

<sup>48</sup> *See* THOMAS, *supra* note 16, at 14 (stating consumers could not fully benefit from the lower cost before Congress passed the Hatch-Waxman Act because “the approval of a generic drug was a needlessly costly, duplicative, and time-consuming process”); *see also* CARRIER, *supra* note 8, at 355 (“On the whole, the Hatch-Waxman Act has been successful in increasing generic entry. Generic drugs, which made up 19 percent of prescriptions for drug products in 1984, increased to 65 percent in 2008.”).

<sup>49</sup> *See* THOMAS, *supra* note 16, at 14–19 (describing procedures for obtaining a generic marketing approval and requirements for filing an ANDA); *see also* CLARK & POINDEXTER, *supra* note 14, at 625–26 (stating it takes 10-15 years for an innovator to develop a marketable product, whereas a generic firm can bring its product into the market “in a fraction of the time”).

<sup>50</sup> *See* HUTT ET AL., *supra* note 28, at 766 (“[G]eneric manufacturers typically undercut the price of the pioneer drug by only about 5 percent during their exclusive marketing period, but then are forced to reduce the price by 50 percent or more as other generic manufacturers receive approvals of their [ANDAs].”); *see also* Abbott & Michel, *supra* note 24, at 27 (“Consumers are always better off with the possibility of competitive entry and lower prices than they are with the certainty of no entry.”). *But see* CLARK & POINDEXTER, *supra* note 14, at 627 (suggesting a possibility that drastically lowering price may “drive out competitors and eventually injure consumers”).

<sup>51</sup> 21 U.S.C. § 355(j)(5)(B)(iv); *see* THOMAS, *supra* note 16, at 24–25.

<sup>52</sup> THOMAS, *supra* note 16, at 18–19.

<sup>53</sup> *See* 35 U.S.C. §§ 102–103, 271 (2006); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (stating an infringement analysis includes the first step of determining the meaning and scope of a claim and the second step of comparing the construed claim with an accused product), *aff’d*, 517 U.S. 370 (1996).

<sup>54</sup> 35 U.S.C. §§ 102–103; *see, e.g.*, *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007).

During the course of litigation, the parties must decide whether to maintain litigation while considering other various legal and business matters.<sup>55</sup> The deciding factors are often the strength of the patent, prospective value of the patent, and the impact of litigation results on competition with other generics.<sup>56</sup> When parties fear intense competition with others, they usually settle and agree on a fixed generic entry date in exchange for certain compensation.<sup>57</sup> If the settlement harms competition, however, potential antitrust implications may arise.<sup>58</sup>

### *E. Antitrust Laws and Regulations*

Federal statutes provide a basis for the current enforcement of antitrust laws in “pay-for-delay” settlements.<sup>59</sup> In the long history of judicial interpretation and application of the statutes, courts developed three analytical standards for evaluating antitrust claims: 1) the rule of reason; 2) the *per se* rule; and 3) the quick look standard.<sup>60</sup> Currently, antitrust tribunals facing “pay-for-delay” settlements disagree on which standard to apply. A pending House bill, however, promotes a *per se* illegal treatment of “pay-for-delay” settlements.<sup>61</sup>

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<sup>55</sup> See SECTION OF ANTITRUST LAW, INTELLECTUAL PROPERTY AND ANTITRUST HANDBOOK, *supra* note 13, at 247 (stating settlements may produce “greater market power and more exclusion than would result if the parties had continued to litigate”); see also CARRIER, *supra* note 8, at 364 (“Settlements are particularly beneficial for patent litigation, which is lengthy, complex, and costly.”).

<sup>56</sup> See HOVENKAMP ET AL., IP AND ANTITRUST, *supra* note 7, § 7.4e2 (“Undoubtedly, what had increased their attraction under [the Hatch-Waxman Act] is the fact . . . that a properly defined settlement-plus-exclusion-payment not only keeps the immediate infringement defendant out of the market for a time but also keeps other generic firms from entering as well.”).

<sup>57</sup> See Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1308 (11th Cir. 2003) (“Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.”); see also Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1079 (2004) (“[I]n the context of Hatch-Waxman even a patent owner with a high probability of success on the merits may have a tremendous incentive to settle the case with a reverse payment.”).

<sup>58</sup> See CARRIER, *supra* note 8, at 363.

<sup>59</sup> Sherman Act, ch. 647, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C. §§ 1–7 (2006)); Clayton Act, Pub. L. No. 63-212, 38 Stat. 730 (1914) (codified as amended at 15 U.S.C. §§ 12–27); Federal Trade Commission Act, Pub. L. No. 63-203, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C. §§ 41–58); see CLARK & POINDEXTER, *supra* note 14, at 632–44 (describing federal antitrust laws and antitrust litigation involving pharmaceutical business entities).

<sup>60</sup> See CLARK & POINDEXTER, *supra* note 14, at 630–31 (“Courts and regulators have struggled over the years to develop appropriate standards for evaluating conduct claimed to unfairly restrict competition.”).

<sup>61</sup> See Ken Letzler & Sonia Pfaffenroth, *Patent Settlement Legislation: Good Medicine or Wrong Prescription?* in ANTITRUST 81, 83 (“[S]upporters would argue that this is a routine application of the *per se* rule to an agreement not to compete.”).

### 1. Existing Federal Antitrust Laws and Enforcement

To address antitrust violations, Congress passed the Sherman Act in 1890,<sup>62</sup> and in 1914 passed the Clayton Act<sup>63</sup> and the Federal Trade Commission Act (“FTC Act”).<sup>64</sup> The Sherman Act prohibits contracts “in restraint of trade or commerce among the several States.”<sup>65</sup> The Clayton Act prohibits certain acquisitions as well.<sup>66</sup> The FTC Act created the Federal Trade Commission (“FTC”) and empowered it to stop, at an early stage, certain practices that are likely to violate the Sherman and Clayton Acts.<sup>67</sup>

Various entities can initiate litigation to enforce the antitrust laws.<sup>68</sup> The FTC and the Antitrust Division of the Department of Justice (“DOJ”) can bring a civil lawsuit.<sup>69</sup> Consumers can sue business entities under the Clayton Act.<sup>70</sup> Furthermore, pursuant to the FTC Act, the FTC may file an administrative complaint against antitrust violators.<sup>71</sup> After proceedings before an administrative law judge and then the full commission, a party may appeal the decision to a court of appeals.<sup>72</sup> In analyzing antitrust claims, courts apply different standards depending on the nature of activity at issue.<sup>73</sup>

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<sup>62</sup> Sherman Act, ch. 647, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C. §§ 1–7).

<sup>63</sup> Clayton Act, Pub. L. No. 63-212, 38 Stat. 730 (1914) (codified as amended at 15 U.S.C. §§ 12–27).

<sup>64</sup> Federal Trade Commission Act, Pub. L. No. 63-203, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C. §§ 41–58).

<sup>65</sup> 15 U.S.C. § 1 (“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States . . . is declared to be illegal.”).

<sup>66</sup> *Id.* § 18 (prohibiting acquisitions whose effects “may be substantially to lessen competition, or to tend to create a monopoly”).

<sup>67</sup> *See* Fed. Trade Comm’n v. Brown Shoe Co., 384 U.S. 316, 322 (1966) (“[The Commission can] arrest trade restraints in their incipency without proof that they amount to an outright violation of § 3 of the Clayton Act or other provisions of the antitrust laws.”); Fed. Trade Comm’n v. Motion Picture Adver. Serv. Co., 344 U.S. 392, 394–95 (1953).

<sup>68</sup> 15 U.S.C. § 15(a) (“Whenever the United States is hereafter injured in its business or property by reason of anything forbidden in the antitrust laws it may sue therefor in the United States district court for the district in which the defendant resides or is found or has an agent . . .”).

<sup>69</sup> *Id.*; *see* SECTION OF ANTITRUST LAW, INTELLECTUAL PROPERTY AND ANTITRUST HANDBOOK, *supra* note 13, at 54–56 (stating the FTC and the DOJ employ similar procedures for civil investigations).

<sup>70</sup> 15 U.S.C. § 15 (“[A]ny person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States . . .”); *see* CLARK & POINDEXTER, *supra* note 14, at 663 (“In evaluating whether a plaintiff has standing to pursue relief under the Clayton Act, courts will also examine the type of allegations made to determine whether a given plaintiff will be an ‘efficient enforcer’ to seek redress for such misconduct.”).

<sup>71</sup> 15 U.S.C. § 45(b).

<sup>72</sup> *Id.* § 45(c) (“Any person, partnership, or corporation required by an order of the Commission to cease and desist from using any method of competition or act or practice may obtain a review of such order in the [circuit] court of appeals of the United States . . .”).

<sup>73</sup> *See* CLARK & POINDEXTER, *supra* note 14, at 644.

## 2. Standards for Antitrust Analysis

Courts have developed three analytical standards: 1) the rule of reason; 2) the *per se* rule; and 3) the quick look standard.<sup>74</sup> These standards call for a different degree of inquiry in examining antitrust violation.<sup>75</sup>

The rule of reason is the default standard courts have applied to most antitrust claims for evaluating whether an “unreasonable restraint” of competition occurs.<sup>76</sup> It involves a detailed three-step analysis<sup>77</sup> starting with the requirement for the plaintiff to prove an “*actual* adverse effect on competition as a whole in the relevant market.”<sup>78</sup> If the proof is acceptable, then the defendant must demonstrate pro-competitive effects.<sup>79</sup> When the defendant meets the burden, the plaintiff must present “less restrictive” alternatives.<sup>80</sup> The first step of this analysis is essential and requires determination of whether the “harm is not only possible but likely and significant.”<sup>81</sup> The analysis, however, tends to be complex because it requires detailed economic analyses to define elements such as the relevant market.<sup>82</sup>

As an exception to the rule of reason, courts developed the *per se* approach for a special class of activities.<sup>83</sup> After evaluating various claims, courts started seeing common practices that had only a “predictable and pernicious anticompetitive effect.”<sup>84</sup> Courts deemed such practices *per se* illegal “without elaborate inquiry as to the precise harm.”<sup>85</sup> According to the Supreme Court, the *per se* illegality is proper

<sup>74</sup> *Id.* at 630–31.

<sup>75</sup> *See id.* at 644–53.

<sup>76</sup> *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997) (“Although the Sherman Act, by its terms, prohibits every agreement ‘in restraint of trade,’ this Court has long recognized that Congress intended to outlaw only unreasonable restraints.”); *see* CLARK & POINDEXTER, *supra* note 14, at 646.

<sup>77</sup> *K.M.B. Warehouse Distributions, Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 127 (2d Cir. 1995) (“Establishing a violation of the rule of reason involves three steps.”); *Capital Imaging Ass’n, P.C., Mohawk Valley Med. Ass’n*, 996 F.2d 537, 543 (2d Cir. 1993).

<sup>78</sup> *K.M.B. Warehouse*, 61 F.3d at 127.

<sup>79</sup> *Id.*; *Capital Imaging*, 996 F.2d at 543.

<sup>80</sup> *K.M.B. Warehouse*, 61 F.3d at 127; *Capital Imaging*, 996 F.2d at 543.

<sup>81</sup> 7 PHILIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW*, 347–48 (2002); *see* *Cal. Dental Ass’n v. Fed. Trade Comm’n*, 526 U.S. 756, 775 n.12 (1999) (“[T]here must be some indication that the court making the decision has properly identified the theoretical basis for the anticompetitive effects and considered whether the effects actually are anticompetitive.”).

<sup>82</sup> *See, e.g., Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) (illustrating an instance where a district court and the second Circuit disagree on how the relevant market should be defined in a pharmaceutical antitrust litigation); *see also* CLARK & POINDEXTER, *supra* note 14, at 647 (“If the rule of reason standard is used, the relevant market for the products and geographic area must be determined as a preliminary step to assessing whether the defendant had sufficient market power to harm competition.”).

<sup>83</sup> *See* AREEDA & HOVENKAMP, *supra* note 81, at 396 (“[A] *per se* rule is merely a special case of the rule of reason.”).

<sup>84</sup> *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997); *see* *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958) (“[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal.”).

<sup>85</sup> *N. Pac. Ry.*, 356 U.S. at 5; *see* CLARK & POINDEXTER, *supra* note 14, at 644 (“The Supreme Court . . . has observed that certain types of behavior are simply so unlikely to have any competitive justifications that such conduct should be conclusively adjudged illegal without any need to consider proffered justifications.”); *see also* AREEDA & HOVENKAMP, *supra* note 81, at 404 (“The root meaning

“[o]nce experience with a particular type of restraint enables the Court to predict with confidence that the rule of reason will condemn it.”<sup>86</sup> Thus, a court should not employ the *per se* standard when “the economic impact is not immediately obvious.”<sup>87</sup>

Between the rule of reason and the *per se* rule lies the quick look standard, or “truncated rule of reason.”<sup>88</sup> It allows a court to conduct less than the full analysis and assume the rest of the factors.<sup>89</sup> The quick look is proper when challenged acts “are not *per se* unlawful but are sufficiently anticompetitive on their face that they do not require a full-blown rule of reason inquiry.”<sup>90</sup> The analysis takes much less time than the rule of reason and yet allows some flexibility for tailoring to particular circumstances.<sup>91</sup> An analyst suggests that the quick look standard, rather than the broad *per se* illegality standard, is suitable for the antitrust analysis of “pay-for-delay” settlements.<sup>92</sup>

### 3. Antitrust Analysis of “Pay-for-Delay” Settlements

In analyzing “pay-for-delay” settlements, the FTC and the courts apply different standards.<sup>93</sup> The Courts of Appeals for the Sixth (“Sixth Circuit”) and Second (“Second Circuit”) Circuits employ the *per se* rule,<sup>94</sup> the FTC and the Court of Appeals for the Federal Circuit (“Federal Circuit”) support the rule of reason,<sup>95</sup> and

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of ‘per se illegality’ is that courts refuse to consider one or more factors that would ordinarily bear on the reasonableness of challenged conduct.”).

<sup>86</sup> *Ariz. v. Maricopa County Med. Soc’y*, 457 U.S. 332, 344 (1982); see *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332 (Fed. Cir. 2008) (agreeing with the finding of the district court that there was no basis to “confidently predict” that the agreement would be unlawful under the rule of reason analysis) *cert. denied*, 129 S. Ct. 2828 (2009).

<sup>87</sup> *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1332.

<sup>88</sup> See CLARK & POINDEXTER, *supra* note 14, at 651–53.

<sup>89</sup> See AREEDA & HOVENKAMP, *supra* note 81, at 393 (“[J]udgments can sometimes be made on the basis of the parties’ agreements in light of what the judges know about the economy and in light of such modest information as may be available at the beginning of the lawsuit.”).

<sup>90</sup> *Cal. Dental Ass’n*, 526 U.S. at 763 (quoting *Cal. Dental Ass’n v. Fed. Trade Comm’n*, 128 F.3d 720, 727 (9th Cir. 1999)).

<sup>91</sup> See AREEDA & HOVENKAMP, *supra* note 81, at 390–95 (stating courts can apply the rule of reason summarily or, if appropriate, conduct “instantaneous balancing in the twinkle of an eye”); Thomas C. Arthur, *A Workable Rule of Reason: A Less Ambitious Antitrust Role for the Federal Courts*, in 68 ANTITRUST L.J. 337, 359–62 (2001) (describing a “sliding scale approach that tailors the inquiry to the particular circumstances”).

<sup>92</sup> See HOVENKAMP, *supra* note 10, at 329 (“[E]xit payments represent a significant threat to competition, making a full rule of reason inquiry unnecessary.”). “A blanket *per se* rule prohibiting all payments to infringement defendants in exchange for promises to stay out of the patentee’s market seems too broad.” *Id.* at 328.

<sup>93</sup> See CARRIER, *supra* note 8, at 357–64 (summarizing several key pharmaceutical antitrust cases and addressing different standards that courts applied in the antitrust analysis); see also 2 SECTION OF ANTITRUST LAW, AM. BAR ASSOC., ANTITRUST LAW DEVELOPMENTS 1434–35 (2007) [hereinafter SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS] (describing the disagreement between the Sixth Circuit and the Eleventh Circuit regarding the antitrust analysis in view of the patent right).

<sup>94</sup> *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 915 (6th Cir. 2003); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2005).

<sup>95</sup> *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009); *Schering-Plough Corp.*, 136 F.T.C. 956, 1208 (2003).

the Court of Appeals for the Eleventh Circuit (“Eleventh Circuit”) takes a quick look.<sup>96</sup>

The Sixth Circuit held that “pay-for-delay” settlements were *per se* illegal in *In re Cardizem CD Antitrust Litigation*.<sup>97</sup> Some commentators support this position because, in their view, “the reduction in uncertain competition itself is sufficient to demonstrate an anticompetitive effect.”<sup>98</sup> In contrast, the Second Circuit took the opposite view and held a “pay-for-delay” settlement as *per se* legal.<sup>99</sup> The court feared that extensive restriction of settlement practice might adversely affect innovation.<sup>100</sup>

The FTC employed the rule of reason in evaluating “pay-for-delay” settlements between Schering-Plough and other drug makers.<sup>101</sup> On appeal, the Eleventh Circuit allowed the settlements but rejected both the rule of reason and the *per se* rule.<sup>102</sup> The court noted the unique environment of “cripple competition” created by the patent exclusion and came up with a three-part test that appeared to be a quick look approach.<sup>103</sup> The test examined “(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.”<sup>104</sup>

The Federal Circuit supported the rule of reason and allowed a “pay-for-delay” agreement in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.<sup>105</sup> The court indicated that the district court properly employed a full rule of reason analysis, although it ended at the first step due to insufficient proof from the plaintiff.<sup>106</sup> Consumers and advocacy groups argued the anti-competitive effects of the agreement, but the court viewed that they were “within the exclusionary zone of the patent.”<sup>107</sup> The Supreme Court declined to review the decision.<sup>108</sup>

The DOJ also endorses the rule of reason, according to its brief filed in a case currently pending in the Second Circuit.<sup>109</sup> It specifically rejected *per se* condemnation of patent settlements under the Sherman Act, noting that the “likelihood of anticompetitive effects not attributable solely to the patent is not so

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<sup>96</sup> See *Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F.3d 1056, 1066 (11th Cir. 2003).

<sup>97</sup> 332 F.3d 896, 915 (6th Cir. 2003).

<sup>98</sup> *Abbott & Michel*, *supra* note 24, at 27.

<sup>99</sup> See *In re Tamoxifen.*, 466 F.3d 187, 208 (2d Cir. 2005) (“[S]o long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly.”).

<sup>100</sup> *Id.* at 203 (“Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.”).

<sup>101</sup> *Schering-Plough Corp.*, 136 F.T.C. 956, 1208 (2003).

<sup>102</sup> *Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F.3d 1056, 1065 (11th Cir. 2003).

<sup>103</sup> *Id.* at 1066.

<sup>104</sup> *Id.*

<sup>105</sup> 544 F.3d 1323, 1330, 1341 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009).

<sup>106</sup> *Id.* at 1332.

<sup>107</sup> *Id.* at 1341.

<sup>108</sup> *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009).

<sup>109</sup> Brief for the United States in Response to the Court’s Invitation, at 20–21, *Arkansas Carpenters Health and Welfare Fund v. Bayer, AG*, No. 05-2851-cv (2009) [hereinafter *DOJ Brief*], available at <http://www.usdoj.gov/atr/cases/f247700/247708.pdf>.

great” as to justify a *per se* treatment.<sup>110</sup> Instead, the DOJ argued “pay-for-delay” settlements are presumptively unlawful, and antitrust defendants must offer evidence to show that the patentee did not purchase reduced competition.<sup>111</sup> The DOJ seems to focus on prohibiting a large payment because it explains that the defendants “clearly rebut the presumption” just by making the payment less than the avoided litigation costs of the patentee.<sup>112</sup> If the payment is greater, simply pointing out the benefits from an early generic entry is not sufficient to overcome the presumption.<sup>113</sup> The antitrust defendants must show that the terms of agreement “reasonably reflected their contemporaneous evaluations of likelihood that a judgment in the patent litigation would have resulted in generic competition before patent expiration.”<sup>114</sup>

Although the recent position of the DOJ for limiting “pay-for-delay” settlements generally accords with the approach of the FTC, the DOJ previously disagreed with the FTC when the FTC sought a Supreme Court review in *Schering-Plough*.<sup>115</sup> The DOJ argued that the Supreme Court should deny the petition for a writ of certiorari because the case did not “present an appropriate opportunity . . . to determine the proper standards for distinguishing legitimate patent settlements . . . from illegitimate settlements.”<sup>116</sup> The Supreme Court declined to hear the appeal from the Eleventh Circuit.<sup>117</sup> Thus, opponents of the “pay-for-delay” practice stress the need for a legislative action.

#### 4. Pending Legislation Addressing “Pay-for-Delay” Settlements

Two bills that specifically address “pay-for-delay” settlements are pending in the current Congress. Senator Herb Kohl (D-WI) introduced one bill (“S. 369”) in February 2009,<sup>118</sup> and Representatives Bobby Rush (D-IL) and Henry Waxman (D-CA) introduced the other (“H.R. 1706”) in March 2009.<sup>119</sup> After an amendment, H.R. 1706 became part of a health care reform bill H.R. 3200.<sup>120</sup> The House then passed a revised health care reform bill (“H.R. 3962”) on November 7, 2009, including Section 2573 limiting “pay-for-delay” settlements.<sup>121</sup>

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<sup>110</sup> *Id.* at 20–21. *But see* Brief for the United States as Amicus Curiae, at 11, Fed. Trade Comm’n v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273) (“[T]he mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful.”).

<sup>111</sup> *DOJ Brief*, *supra* note 109, at 21, 27.

<sup>112</sup> *Id.* at 28.

<sup>113</sup> *Id.* at 29–32.

<sup>114</sup> *Id.* at 30–31. *But see* Brief for the United States as Amicus Curiae, *supra* note 110, at 12 (criticizing the FTC that it apparently placed “undue weight on the parties’ subjective views of the strength of the claims as reflected in the settlement agreement, as opposed to a more objective assessment of the claims based on evidence extrinsic to the settlement”).

<sup>115</sup> Brief for the United States as Amicus Curiae, *supra* note 110, at 8.

<sup>116</sup> *Id.*

<sup>117</sup> Fed. Trade Comm’n v. Schering-Plough Corp., 548 U.S. 919 (2006).

<sup>118</sup> Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009).

<sup>119</sup> Protecting Consumer Access to Generic Drugs Act, H.R. 1706, 111th Cong. (2009).

<sup>120</sup> See America’s Affordable Health Choice Act of 2009, H.R. 3200, 111th Cong. § 2563 (2009).

<sup>121</sup> See Affordable Health Care for America Act, H.R. 3962, 111th Cong. § 2573(b) (2009); 155 CONG. REC. H12968 (2009). Section 2573 of H.R. 3962 remains essentially the same as H.R. 1706.

H.R. 3962 prohibits settlements where “an ANDA filer receives anything of value” more than the right to enter the market before the exclusivity period of the patentee expires.<sup>122</sup> As such, a settlement agreement would violate the FTC Act if it grants a generic entry before the patent expiration and additionally allows some payment from the patentee to the accused infringer.<sup>123</sup> The bill, however, does have a section providing an exception to this blanket prohibition of “pay-for-delay” settlements.<sup>124</sup> It allows the FTC to promulgate rules and exempt certain agreements if the Commission finds that they are “in furtherance of market competition and for the benefit of consumers.”<sup>125</sup>

S. 369 was originally similar to H.R. 1706 and proposed to ban settlements where “an ANDA filer receives anything of value” more than the right to enter the market before the patent expiration.<sup>126</sup> The bill then underwent a substantive amendment to permit some “pay-for-delay” settlements.<sup>127</sup> The amended S. 369 treats “pay-for-delay” settlements as presumptively unlawful, except when the settlement parties can show pro-competitive benefits outweighing anti-competitive effects by clear and convincing evidence.<sup>128</sup> To overcome the presumption of illegality, parties of a proposed agreement may present evidence to support pro-competitive effects of the agreement.<sup>129</sup> In examining whether the parties have met the burden of proof, the fact finder may consider seven factors listed in the bill.<sup>130</sup> The factors include the timing of an agreement with respect to the remaining patent life<sup>131</sup> and terms of the agreement such as the amount of payment.<sup>132</sup> The fact finder may also consider the expected economic gain and loss by generic and brand-name firms after the resolution of the dispute.<sup>133</sup>

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*See* Protecting Consumer Access to Generics Drugs Act, H.R. 1706, 111th Cong. (2009); Affordable Health Care for America Act, H.R. 3962, 111th Cong. § 2573 (2009).

<sup>122</sup> *See* Affordable Health Care for America Act, H.R. 3962, 111th Cong. § 2573(b) (2009).

<sup>123</sup> *See id.*

<sup>124</sup> *See id.*

<sup>125</sup> *Id.*

<sup>126</sup> *See* Preserve Access to Affordable Generics Act, S. 369, 111th Cong. § 29(a)(1) (2009).

<sup>127</sup> *See id.* § 28(a)(2)(A)–(B). *See* 155 CONG. REC. D1181 (daily ed. Oct. 15, 2009).

<sup>128</sup> *See* Preserve Access to Affordable Generics Act, S. 369, 111th Cong. § 28(a)(2)(A)–(B) (2009).

<sup>129</sup> *Id.* § 28(b).

<sup>130</sup> *Id.*

(1) the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product; (2) the value to consumers of the competition from the ANDA product allowed under the agreement; (3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim; (4) the revenue the ANDA filer would have received by winning the patent litigation; (5) the reduction in the NDA holder’s revenues if it had lost the patent litigation; (6) the time period between the date of the agreement conveying value to the ANDA filer and the date of the settlement of the patent infringement claim; and (7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.

*Id.*

<sup>131</sup> *Id.* § 28(b)(1).

<sup>132</sup> *Id.* § 28(b)(3).

<sup>133</sup> *Id.* § 28(b)(4)–(5).

Congress has made some progress in the House and the Senate to limit “sweetheart deals” between pharmaceutical litigants.<sup>134</sup> It is, however, uncertain whether Congress will pass a law drawing a fine line between the patent zone and the antitrust zone.<sup>135</sup>

## II. ANALYSIS

A recurring problem in the antitrust analysis of “pay-for-delay” settlements is that the FTC and court decisions are inconsistent, primarily because of the application of conflicting standards.<sup>136</sup> To illustrate the problem, an analysis of these standards and their applicability to “pay-for-delay” settlements is presented below. The analysis examines the merits and demerits of employing each of the standards based on two hypothetical examples involving “pay-for-delay” settlements. The comparison reveals that the quick look analysis is more suitable for the problem at hand compared to the impractical rule of reason and the oversimplified *per se* rule.<sup>137</sup> Pending House bill H.R. 3962 that takes the *per se* approach, the amended S. 369 that imposes a presumption, and the DOJ approach that employs the rule of reason are then analyzed to evaluate their potential effects on the pharmaceutical industry.

### A. Evaluation of Antitrust Analysis Under Each of Three Standards

The FTC and the courts have analyzed “pay-for-delay” settlements under the rule of reason, the *per se* rule, and the quick look standard.<sup>138</sup> The following hypothetical examples show that the quick look standard appears to be the most

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<sup>134</sup> Statement of FTC Chairman, Jon Leibowitz, Senate Judiciary Committee’s Passage of the Preserve Access to Affordable Generics Act (S. 369), Oct. 15, 2009, <http://www.ftc.gov/opa/2009/10/pfdvote.shtm>.

<sup>135</sup> See *Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs: Hearing Before the Subcomm. on Courts and Competition Policy, 111th Cong. 19 (2009)* (statement of the Federal Trade Commission), available at [http://judiciary.house.gov/hearings/pdf/Feinstein\\_090603.pdf](http://judiciary.house.gov/hearings/pdf/Feinstein_090603.pdf) (“H.R. 1706 offers a straightforward means to quickly combat anticompetitive conduct that is pervasive and costly to consumers, while also providing flexibility to protect procompetitive arrangements.”). But see *Pay to Delay: Are Patent Settlements That Delay Generic Drug Market Entry Anticompetitive?: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. On the Judiciary, 111th Cong. 6 (2009)* (statement of Guy Donatiello, Endo Pharmaceuticals Inc.), available at <http://judiciary.house.gov/hearings/pdf/Donatiello090603.pdf> (“H.R. 1706 would add cost and uncertainty to bringing new branded and generic medicines to patients. Instead of an across-the-board ban, enforcement agencies and courts should continue to evaluate patent settlements on a case-by-case basis. . .”).

<sup>136</sup> See CLARK & POINDEXTER, *supra* note 14, at 644–53 (providing summaries of pharmaceutical antitrust cases to illustrate the application of different standards in the antitrust analysis); Ronald W. Davis, *Reverse Payment Patent Settlements: A View into the Abyss, and a Modest Approach*, in ANTITRUST 26 (Fall 2006).

<sup>137</sup> See HOVENKAMP, *supra* note 10, at 328 (“A blanket *per se* rule . . . seems too broad.”); CLARK & POINDEXTER, *supra* note 14, at 651 (stating the quick look standard is “particularly helpful” for examining conduct that is not *per se* illegal but has anti-competitive effects).

<sup>138</sup> See CLARK & POINDEXTER, *supra* note 14, at 644–53.

suitable because it allows quick balancing of some particularly relevant factors and accurately predicts the effects of “pay-for-delay” settlements.

### *1. Hypothetical “Pay-for-Delay” Settlements*

Two hypothetical settlements between the innovator and the first ANDA generic firm are presented below. The first scenario illustrates a more pro-competitive settlement, and the second scenario illustrates a more anti-competitive settlement.

In the first scenario, the parties settle two years before the patent expiration date. The agreement involves a payment of expected litigation costs to the generic firm and allows for market entry six months before the patent expiration. Additionally, the patent claims a novel drug substance, and four subsequent ANDA filers are eagerly waiting to start marketing their products. The patentee believes it will prevail in the litigation, but does not wish to risk patent invalidation because it would allow the entry of multiple generic alternatives.

In the second scenario, the settlement involves a payment substantially exceeding expected litigation costs but does not allow the generic entry until the patent expires. The patent claims a product with a new drug delivery mechanism that is a relatively simple modification of an existing mechanism. The generic firm believes it will prevail in the litigation, but it wishes to obtain an upfront payment for funding other projects. Below, these hypothetical settlements are evaluated under each of the three standards.

#### *a. Analysis Under the Quick Look Standard*

The quick look analysis will properly predict the effects of both hypothetical settlements. Consideration of at least two factors, the patent subject matter and the generic entry date, readily reveals the pro-competitive and anti-competitive nature of the first and second agreements, respectively.

In the first scenario, the patent claims a novel chemical substance. Such patents often survive invalidity challenges because it is usually hard to prove the obviousness of new chemical substances with pharmaceutical benefits.<sup>139</sup> The generic firm therefore has a lower expected chance of invalidating the patent. Also, the settlement provides generic entry six months early, which enhances competition and benefits the consumer. The generic firm secures a fixed entry date and thus does not need to continue expensive litigation. While enjoying the one hundred and eighty-day generic exclusivity under the Hatch-Waxman Act, the firm can develop and establish the generic market.<sup>140</sup> Once the patent expires, the four generics can immediately join the market, and inexpensive generics can easily reach the

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<sup>139</sup> See, e.g., *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1364 (Fed. Cir. 2007) (holding a patent claim on a new chemical compound non-obvious under 35 U.S.C. § 103(a) (2006)).

<sup>140</sup> See 21 U.S.C. § 355(j)(5)(B)(iv) (2006) (providing 180 day-exclusivity).

consumer.<sup>141</sup> This quick look analysis shows likely pro-competitive benefits of the settlement without extensive evaluation.

In the second scenario, the generic firm has a higher chance of invalidating the patent due to the apparent obviousness of the claimed subject matter.<sup>142</sup> The agreement allows the market entry of the first ANDA filer on the patent expiration date, but not other generics due to the one hundred and eighty-day exclusivity period that starts when the first filer begins marketing.<sup>143</sup> It significantly delays the entry of subsequent filers, and thus an antitrust tribunal may quickly determine that the defendants do not show a threshold level of pro-consumer effects. The expenditure of time and resources for the quick look analysis will be substantially lower than that for the detailed rule of reason analysis.<sup>144</sup>

### *b. Analysis Under the Rule of Reason*

The rule of reason is the extended version of the quick look analysis discussed above, and it will eventually lead to accurate predictions.<sup>145</sup> It is consistent with the traditional evaluation of general antitrust claims, and offers an accurate analysis in line with extensive case law.<sup>146</sup>

Under this approach, however, there are numerous complex and important elements to examine.<sup>147</sup> For example, the antitrust tribunal must first define the relevant market in each scenario. It is, however, unclear whether the market should include the brand-name and generic products as well as other drugs used for the same medical condition.<sup>148</sup> Also, the evaluation of many factors in addition to those considered in the quick look may lead to inconsistent analyses because the factors can be weighed against each other in quite different manners.<sup>149</sup> For example, the

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<sup>141</sup> See *Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. on Courts and Competition Policy*, 111th Cong. 6 (2009) (statement of William P. (Bill) Kennedy, Co-Owner of Nephron Pharmaceuticals Corp.), available at <http://judiciary.house.gov/hearings/pdf/Kennedy090603.pdf> (“[W]ith a third or fourth competitor in the market, the generic drug pricing model takes over, allowing for pricing to reach truly ‘pro-consumer’ levels.”).

<sup>142</sup> 35 U.S.C. § 103(a); see, e.g., *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415–16 (2007).

<sup>143</sup> 21 U.S.C. § 355(j)(5)(B)(iv).

<sup>144</sup> See *AREEDA & HOVENKAMP*, *supra* note 81, at 391–93 (suggesting a court taking a rule of reason approach in a quick look form does not need to require a full trial and could summarily hold a challenged activity as “facially unreasonable”).

<sup>145</sup> See *CLARK & POINDEXTER*, *supra* note 14, at 646–53.

<sup>146</sup> See *Cont’l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977); *CLARK & POINDEXTER*, *supra* note 14, at 646.

<sup>147</sup> See *K.M.B. Warehouse Distributions, Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 127 (2d Cir. 1995).

<sup>148</sup> See *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) (disagreeing with the district court on how the relevant market should be defined in a pharmaceutical antitrust litigation); *HOVENKAMP*, *supra* note 10, at 329 (“[M]arket definition questions in the pharmaceutical industry are particularly troublesome because of the high degree of product differentiation that distinguishes branded drugs from one another, notwithstanding considerable overlap in the treatment of certain conditions or symptoms.”); see also *CLARK & POINDEXTER*, *supra* note 14, at 648–49 (pointing out difficulties in defining the relevant market in the rule of reason analysis).

<sup>149</sup> See, e.g., *Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F.3d 1056, 1065 (11th Cir. 2003) (criticizing the analysis of the FTC by stating that “[d]espite the appearance that it openly considered [the settlement parties] procompetitive affirmative defense, the Commission

strength of a patent could be a primary factor in one court, whereas the size of a payment could be a factor with a higher weight in another court.<sup>150</sup>

In addition, the detailed analysis may cause a significant delay and have a negative impact on the highly time-sensitive pharmaceutical industry.<sup>151</sup> If the parties trying to settle before the patent expiration have to wait until the FTC conducts a thorough analysis, the settlement may be significantly delayed, and the pro-consumer effect may be negated. A quicker but less complicated alternative will be the *per se* analysis.<sup>152</sup>

### *c. Analysis Under the Per Se Rule*

The Sixth Circuit, applying a *per se* rule, would hold both hypothetical settlements as *per se* illegal because they involve a payment. Thus, this approach has the disadvantage of prohibiting a settlement that is likely to produce pro-competitive benefits such as the first example.

The blanket condemnation of “pay-for-delay” practice draws support from a probabilistic view of patent property, which regards the patent right as only a “right to try to exclude.”<sup>153</sup> This view, however, conflicts with the presumption of validity for issued patents under patent law.<sup>154</sup> Once the USPTO examines a patent application and decides its patentability, the patentee should be able to enjoy the exclusive right until the patent expires.<sup>155</sup> In the first scenario, the patentee agrees to abandon a part of the exclusivity and pay the anticipated litigation cost. Thus, the agreement does not seem to be the abuse of the exclusive right granted to the patentee.

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immediately condemned the settlements because of their absolute anti-competitive nature, and discounted the merits of the patent litigation.”)

<sup>150</sup> See HOVENKAMP, *supra* note 10, at 330–34 (listing the factors determining reasonableness including the validity and coverage of the patent, the relative size of the payment, and the entry ability of third parties).

<sup>151</sup> See CLARK & POINDEXTER, *supra* note 14, at 646–47 (“Some critics have called the standard ‘a euphemism for an endless economic inquiry resulting in a defense verdict’ because the rule of reason standard requires so much time and expense.”); see also Willand K. Tom, *The DOJ/FTC Report on Antitrust Enforcement and Intellectual Property Rights*, in ANTITRUST 35, 36–37 (Summer 2007) (questioning whether the DOJ approach based on the relative likelihood of success of the parties claims, viewed *ex ante*, would serve “the very purpose of settling the case . . . to avoid a judicial determination of the merits of the parties’ claims.”).

<sup>152</sup> See AREEDA & HOVENKAMP, *supra* note 81, at 396–404; Letzler & Pfaffenroth, *supra* note 61, at 83 (“[T]he proposed [*per se* rule] legislation would enact a rule more sweeping than the position the FTC has taken in any of its cases to date.”).

<sup>153</sup> Petition for a Writ of Certiorari at 16, Fed. Trade Comm’n v. Schering-Plough Corp., 548 U.S. 919 (2005) (No. 05-273), 2005 WL 2105243. *But see* Carl Schenck, A.G. v. Nortron Corp., 713 F.2d 782, 786 n.3 (Fed. Cir. 1983) (“The patent right is but the right to exclude others, the very definition of ‘property.’ That the property right . . . may be *used* in a scheme violative of antitrust laws creates no ‘conflict’ between laws establishing any of those property rights and the antitrust laws.” (emphasis in original)).

<sup>154</sup> 35 U.S.C. § 282 (2006); see Davis, *supra* note 136, at 32.

<sup>155</sup> See 35 U.S.C. § 282. *But see* CARRIER, *supra* note 8, at 346 (“In the 1990s, generics won nearly 75 percent of their challenges to patents on drugs such as Prozac, Zantac, Taxol, and Plantinol.”).

The Sixth Circuit recognized the merit of the *per se* rule in terms of the conservation of judicial resources.<sup>156</sup> The Supreme Court, however, stated the *per se* approach is proper only when one can “predict with confidence that the rule of reason will condemn it.”<sup>157</sup> Additionally, the application of the *per se* rule should be avoided when “the economic impact is not immediately obvious.”<sup>158</sup> The antitrust analysis of “pay-for-delay” settlements and their economic impact on innovation and the health care industry involve three interrelated regulatory schemes and require careful balancing of key factors. Currently, experience with this relatively new and unfamiliar business practice is not sufficient to warrant the *per se* treatment.<sup>159</sup>

### B. Evaluation of Proposed Legislation and DOJ Approach

H.R. 3962 pending in current Congress condemns “pay-for-delay” settlements as *per se* illegal.<sup>160</sup> Thus, as the above *per se* analysis shows, the legislation is likely to prohibit pro-competitive “pay-for-delay” settlements involving compensation to the generic firm.<sup>161</sup> Amended S. 369 and the DOJ approach may properly predict the pro-competitive nature of the settlements. They are, however, likely to require lengthy proceedings to conduct overly detailed analyses.

#### 1. Per Se Illegal Treatment in House Bill

H.R. 3962 prohibits all “pay-for-delay” settlements where the generic firm starts marketing its product before the patent expiration and receives some payment from the patentee.<sup>162</sup> This is essentially the *per se* illegal treatment of “pay-for-delay” settlements and provides antitrust defendants with no opportunity to argue potential

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<sup>156</sup> See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 909 (6th Cir. 2003) (“[T]he virtue/vice of the *per se* rule is that it allows courts to presume that certain behaviors as a class are anticompetitive without expending judicial resources to evaluate the actual anticompetitive effects or procompetitive justifications in a particular case.”).

<sup>157</sup> *Ariz. v. Maricopa County Med. Soc’y*, 457 U.S. 332, 344 (1982).

<sup>158</sup> *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009).

<sup>159</sup> See CLARK & POINDEXTER, *supra* note 14, at 653 (“[T]he three standards that are used for evaluating whether challenged conduct violates the antitrust laws continue to be reassessed and refined, particularly when they are applied to industries, such as health care, for which the courts do not have sufficient familiarity to understand the economic and other applicable criteria.”).

<sup>160</sup> See Letzler & Pfaffenroth, *supra* note 61, at 83 (“The supporters would argue that this is a routine application of the *per se* rule to an agreement not to compete.”).

<sup>161</sup> See *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (“If any settlement agreement is thus to be classified as involving a forbidden ‘reverse payment,’ we shall have no more patent settlements.”).

<sup>162</sup> See Affordable Health Care for America Act, H.R. 3962, 111th Cong. § 2573(b) (2009) (providing it is unlawful to enter into an agreement where “an ANDA filer receives anything of value,” and “the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales, for any period of time,” except when the value received by the ANDA filer includes no more than the right to market the drug before the expiration of the patent or any other statutory exclusivity).

pro-competitive effects of the settlement.<sup>163</sup> This quick condemnation is unwarranted unless the antitrust tribunal finds some indication that a particular settlement is intended to mask sham litigation over objectively baseless claims.<sup>164</sup>

As an exception to the blanket condemnation of “pay-for-delay” settlements, the bill provides that the FTC may allow certain settlement agreements when the commission finds pro-competitive and pro-consumer effects.<sup>165</sup> This FTC exemption, however, may have a limited effect because the FTC may not be willing to promulgate specific rules.<sup>166</sup> Instead, the FTC and the DOJ are likely to issue only guidelines to assist practitioners, as they have done in the past.<sup>167</sup> Thus, the FTC exemption in the proposed bill may not produce the intended results.

## 2. *Effects of the Per Se Illegal Treatment*

H.R. 3962 prohibiting the “pay-for-delay” practice is likely to discourage generic challenges of at least some patents because the limited availability of a desirable settlement increases uncertainty and the cost of litigation.<sup>168</sup> Even if a generic firm believes it could prevail in litigation, it may have to settle with an unfavorable agreement without any compensation besides the early market entry. The fixed date of generic entry before the patent expiration benefits the generic firm and the consumer, but the firm still needs to compete with well-established brand-name products. Thus, the financial benefit the generic firm can obtain from the early

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<sup>163</sup> *But see id.* (providing that certain agreements may be exempt if the FTC finds the agreements to be “in furtherance of market competition and for the benefit of consumers”).

<sup>164</sup> *See, e.g.,* *Profl Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 51 (1993) (describing sham litigation based on an objectively baseless claim).

<sup>165</sup> *See* Affordable Health Care for America Act, H.R. 3962, 111th Cong. § 2573(b) (2009) (“The Federal Trade Commission may, by rule promulgated under section 553 of title 5, United States Code, exempt certain agreements . . . if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers.”).

<sup>166</sup> *See* Letzler & Pfaffenroth, *supra* note 61, at 85.

It is one thing to pass a statute that generally gets it right and let the agency use its rule-making authority to fill gaps in the law, but to ask the FTC to take a statute that as written gets it wrong and try to fix it by carving out exceptions that are at odds with premise of the bill looks fundamentally inconsistent with the appropriate division of responsibility between the legislative branch and the executive branch.

*Id.*

<sup>167</sup> *See* CLARK & POINDEXTER, *supra* note 14, at 631 (listing some of the guidelines important to regulators and practitioners involved with the pharmaceutical industry—The Antitrust Guidelines for the Licensing of Intellectual Property (1995), The Statements of Antitrust Enforcement Policy in Health Care Guidelines (1996), The Horizontal Merger Guidelines (1997), The Commentary on the Horizontal Merger Guidelines (2006), and The Guidelines for Collaborations by Competitors (2000)).

<sup>168</sup> *See Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce*, 111th Cong. 2 (2009) (testimony of Theodore C. Whitehouse, Willkie Far & Gallagher LLP on behalf of Teva Pharmaceuticals USA, Inc.), *available at* [http://energycommerce.house.gov/Press\\_111/20090331/testimony\\_whitehouse.pdf](http://energycommerce.house.gov/Press_111/20090331/testimony_whitehouse.pdf) (“Based on its considerable experience with Hatch-Waxman litigation, Teva strongly believes that settlements of those cases are absolutely necessary part of the Hatch-Waxman process.”).

market entry remains uncertain, as compared to the actual payment from the patentee. The lack of reasonable compensation could seriously harm smaller generic firms needing resources for developing their own products and surviving the current weak economy.<sup>169</sup> The reduction of incentives for generics may lead to fewer generic players in the market, which could harm consumers.<sup>170</sup> Causing such a negative impact on consumers is contrary to the purpose of the Hatch-Waxman Act.<sup>171</sup> Thus, the proposed bill needs modifications to permit settlements with a certain level of potential pro-competitive effects.<sup>172</sup>

One could argue that the bill does not prohibit all settlements because it allows exceptions when the FTC agrees.<sup>173</sup> However, whether a settlement falls within the exception is subject to the FTC discretion, and business entities cannot readily predict what kind of agreements will qualify for the exception. To encourage a swift resolution of litigation with a lawful settlement, the exception should be a safe harbor provision with more specific requirements to allow a quick evaluation.<sup>174</sup>

### 3. *Complex Analysis Under Senate Bill and DOJ Approach*

The tests that the Senate bill and the DOJ approach provide lead to lengthy and complex analyses not suitable for examining the “pay-for-delay” settlements. The amended S. 369 presumes “pay-for-delay” settlements unlawful, but the settlement parties can overcome the presumption by showing pro-competitive effects of the agreement.<sup>175</sup> The antitrust tribunal then employs a seven-factor test to examine

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<sup>169</sup> See Marc G. Schildkraut, *Patent-splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1063 (2004) (“A cash-strapped alleged infringer . . . needs to receive cash earlier rather than later.”).

<sup>170</sup> See Letzler & Pfaffenroth, *supra* note 61, at 84 (“Making settlements harder will reduce the incentive to challenge a patent.”).

<sup>171</sup> See SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS, *supra* note 93, at 1433 (“The Hatch-Waxman Act was an attempt to streamline the procedure for obtaining FDA approval of generic pharmaceuticals . . . and to provide incentives for cheaper generics to come to market.”).

<sup>172</sup> See *Pay to Delay: Are Patent Settlements That Delay Generic Drug Market Entry Anticompetitive?*, Hearing on H.R. 1706 Before the Subcomm. on Courts and Competition Policy, 111th Cong. 2 (2009) (statement of Bret M. Dickey, Senior Vice President, Compass Lexecon), available at <http://judiciary.house.gov/hearings/pdf/Dickey090603.pdf>. “[E]conomic models demonstrate that when the real-world complexities of litigation are accounted for [reverse payment] settlements can in fact benefit consumers.” *Id.* “[T]he competitive effects of a particular settlement will depend importantly upon the underlying strength of the patent.” *Id.* at 3.

<sup>173</sup> See *Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too much for Prescription Drugs: Hearing on H.R. 1706 Before the Subcomm. on Courts and Competition Policy*, 111th Cong. 19 (2009) (statement of Federal Trade Commission), available at <http://judiciary.house.gov/hearings/pdf/Feinstein090603.pdf> (stating the proposed bill “provides flexibility by authorizing the FTC to adopt rules to exempt other agreements from the general prohibition”). *But see* Letzler & Pfaffenroth, *supra* note 61, at 85 (criticizing the idea that a statute generally “gets it wrong” and the FTC must “fix it by carving out exceptions”).

<sup>174</sup> See 35 U.S.C. § 271(e) (2006); *see also* Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1259 (Fed. Cir. 2008) (addressing a safe harbor provision of patent infringement for activities in relation to the FDA regulatory process).

<sup>175</sup> See Preserve Access to Affordable Generics Act, S. 369, 111th Cong. § 28(a)(2)(A), (b) (2009).

whether the evidence is sufficient to overcome the presumption.<sup>176</sup> This analysis under multiple factors would be administratively inconvenient, less predictable, and as complex as the rule of reason analysis under the DOJ approach.

Besides the length of the list, the amended S. 369 defines some factors only vaguely. One example is the factor considering the revenue loss by the patent holder upon losing the patent litigation.<sup>177</sup> The loss in the patent litigation could be obtaining a judgment of patent invalidity or non-infringement. The revenue loss from an invalidity judgment may be greater than that from a non-infringement judgment because patent invalidation could allow other generics to enter the market as well.<sup>178</sup> Amended S. 369, however, simply defines the revenue loss as the reduction when the patentee has lost the patent litigation and does not adequately identify other factors, such as reduction in future revenue after other generics have entered the market.<sup>179</sup> Furthermore, the estimate of the revenue loss would depend on various conditions such as the number and timing of generic entries and is thus likely to be speculative. The multi-factor test in the amended S. 369 only raises questions and leads to continued litigation when parties are willing to settle.<sup>180</sup>

Similarly, the DOJ approach employing the rule of reason standard requires overly broad and expensive analysis unfavorable for efficient enforcement.<sup>181</sup> Also, this approach is not very effective in preventing settlements with lower payments but perceived anti-competitive effects. The DOJ states that the parties can “clearly rebut the presumption if they show the payment was no more than an amount commensurate with the patent holder’s avoided litigation costs.”<sup>182</sup> The size of the payment is such a dispositive factor that companies can easily make a seemingly lawful deal even if it unreasonably restrains competition. Pharmaceutical litigations arising out of the Hatch-Waxman framework largely differ from one another, and the antitrust analysis should be more fact-specific in order to properly block anti-competitive settlements.<sup>183</sup>

Thus, the test proposed in S. 369 and the DOJ rule of reason approach are not suitable for the antitrust analysis of “pay-for-delay” settlements. A more effective approach is to identify only the key elements and quickly balance the effects of “pay-for-delay” settlements. Additionally, there should be a safe harbor provision with

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<sup>176</sup> *Id.* § 28(b).

<sup>177</sup> *Id.* § 28(b)(5).

<sup>178</sup> See *Pay to Delay: Are Patent Settlements That Delay Generic Drug Market Entry Anticompetitive?: Hearing on H.R. 1706 Before the Subcomm. on Courts and Competition Policy, 111th Cong. 4* (2009) (statement of Bret M. Dickey, Senior Vice President, Compass Lexecon), available at <http://judiciary.house.gov/hearings/pdf/Dickey090603.pdf> (“The use of overly simple economic models can inappropriately lead to the conclusion that ‘reverse payment’ settlements will always reduce competition.”).

<sup>179</sup> See Preserve Access to Affordable Generics Act, S. 369, 111th Cong. § 28(b)(5) (2009).

<sup>180</sup> See *DOJ Brief, supra* note 109, at 25–26 (noting concerns over unduly complicated litigation).

<sup>181</sup> See Arthur, *supra* note 91, at 341 (“A standard that is overly cumbersome and expensive will hinder effective enforcement.”).

<sup>182</sup> *DOJ Brief, supra* note 109, at 25–26.

<sup>183</sup> See CLARK & POINDEXTER, *supra* note 14, at 692 (grouping Hatch-Waxman Act settlements into three categories, and stating the traditional rule of reason does not work for one group of settlements where the agreement itself looks like an antitrust violation but the presence of intellectual property rights may absolve all of the antitrust issues).

specific requirements so that practitioners can evaluate whether a proposed settlement falls within the provision.<sup>184</sup>

### III. PROPOSAL

This comment proposes to modify the pending legislation to allow “pay-for-delay” settlements if their pro-competitive effects are sufficient under the quick look standard. Congress should also consider including a safe harbor provision that codifies specific conditions required for a settlement agreement to be lawful.<sup>185</sup>

#### A. Requirement to Show Sufficient Pro-Competitive Effects

Settlements that promote competition are legal under the antitrust laws.<sup>186</sup> Thus, the pending House bill should be modified to permit “pay-for-delay” settlements if the parties can show sufficient pro-competitive effects. The parties may show that their agreement allows multiple generics to enter months before patent expiration and does not involve a disproportionately large payment.<sup>187</sup> Instead of full investigations under the seven-factor test in the Senate bill or the DOJ rule of reason, this approach contemplates applying the quick look standard in a sliding scale.

Under the proposed approach, an antitrust tribunal may first consider several key factors such as the size of the payment, the patented subject matter, and the entry ability of generics.<sup>188</sup> It then determines the level of quickness suitable for the particular circumstance. If the settlement has obvious anti-competitive effects such as the unavailability of early generic entries, the burden shifts to the defendants to provide justifications of the settlement. The tribunal will then balance the likely anti-competitive and pro-competitive effects. On the other hand, if the anti-competitive effects are not immediately obvious, the tribunal may require some showing of actual anti-competitive effects, instead of presuming illegality. Some litigations within the Hatch-Waxman context are quite complex, involving multiple parties and exclusivity provisions. In such situations, the tribunal can conduct an

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<sup>184</sup> See 35 U.S.C. § 271(e) (2006) (providing a safe harbor for patent infringement).

<sup>185</sup> See Arthur, *supra* note 91, at 359–62 (describing an analysis under a variation of the quick look standard, which takes a “sliding scale approach that tailors the inquiry to the particular circumstances”); see also Tom, *supra* note 151, at 37 (stating the DOJ has proposed an analysis involving a “limited examination into the relative merits of the patent claims”).

<sup>186</sup> See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008) (“Settlement of patent claims by agreement between the parties—including exchange of consideration—rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition.”), *cert. denied*, 129 S. Ct. 2828 (2009).

<sup>187</sup> See HOVENKAMP, *supra* note 10, at 334 (“[T]he combination of a ‘large’ payment from the patentee to the challenger, plus physical or legal conditions that make it unlikely that third parties can immediately enter the market, creates a strong presumption of unreasonableness.”).

<sup>188</sup> See *id.* at 330; HUTT ET AL., *supra* note 28, at 764 (“[T]he first generic competitor results in only about a 5 percent reduction in price, whereas the second brings the price down to about 50 percent of the pioneer drug price. . . . With a large number of competitors it can reach 10 percent or lower.”).

analysis that is somewhat detailed but still quicker, as compared to the rule of reason analysis.

The proposed approach can provide more flexible and fact-specific analyses than the *per se* rule and does not require lengthy court proceedings as does the rule of reason standard. In conducting a quick look analysis, the antitrust tribunal may decide on pleadings and arguments or order a “mediated mini-trial” that has “proved useful in disputes involving mixed questions of law and fact in patent infringement cases.”<sup>189</sup>

### *B. Effect of the Modified Legislation*

The modified legislation will effectively block only the anti-competitive settlements where parties cannot prove sufficient pro-competitive effects and “soundness of settled patent claims” under the circumstances.<sup>190</sup> It permits objectively reasonable settlements and does not disturb the policy favoring settlements over unnecessary litigation.<sup>191</sup> On the other hand, the *per se* illegal treatment in the pending House bill fails to acknowledge the patent zone protected by patent law and its exclusionary effect.<sup>192</sup> Such a drastic measure may be necessary to reduce the health care costs, even if some pro-competitive agreements could be prohibited as well.<sup>193</sup> Before taking a drastic measure that has a conceivable detrimental effect, however, Congress should consider a more conservative approach along with a measure to make the “pay-for-delay” strategy less beneficial. The measure can include a modification of the Hatch-Waxman Act itself to provide drug makers certain incentives for continuing litigation rather than settling it.<sup>194</sup>

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<sup>189</sup> SECTION OF ANTITRUST LAW, AM. BAR ASSOC., THE ANTITRUST COUNTERATTACK IN PATENT INFRINGEMENT LITIGATION 181 (1995) [hereinafter SECTION OF ANTITRUST LAW, THE ANTITRUST COUNTERATTACK]. *But see* CARRIER, *supra* note 8, at 375.

The appropriate treatment of patent settlements thus depends on the validity of the patent and existence of infringement. But the most straightforward way to determine these issues, patent litigation, is not appropriate in this setting. Determining patent validity and infringement would require significant analysis and testimony on complex issues such as patent claim interpretation and infringement analysis. Such inquiries, which could take weeks, cannot be inserted as mini-trials within antitrust cases.

CARRIER, *supra* note 8, at 375.

<sup>190</sup> *See* Hovenkamp, *supra* note 12, at 1735.

<sup>191</sup> *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008) (“[T]here is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation.”), *cert. denied*, 129 S. Ct. 2828 (2009).

<sup>192</sup> *See* Hovenkamp, *supra* note 12, at 1733–34 (describing an analytical framework that allows defendants in antitrust proceedings to present “general defenses that arise in exclusive dealing claims” and “additional considerations that might arise from the presence of the IP right”).

<sup>193</sup> *See* CARRIER, *supra* note 8, at 345 (“Consumers spend billions of dollars on prescription drugs. Senior citizens choose between medicine and food. . . . [A] tidal wave of high drug prices is crashing across the U.S. economy. One of the primary culprits has been the increase in [“pay-for-delay” settlements].”).

<sup>194</sup> *See Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. on Courts and Competition Policy*, 111th Cong. 13 (2009) (statement of Bernard C. Sherman, CEO, Apotex Inc.), [http://energycommerce.house.gov/Press\\_111/20090331/testimony\\_sherman.pdf](http://energycommerce.house.gov/Press_111/20090331/testimony_sherman.pdf) (proposing an amendment to allow a subsequent ANDA filer who wins

One possible objection to the proposed quick look analysis is that considering the patented subject matter requires some familiarity with the patent laws and technical matters. The FTC is well-equipped for analyzing violations of antitrust laws rather than patent laws, and can only conduct limited inquiries into the patent matters. To address technical issues properly, an antitrust tribunal may have a committee consisting of scientific experts from each side and a few neutral experts, as in arbitration proceedings.<sup>195</sup>

Another possible objection is that the quick look may create inconsistency in terms of the amount or depth of the quick look.<sup>196</sup> Flexible methods taking a sliding scale approach could be subject to a varying degree of discretion.<sup>197</sup> Antitrust issues are, however, fact-specific and unique in each situation, and thus courts have employed the rule of reason as a default standard.<sup>198</sup> The truncated rule of reason is well suited because lengthy proceedings might prevent swift entries of generic products. To facilitate a uniform analysis, Congress should consider a safe harbor provision that codifies specific conditions for an agreement to be lawful, similar to the issue of fair use in copyright law.<sup>199</sup> The safe harbor provision will help drug makers evaluate whether a proposed settlement agreement will survive antitrust scrutiny.

The modified legislation applying the quick look standard to “pay-for-delay” settlements combined with the measures for uniform antitrust analyses will effectively block anti-competitive settlements and protect consumer access to generic drugs by allowing pro-competitive settlements.

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litigation to share the generic exclusivity with the first ANDA filer so that the subsequent ANDA filer has incentives to continue litigation); *see also* Drug Price Competition Act of 2009, S. 1315, 111th Cong. §2(a) (2009) (proposing to expand the application of generic exclusivity to a subsequent ANDA filer that receives a favorable court decision).

<sup>195</sup> *See* Richard A. Posner, *Antitrust in the New Economy*, 68 ANTITRUST L.J. 925, 937 (2001); SECTION OF ANTITRUST LAW, THE ANTITRUST COUNTERATTACK, *supra* note 189, at 185.

In 1982, the Patent Act was amended to add Section 294, which stated that parties were authorized to arbitrate questions of patent validity and infringement. . . . In another important international patent-antitrust dispute, the parties achieved similar success when they chose an effective arbitration panel. . . . The arbitration was described as a ‘full blown federal trial on an expedited basis.’ What would have taken years and millions of dollars under traditional litigation was resolved in nine months.

SECTION OF ANTITRUST LAW, THE ANTITRUST COUNTERATTACK, *supra*.

<sup>196</sup> *See* Cal. Dental Ass’n v. Fed. Trade Comm’n, 526 U.S. 756, 779 (1999); *see also* AREEDA & HOVENKAMP, *supra* note 81, at 393 (“[J]udgments can sometimes be made on the basis of the parties’ agreements in light of what the judges know about the economy and in light of such modest information as may be available at the beginning of the lawsuit.”).

<sup>197</sup> *But see* Arthur, *supra* note 91, at 362 (suggesting many lower courts have ample judicial experience in applying the quick look standard to general antitrust claims).

<sup>198</sup> *See* Cont’l T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49 (1977) (“Since the early years of this century a judicial gloss on this statutory language [of the Sherman Act] has established the ‘rule of reason’ as the prevailing standard of analysis.”); CLARK & POINDEXTER, *supra* note 14, at 646.

<sup>199</sup> *See* 17 U.S.C. § 107 (2006) (providing that the determination whether the use of a copyrighted work constitutes a fair use requires the consideration of “(1) the purpose and character of the use . . . (2) the nature of the copyrighted work; (3) the amount and substantiality of the portion used . . . and (4) the effect of the use upon the potential market”).

## CONCLUSION

Intense debates on the legislation addressing “pay-for-delay” settlements indicate the strong need for a law that facilitates consumer access to generics and yet protects “legitimate rewards of patent monopoly” attainable only after extensive research and investment.<sup>200</sup> The House bill pending in current Congress categorically prohibits “pay-for-delay” settlements, which could harm the pharmaceutical industry by eliminating a way out of frequent litigation and thus discouraging patent challenges.<sup>201</sup> Some settlements provide earlier generic entries,<sup>202</sup> and others allow possibly invalid patents to remain in effect.<sup>203</sup> A more flexible approach allowing “pay-for-delay” settlements based on the level of plausible pro-competitive effects is more suitable for preventing the erosion of the antitrust zone into the patent zone, and vice versa.

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<sup>200</sup> United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1128 (D.C. Cir. 1981); see 155 CONG. REC. H12889 (2009) (statement of Rep. Lamar Smith) (“[T]he proposed solution to this problem, incorporated in Sec. 2573, goes too far. The [H.R. 3962] bill calls for a ban on all Hatch-Waxman settlements that feature any consideration, such as cash or an exchange of patents, in addition to the date of entry.”); see also *Pay to Delay: Are Patent Settlements That Delay Generic Drug Market Entry Anticompetitive?: Hearing on H.R. 1706 Before the Subcomm. on Courts and Competition Policy*, 111th Cong. 1 (2009) (statement of William Vaughan, Senior Health Policy Analyst Consumers Union), <http://judiciary.house.gov/hearings/pdf/Vaughan090603.pdf> (“Consumers Union absolutely believes that payments between brand and generic drug companies that delay the entry of generic drugs are bad for consumers and are the very definition of anti-competitive behavior.”).

<sup>201</sup> See *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (“A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger’s settlement options should he be sued for infringement, and so might well be thought anticompetitive.”); *Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. on Courts and Competition Policy*, 111th Cong. 2 (2009) (statement of Theodore C. Whitehouse, Willkie Far & Gallagher LLP on behalf of Teva Pharmaceuticals USA, Inc.), available at [http://energycommerce.house.gov/Press\\_111/20090331/testimony\\_whitehouse.pdf](http://energycommerce.house.gov/Press_111/20090331/testimony_whitehouse.pdf).

<sup>202</sup> See *Pay to Delay: Are Patent Settlements That Delay Generic Drug Market Entry Anticompetitive?: Hearing on H.R. 1706 Before the Subcomm. on Courts and Competition Policy*, 111th Cong. 8 (2009) (statement of Heather Bresch, Chief Operating Officer, Mylan Inc.), available at <http://judiciary.house.gov/hearings/pdf/Bresch090603.pdf> (“[T]he breast cancer treatment Tamoxifen® allowed a generic version to enter the market nine years before the date the relevant patent expired.”).

<sup>203</sup> McLean, *supra* note 2, at 122, 126 (describing a situation where a “pay-for-delay” settlement would have allowed an invalid patent to remain in effect and keep generics off the market).