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## A Pharmaceutical Park Place: Why the Supreme Court Should Modify the Scope of the Patent Test for Reverse Payment Deals

David Ernest Balajthy

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NOTES

**A PHARMACEUTICAL PARK PLACE: WHY THE  
SUPREME COURT SHOULD MODIFY THE SCOPE  
OF THE PATENT TEST FOR REVERSE PAYMENT  
DEALS**

*David Ernest Balajthy\**

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## I. INTRODUCTION

“[P]harmaceuticals are the poster child for the patent system.”

Richard A. Posner, Judge for the Seventh Circuit Court of Appeals<sup>1</sup>

The pharmaceutical patent system has been hailed as a resounding success and as a model for patent schemes in other markets,<sup>2</sup> so it might be surprising to find out that this system is engaging in a practice that is potentially costing consumers billions of dollars a year.<sup>3</sup> The practice is called “reverse payment” or “pay-for-delay” agreements.<sup>4</sup> Before introducing a generic drug, a company typically must file a legal proceeding against the brand-name manufacturer. This proceeding attempts to invalidate the drug’s protective patents or show that the generic version does not violate these patents.<sup>5</sup> However, the recent development of reverse payment deals involves the holder of a drug’s patent, typically a brand-name manufacturer, paying a generic drug company to refrain from producing generic versions of that drug for a certain period of time.<sup>6</sup> The deals are “reverse” in that the money flows from the patent holder to the potential patent infringer. These deals have become increasingly common and have been criticized by consumer groups as restraining trade and “delaying the introduction of inexpensive generic drugs.”<sup>7</sup>

A split has recently developed in circuit courts regarding the legality of reverse payment deals under antitrust laws. Recently, the Second, Eleventh, and Federal Circuit Courts have held that these deals are legal as long as the restriction on competition does not exceed the scope of the patent under the so-called “scope-of-the-patent” test.<sup>8</sup> The Federal Trade Commission (FTC),

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<sup>1</sup> Richard A. Posner, *Why There Are Too Many Patents in America*, ATLANTIC (July 12, 2012, 10:20 AM), <http://www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/>.

<sup>2</sup> *Id.*

<sup>3</sup> J. Thomas Rosch, Comm’r, Fed. Trade Comm’n, *Pharmaceutical Patent Settlements and the Supreme Court*, in FED. TRADE COMMISSION 13 (Sept. 21, 2012), <http://www.ftc.gov/speeches/rosch/120921cbipharmaspeech.pdf>.

<sup>4</sup> *Id.*

<sup>5</sup> Aaron S. Kesselheim et al., “Pay for Delay” Settlements of Disputes Over Pharmaceutical Patents, *NEW ENG. J. MED.* 365:1439–45 (Oct. 13, 2011), available at <http://www.nejm.org/doi/full/10.1056/NEJMhle1102235>.

<sup>6</sup> *Id.* at 1439.

<sup>7</sup> *Id.*

<sup>8</sup> *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005); *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).

on the other hand, has been adamantly against reverse payment deals, claiming that they are restraints on trade.<sup>9</sup> In a recent opinion, the Third Circuit held that reverse payment deals are presumptively illegal, explicitly rejecting the scope-of-the-patent test used by the Second, Eleventh, and Federal Circuit Courts.<sup>10</sup> In response to this circuit split, on December 7, 2012 the Supreme Court granted certiorari to *Federal Trade Commission v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012) (*Watson*), a case that raises this very issue.<sup>11</sup> The Supreme Court has yet to issue an opinion on this case.<sup>12</sup>

Judge Richard Posner, who has become an authority on the American patent system, claims that the pharmaceutical industry is somewhat unique in its need for strong patent protection as the peculiarities of the industry reflect underlying principles of patent law.<sup>13</sup> The three reasons he provides for this opinion are: (1) the expensive nature of developing new drugs; (2) the patent clock beginning to run when the patent is granted, even though pharmaceutical companies still need to invest time in testing the drug before it can be marketed; and (3) the cost of inventing a drug far outweighing the cost of producing a drug, leaving little incentive to engage in the expensive process of developing a new drug if copying were permitted.<sup>14</sup>

First, this Note will review the legal history, policy considerations, and relevant statutes relating to patent protection in the pharmaceutical industry. It will then provide the reasoning behind the Second Circuit's support of the scope-of-the-patent test, as well as the Third Circuit's rejection of this test. This Note concludes by proposing a simple modification to the scope-of-the-patent test which accounts for deals that could pose a restraint on trade and acts as a viable compromise between the two positions.

## II. BACKGROUND

In order to fully understand the difference between the Third Circuit's view and that of the Second, Eleventh, and Federal Circuits regarding the legality of reverse payment deals, it is necessary to delve into the historical development and present implications of the conflict. First, this Note will review the legal

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<sup>9</sup> Kesselheim et al., *supra* note 5, at 1439.

<sup>10</sup> *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

<sup>11</sup> Jillian Centanni, *Supreme Court to Examine Pay-For-Delay Settlements*, IPLAWALERT.COM (Dec. 17, 2012, 10:36 AM), <http://www.iplawalert.com/2012/12/articles/patent-1/supreme-court-to-examine-payfordelay-settlements/>.

<sup>12</sup> *Id.*

<sup>13</sup> Posner, *supra* note 1.

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

history, policy considerations, and legislative purpose of patent protection in the pharmaceutical industry. Second, it will address the relevant statutes concerning patent protection in the pharmaceutical industry.

Patents are a form of intellectual property authorized by the U.S. Constitution in Article I, Section Eight, which states, “Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>15</sup>

Patents provide patentees with “the right to exclude others from making, using, offering for sale, or selling” inventions they have patented.<sup>16</sup> Patents can be granted for processes as well as tangible inventions.<sup>17</sup> Generally, a patent provides a twenty-year period of exclusivity to the patentee, starting from the date on which the patent application was filed.<sup>18</sup>

The United States Patent and Trademark Office (USPTO), part of the Department of Commerce, is the administrative body that is tasked with the duty to evaluate and issue patents.<sup>19</sup> The USPTO advises the President, Security of Commerce, and other governmental agencies on patent-related policies.<sup>20</sup>

#### A. STATUTORY AND POLICY BACKGROUND FOR THE PATENT PROTECTION OF PHARMACEUTICALS

The most important piece of legislation in the area of pharmaceutical patent law is the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act.<sup>21</sup> The Hatch-Waxman Act amended the Federal Food, Drug and Cosmetic Act<sup>22</sup> and the Patent Act<sup>23</sup> and has been credited with achieving a “sensitive balance between patent protection

<sup>15</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>16</sup> 35 U.S.C. § 154(a)(1) (2012).

<sup>17</sup> *Id.*

<sup>18</sup> *Id.* § 154(a)(2).

<sup>19</sup> United States Patent and Trademark Office, THE USPTO: WHO WE ARE (Apr. 3, 2013), available at <http://www.uspto.gov/about/index.jsp>.

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

<sup>21</sup> Drug Price Competition and Patent Term Restoration Act, Section 505(j), 21 U.S.C. § 355(j); Martha Rumore, *The Hatch-Waxman Act—25 Years Later: Keeping the Pharmaceutical Scales Balanced*, PHARMACY TIMES (Aug. 15, 2009), <http://www.pharmacytimes.com/publications/supplement/2009/GenericSupplement0809/Generic-HatchWaxman-0809>; 21 U.S.C. § 355.

<sup>22</sup> Rumore, *supra* note 21 (citing Food, Drug, Cosmetic Act, Pub. L. No. 75-717, ch. 675, 52 Stat. 1040 (June 25, 1938) (codified as amended at 21 U.S.C. §§ 301–399 (2002) at 355 (2006))).

<sup>23</sup> 35 U.S.C. §§ 1–376 (2012).

and encouraging generic entry.”<sup>24</sup> The Hatch-Waxman Act transformed the generic drug market by allowing for more efficient administrative approval of generic drugs.<sup>25</sup> Prior to the Act, Federal Drug Administration (FDA) approval of generic drugs required costly and duplicative clinical trials. The Act created the Abbreviated New Drug Application (ANDA), which provides the opportunity for generic drug manufacturers to obtain FDA approval by providing proof that the active ingredient is biologically equivalent to the ingredient the brand-name manufacturers use.<sup>26</sup> The ANDA system requires generic drug manufacturers to choose one of the available certification options: they must either claim that no patent was filed for the drug (a paragraph I certification), claim that the patent has expired for the drug (a paragraph II certification), claim that the patent will expire and guarantee that they will not market the generic drug until the patents protecting the brand-name drug have expired (a paragraph III certification), or seek certification through a “Paragraph IV challenge,” which either challenges the validity of the brand-name manufacturer’s patents or attempts to show that the generic drug does not violate those patents.<sup>27</sup> A Paragraph IV challenge requires a generic drug manufacturer to examine preexisting patents that have been registered with the FDA, which can be a lengthy process.<sup>28</sup>

A pharmaceutical drug is typically covered by multiple patents, including a patent protecting the primary active ingredient and patents for more minor characteristics, such as coating or different formulations of the primary ingredient.<sup>29</sup> These secondary patents can have the effect of lengthening the protection of the covered drug, as the patents for active ingredients may expire prior to these secondary patents.<sup>30</sup> As the primary patents expire, these secondary patents prevent generic manufacturers from producing a generic drug.<sup>31</sup> Generic drug manufacturers sometimes use Paragraph IV challenges to attack these secondary patents because secondary patents protect characteristics that are often replaceable and able to be substituted when the generic drug manufacturer manufactures its drug.<sup>32</sup> These changes can often be made without seriously altering the drug’s potency.<sup>33</sup> The FDA grants patent rights to

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<sup>24</sup> *Id.*; 35 U.S.C. § 271 (2006).

<sup>25</sup> Kesselheim et al., *supra* note 5, at 1439.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*; 21 U.S.C. § 355(j)(2)(A)(vii) (2012).

<sup>28</sup> Kesselheim et al., *supra* note 5, at 1439.

<sup>29</sup> *Id.* at 1439–40.

<sup>30</sup> *Id.* at 1440.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

the first generic manufacturer to file a successful Paragraph IV claim, so the process is essentially a race to the finish line.<sup>34</sup> Whichever manufacturer succeeds in this race is entitled to 180 days of exclusive rights to manufacture a generic version of the drug.<sup>35</sup> This grant creates a duopoly in the market with respect to that drug, because the drug is typically offered at its original price during this period.<sup>36</sup> This provides a strong incentive for generic drug manufacturers to file a Paragraph IV challenge, even if it means challenging illegitimate or weak patents.<sup>37</sup> Brand-name manufacturers deploy a tactic of their own, however. Because the filing of a Paragraph IV challenge constitutes a technical infringement of their patent, manufacturers can respond by filing lawsuit for patent infringement.<sup>38</sup> This lawsuit triggers a thirty-month stay of approval under ANDA, which delays generic manufacturers' challenges and creates opportunities for reverse payment deals.<sup>39</sup>

According to the FDA, Paragraph IV challenges have steadily increased in frequency since the 1980s, when only 2% of ANDAs contained Paragraph IV certifications.<sup>40</sup> From 1998–2000, approximately 20% of all ANDAs contained Paragraph IV certifications.<sup>41</sup> During this period, generic drug manufacturers were quite successful in their Paragraph IV challenges, winning approximately two-thirds of the challenges.<sup>42</sup> Likely in response to this increase in challenges, pharmaceutical manufacturers began to pursue an alternative to litigation in order to protect their patents in the late 1990s: reverse payment agreements.<sup>43</sup> When a brand-name drug manufacturer faced a Paragraph IV challenge for patent validity or claims that a generic version did not violate its patents, it would pay a substantial sum of money to quell the first generic drug manufacturer with a successful Paragraph IV challenge.<sup>44</sup> In return, the generic drug manufacturer promised not to market their drug for a certain period of time and agreed not to sell or transfer its right to produce its drug for the 180

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<sup>34</sup> *Id.*

<sup>35</sup> *Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act*, FOOD & DRUG ADMIN. (June 1998), <http://www.fda.gov/downloads/Drugs/Guidances/ucm079342.pdf>.

<sup>36</sup> Kesselheim et al., *supra* note 5, at 1440.

<sup>37</sup> *Id.*

<sup>38</sup> 35 U.S.C. § 271(e)(2) (2012).

<sup>39</sup> Kesselheim et al., *supra* note 5, at 1440.

<sup>40</sup> *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, FED. TRADE COMM'N, July 2002, at 10, <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

<sup>41</sup> Kesselheim et al., *supra* note 5, at 1440.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*



days allotted to them by the FDA.<sup>45</sup> This practice sparked a debate over whether these deals should be considered an illegal restraint on trade under laws that regulate anti-competitive behavior.<sup>46</sup>

#### B. THE ROLE OF ANTITRUST LEGISLATION IN REVERSE PAYMENT DEALS

The Sherman Antitrust Act of 1890 is a tool with which the federal government battles illegal restraints on trade.<sup>47</sup> The Act declares that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.”<sup>48</sup> This Section of the act deals specifically with collusive agreements in restraint on trade.<sup>49</sup> The Sherman Antitrust Act also places an affirmative duty on the government to investigate and prosecute potential practices that could potentially violate the Act.<sup>50</sup> Another landmark piece of antitrust legislation is the Clayton Act of 1914. The Clayton Act also implemented measures that combat practices that Congress deemed to be illegal restraints on trade.<sup>51</sup> Another crucial piece of legislation in this area is the Federal Trade Commission Act (FTC Act), which created the Federal Trade Commission (FTC).<sup>52</sup> The FTC has the responsibility of investigating potential violations of the Sherman Antitrust Act and the Clayton Act.<sup>53</sup>

There are three main ways in which a legal proceeding involving an antitrust claim can begin.<sup>54</sup> The first is that the FTC and the Antitrust Division of the

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<sup>45</sup> See, e.g., Sheryl Gay Stolberg & Jeff Gerth, *How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, <http://partners.nytimes.com/library/national/science/health/072300hth-generic-drugs.html> (discussing patent dispute between Zenith Goldline Pharmaceuticals and Abbott Laboratories).

<sup>46</sup> Alison Frankel, *3rd Circuit Shocker: Pay-for-Delay Drug Settlements are Illegal*, THOMSON REUTERS (July 16, 2012), [http://newsandinsight.thomsonreuters.com/Legal/News/2012/07\\_-\\_July/3rd\\_Circuit\\_shocker\\_Pay-for-delay\\_drug\\_settlements\\_are\\_illegal/](http://newsandinsight.thomsonreuters.com/Legal/News/2012/07_-_July/3rd_Circuit_shocker_Pay-for-delay_drug_settlements_are_illegal/).

<sup>47</sup> 15 U.S.C. § 1 (2006).

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> See 15 U.S.C. §§ 12–27 (2002); Labor Disputes; Mediation and Injunctive Relief, 29 U.S.C. §§ 52–53 (2006) (prohibiting certain anticompetitive behavior, such as price discrimination and certain mergers and acquisitions).

<sup>52</sup> 15 U.S.C. §§ 41–58 (2006).

<sup>53</sup> See *FTC v. Brown Shoe Co.*, 384 U.S. 316, 322 (1966) (“[The Commission is permitted to] 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.”).

<sup>54</sup> Onoe, *supra* note 8, at 534.

Department of Justice may bring a civil lawsuit against an alleged colluder.<sup>55</sup> Second, the Clayton Act empowers consumers to sue businesses for violations of its provisions.<sup>56</sup> Third, the FTC may file an administrative complaint under its statute for an alleged violation. For nongovernmental parties, these options require that a customer suffered an injury of the kind that the antitrust laws were designed to protect against. This complaint may be appealed.<sup>57</sup>

Courts have developed three different standards in evaluating antitrust claims that allege collusive anticompetitive conduct.<sup>58</sup> The first standard is the “rule of reason” standard. This is the primary method that courts use to determine whether a “restraint” of competition has occurred.<sup>59</sup> This involves a three-step analysis: (1) the plaintiff must prove an “actual adverse effect on competition as a whole in the relevant market”;<sup>60</sup> (2) if the plaintiff meets its initial burden, the defendant must show that there are pro-competitive effects of the allegedly collusive behavior;<sup>61</sup> (3) if the defendant satisfies this standard, the plaintiff must recommend “less restrictive” alternatives.<sup>62</sup>

Courts developed the second standard, the “per se” approach, because they believed that the “rule of reason” standard was too onerous for application to certain types of activities that posed clear risks to competition.<sup>63</sup> These types of activities include particularly repugnant and restrictive anticompetitive behaviors and the Supreme Court has held that such violations should be found to be per se violations “[o]nce experience with a particular kind of restraint

<sup>55</sup> *Id.*; see also SECTION OF ANTITRUST LAW, AM. BAR ASSOC., INTELLECTUAL PROPERTY AND ANTITRUST HANDBOOK 54–56, 58 (2007) (stating that the FTC and the DOJ employ similar procedures for civil investigations).

<sup>56</sup> Onoe, *supra* note 8, at 535; 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 . . .”).

<sup>57</sup> Onoe, *supra* note 8, at 535; 15 U.S.C. § 45(b)–(c) (2006).

<sup>58</sup> Onoe, *supra* note 8, at 536.

<sup>59</sup> *Id.*; *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.”).

<sup>60</sup> *K.M.B. Warehouse Distrib., Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 127 (2d Cir. 1995); see also *Bd. of Trade of Chi. v. United States*, 246 U.S. 231, 238 (1918) (stating a “court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual as probable”).

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

<sup>62</sup> *Id.*

<sup>63</sup> See, e.g., *United States v. Socony-Vacuum Oil Co. et al.*, 310 U.S. 150 (1940) (the Supreme Court finding *Socony-Vacuum Oil Co.*, and others, violated section 1 of the Sherman Antitrust Act, on a per se basis).

enables the Court to predict with confidence that the rule of reason will condemn it.”<sup>64</sup>

The third form of analysis that courts have adopted in evaluating antitrust cases is the “quick look” standard.<sup>65</sup> This method allows courts to simply take a cursory look at an antitrust case when the actions forming the basis for the claim “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>66</sup>

#### C. PENDING LEGISLATION

There is legislation pending in the Senate that seeks to prohibit reverse payment deals. It is called the Preserve Access to Affordable Generics Act, commonly referred to as the Kohl bill due to its original sponsor, Senator Herbert Kohl from Wisconsin.<sup>67</sup> Although the Kohl bill died in committee, it was reintroduced with little change on February 4, 2013 by Senators Klobuchar, Grassley, Curbin, Franken, and Johnson.<sup>68</sup> The bill, if passed, would create a presumption of illegality for reverse payment deals, defined as a generic drug company’s transfer of (1) “anything of value” from a brand-name drug manufacturer, and its agreement (2) “to limit or forego research, development, manufacturing, marketing, or sales of the [generic] product for any period of time.”<sup>69</sup> The Act would allow the presumption to be overcome by “clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects.”<sup>70</sup>

The Act does not prohibit certain behaviors, however, including deals in which

- (1) the value that the generic company receives is no more than the right to market its product prior to the expiration of the allegedly infringed patent or other statutory exclusivity; (2) the payment is for reasonable litigation expenses not exceeding \$7.5

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<sup>64</sup> *Ariz. v. Maricopa Cnty. Med. Soc’y*, 457 U.S. 332, 344 (1982).

<sup>65</sup> *Onoe*, *supra* note 8, at 537.

<sup>66</sup> *Id.*; *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 763.

<sup>67</sup> William H. Rooney, Elai Katz, Amy R. Fitzpatrick, Michelle Leutzing & Peter J. Scoolidge, *Review of Reverse-Payment Agreements*, 5 COMPETITION POL’Y INT’L, no. 2, 2009 at 133.

<sup>68</sup> Tony Dutra, *Klobuchar Reintroduces Bill in Senate to Limit Pay-For-Delay Drug Settlements*, BLOOMBERG L. REP., <http://about.bloomberglaw.com/law-reports/klobuchar-reintroduces-bill-in-senate-to-limit-pay-for-delay-drug-settlements/>; S. 214, 113th Cong. (2013).

<sup>69</sup> S. 214, 113th Cong. (2013).

<sup>70</sup> *Id.*

million; or (3) the brand company covenants not to sue for patent infringement by the generic product.<sup>71</sup>

#### D. THE CURRENT CLIMATE OF REVERSE PAYMENT DEALS IN THE PHARMACEUTICAL PATENT INDUSTRY

The current pharmaceutical industry environment is ambiguous and volatile. Some courts have found that reverse payment deals are presumptively legal and are not unreasonable restraints on trade, provided that they meet the scope-of-the-patent test.<sup>72</sup> The scope-of-the-patent test has been adopted by the Second, Eleventh, and Federal Circuit Courts.<sup>73</sup> The scope-of-the-patent test does not utilize antitrust scrutiny when examining reverse payment agreements.<sup>74</sup> The test permits reverse payment agreements as long as “(1) the exclusion does not exceed the patent’s scope, (2) the patent holder’s claim of infringement was not objectively baseless, and (3) the patent was not procured by fraud on the [US]PTO.”<sup>75</sup> On the other hand, the Federal Trade Commission has openly criticized reverse payment deals, long calling for courts to find them illegal.<sup>76</sup> The Third Circuit became the first to side with the FTC and, in doing so, has created a split among the courts.<sup>77</sup>

##### 1. *The Stance of the Second Circuit: In re Tamoxifen Citrate Antitrust Litigation.*

a. *Facts and Procedural History.* The rationale behind the scope-of-the-patent test is perhaps best laid out in *In re Tamoxifen Citrate Antitrust Litigation* (*Tamoxifen*) for the purposes of this Note. The Second Circuit ruled in *Tamoxifen* that reverse payment agreements are presumptively legal and do not constitute an illegal restraint on trade unless they fall outside the scope of the patent.<sup>78</sup> The case involved the drug Tamoxifen, which Imperial Chemical Industries, PLC patented on August 20, 1985, and sold through its subsidiary, Zeneca.<sup>79</sup> Tamoxifen was the most prescribed drug for cancer in the world.<sup>80</sup> Four months after the FDA awarded Imperial the patent for Tamoxifen, Barr

<sup>71</sup> *Id.*

<sup>72</sup> *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012).

<sup>73</sup> *Onoe*, *supra* note 7, at 537–38.

<sup>74</sup> *In re K-Dur Antitrust Litig.*, 686 F.3d at 214.

<sup>75</sup> *Id.*; see also *In re Ciproflaxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) (advocating for the scope-of-the-patent test and elaborating on its elements).

<sup>76</sup> See *Fed. Trade Comm’n v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012) (arguing that such reverse payment settlements are unfair and violate federal antitrust laws).

<sup>77</sup> *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

<sup>78</sup> *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006).

<sup>79</sup> *Id.* at 193.

<sup>80</sup> *Id.*

Laboratories, Inc., a generic drug manufacturer, filed an ANDA with the FDA (which was later amended to include a Paragraph IV challenge) in an attempt to market a generic version of Tamoxifen.<sup>81</sup> In response, Imperial filed a patent infringement lawsuit against Barr as well as Barr's raw material supplier in the Southern District of New York.<sup>82</sup> The district court concluded that the patent Imperial held for Tamoxifen was invalid due to its apparent withholding of safety information from the PTO when the patent was filed.<sup>83</sup>

Imperial subsequently appealed the decision to the United States Court of Appeals for the Federal Circuit, after which the parties entered into a private agreement. In the agreement, Zeneca granted Barr a non-exclusive license to sell Zeneca-manufactured Tamoxifen in exchange for \$21 million and Barr agreeing to change its ANDA Paragraph IV challenge to a paragraph III challenge, thereby agreeing that it would not market its own generic version of Tamoxifen until Zeneca's patent expired in 2002.<sup>84</sup> Furthermore, the parties agreed that Zeneca was to pay Heumann, Barr's raw material provider, \$9.5 million up-front and another \$35.9 million over the next ten years. Finally, the parties agreed that if the Tamoxifen patent was found invalid on appeal, Barr would be allowed to revert to a Paragraph IV ANDA challenge.<sup>85</sup>

While other generic drug companies (such as Pharmachemie and Mylan) waged a legal battle to obtain rights to Tamoxifen, Zeneca and Barr were besieged with thirty lawsuits filed by consumers and consumer groups decrying their reverse payment deal.<sup>86</sup> The Judicial Panel on Multidistrict Litigation transferred these lawsuits to the United States District Court for the Eastern District of New York where they were subsequently consolidated into a class action complaint.<sup>87</sup> The plaintiffs in *Tamoxifen*, consumers of the drug and consumer protection groups, claimed that Barr would seek to prevent any other manufacturer from marketing another generic version of Tamoxifen pursuant to its agreement with Zeneca.<sup>88</sup> Indeed, when Imperial's patent on Tamoxifen expired five years later, Barr invoked its right to a 180-day exclusivity period that resulted from its status as the first ANDA filer with a Paragraph IV

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<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.* at 193–94; see also *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 125–26 (E.D.N.Y. 2003).

<sup>85</sup> *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 194 (2d Cir. 2005).

<sup>86</sup> *Id.* at 195, 196.

<sup>87</sup> *Id.* at 196.

<sup>88</sup> *Id.*

challenge, effectively preventing other generic drug companies from marketing their generic copies of Tamoxifen during that period.<sup>89</sup>

The plaintiffs made five allegations: that the reverse payment deal unlawfully

- (1) enabled Zeneca and Barr to resuscitate a patent that the district court had already held to be invalid and unenforceable; (2) facilitated Zeneca's continuing monopolization of the market for Tamoxifen; (3) provided for the sharing of unlawful monopoly profits between Zeneca and Barr; (4) maintained an artificially high price for Tamoxifen; and (5) prevented competition from other generic manufacturers of Tamoxifen.<sup>90</sup>

The District Court granted the defendant's motion to dismiss for failure to state a claim upon which relief could be granted.<sup>91</sup> The District Court concluded that "although market-division agreements between a monopolist and a potential competitor ordinarily violate the Sherman Act, they are not necessarily unlawful when the monopolist is a patent holder."<sup>92</sup> Furthermore, the court reasoned that "a patent holder may settle patent litigation by entering into a licensing agreement with the alleged infringer without running afoul of the Sherman Act," but "a patent holder is prohibited from acting in bad faith 'beyond the limits of the patent monopoly' to restrain or monopolize trade."<sup>93</sup> The district court dismissed all of the plaintiffs' Sherman Act claims as well as their state claims, which alleged antitrust violations of state laws, consumer protection laws, and unfair competition laws.<sup>94</sup> The plaintiffs appealed to the Second Circuit and the defendants filed a motion to transfer the case to the Federal Circuit on the grounds that the Second Circuit lacked jurisdiction to hear patent challenges, typically heard by the Federal Circuit Court.<sup>95</sup> The Second Circuit denied the defendants' motion to transfer and affirmed the decision of the district court.<sup>96</sup>

*b. The Rationale of the Second Circuit Court.* The Second Circuit first rejected the defendants' claim that it lacked jurisdiction.<sup>97</sup> The Federal Circuit has

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<sup>89</sup> *Id.*

<sup>90</sup> *Id.* at 196–97.

<sup>91</sup> *Id.* at 197.

<sup>92</sup> *Id.*; *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 128–29 (E.D.N.Y. 2003).

<sup>93</sup> *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 194, 197 (2d Cir. 2005) (citing *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 128–29 (E.D.N.Y. 2003)).

<sup>94</sup> *Id.* at 198.

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* at 199.

<sup>97</sup> *Id.*

exclusive jurisdiction over cases on appeal from a federal district court under section 1338 of title 28, which states that federal district courts have original and exclusive jurisdiction over “any civil action arising under any Act of Congress relating to patents.”<sup>98</sup> The test for whether a case “arises under” federal patent law is whether “a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff’s right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded complaints.”<sup>99</sup> The Second Circuit concluded that it did, indeed, have jurisdiction because the plaintiffs were not asking it to rule on the validity of the patents involved, but rather on the validity of the reverse payment deal and whether there had been an antitrust violation.<sup>100</sup>

With respect to the plaintiffs’ antitrust claims, the court noted the competing principles between antitrust law and patent law.<sup>101</sup> The court noted that the goal of the Sherman Act was to prevent an entity from “monopol[izing] any part of the trade or commerce among the several States,”<sup>102</sup> while patent law is, in essence, “the right to exclude others from profiting by the patented invention.”<sup>103</sup> The Second Circuit found that the tensions between the underlying principles of these areas of law complicated the appeal.<sup>104</sup>

Interestingly, prior to addressing the plaintiff’s complaint, the court stated that it approached the problem through a lens that encouraged private settlement of disputes.<sup>105</sup> The Court further noted that the Sherman Act does not prevent parties with a patent dispute from settling the matter outside of court.<sup>106</sup> The Second Circuit went on to note that restricting patent settlements may be contrary to the goals of patent law.<sup>107</sup> In support of this notion the court noted that these restrictions would cause an increase in patent litigation,

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<sup>98</sup> 28 U.S.C. § 1338(a); 28 U.S.C. § 1295(a)(1).

<sup>99</sup> *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 199 (2d Cir. 2005) (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988)).

<sup>100</sup> *Id.* at 200.

<sup>101</sup> *Id.* at 201–02.

<sup>102</sup> *Id.* at 201.

<sup>103</sup> *Id.* at 202 (citing 15 U.S.C. § 1; *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980)).

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

<sup>105</sup> *Id.* (“Where a case is complex and expensive, and resolution of the case will benefit the public, the public has a strong interest in settlement.” (quoting *United States v. Glens Falls Newspapers, Inc.*, 160 F.3d 853, 856 (2d Cir. 1998))).

<sup>106</sup> *Id.* (citing *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931)); *cf.* *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001).

<sup>107</sup> *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2d Cir. 2005).

which would “heighten the uncertainty surrounding patents and might delay innovation.”<sup>108</sup> While the Second Circuit recognized that forcing patent litigation to continue could benefit consumers “in some instances,” it found this benefit to be outweighed by the greater efficiencies that patent settlements provide for.<sup>109</sup> The court stated that such settlements allow for the disposal of cases which would otherwise “block or delay” the introduction of “valuable inventions.”<sup>110</sup> In passing, the court also indicated that intent is a critical factor in determining whether such a settlement is illegal.<sup>111</sup> It cited the Fourth Circuit, stating “[i]t is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain or monopolize trade that antitrust violations may occur.”<sup>112</sup>

The Second Circuit also refuted the plaintiffs’ premise that the district court’s ruling that Imperial’s Tamoxifen patent was invalid (*Tamoxifen I*) would have been upheld on review.<sup>113</sup> The court stated that it did not have the power to take into account what the result of *Tamoxifen I* would have been on review because the Federal Circuit Court had exclusive jurisdiction over such patent cases. It also stated that assessing the possible outcome of *Tamoxifen I* on review would be “of limited value” in evaluating the behavior of the parties when entering into the reverse payment agreement.<sup>114</sup> The court found the fact that Zeneca settled after it lost its case to Barr in the district court unpersuasive as the sole argument that the settlement was unlawful.<sup>115</sup>

The Second Circuit then turned to the validity of the reverse payment deal. The court noted that plaintiffs challenging the validity of such agreements need to provide “something more” than just evidence that the deal existed.<sup>116</sup> The plaintiffs claimed that the value of the reverse payments from Zeneca to Barr was significantly greater than the result of Barr’s best case scenario—winning the appeal and marketing its own product—and that the size of the deal, in addition to its existence violated the Sherman Antitrust Act.<sup>117</sup> Despite the

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<sup>108</sup> *Id.* at 203 (citing *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003), *cert. denied*, 125 S. Ct. 308 (2004)).

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

<sup>111</sup> *Id.* at 205.

<sup>112</sup> *Id.* at 203; *Duplan Corp. v. Deering Milliken, Inc.*, 540 F.2d 1215, 1220 (4th Cir. 1976).

<sup>113</sup> *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 203–04; *see also* *Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992).

<sup>114</sup> *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 203–04 (citing *Whitmore v. Arkansas*, 495 U.S. 149, 159–60 (1990)).

<sup>115</sup> *Id.* at 205.

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

<sup>117</sup> *Id.*



specificity of this pleading, however, the Second Circuit nonetheless considered whether the mere existence of a reverse payment deal was legal under the Sherman Antitrust Act.<sup>118</sup> It held that the mere existence of a reverse payment deal did not constitute a per se violation.<sup>119</sup> The Second Circuit cited several reasons for deciding against per se illegality. First, it found that a reverse payment by itself does not turn an otherwise lawful deal into an unlawful one.<sup>120</sup> The court further stated “[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.”<sup>121</sup>

Crucial to the Second Circuit’s decision was the current infrastructure designed to address challenges to pharmaceutical patents—an infrastructure created by the Hatch-Waxman Act.<sup>122</sup> The court quoted a rationale previously articulated by the Eleventh Circuit, stating that the

Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, [the generic challengers] gain[] considerable leverage in patent litigation: the exposure to liability amount[s] to litigation costs, but pale[s] in comparison to the immense volume of generic sales and profits.<sup>123</sup>

Accepting this reasoning, the court was not persuaded to declare reverse payments illegal per se.<sup>124</sup>

Next, the court determined the legality of “excessive” reverse payment deals concluding that even though reverse payment deals may be a natural result of the Hatch-Waxman Act’s infrastructure, they may be illegal in some circumstances.<sup>125</sup> The court reasoned that the deals could be used to mask price-fixing behavior, giving the example of a company that obtains a patent knowing it is likely invalid, that nevertheless sues its competitors and settles the

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<sup>118</sup> *Id.*

<sup>119</sup> *Id.* at 206.

<sup>120</sup> *Id.* (citing *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1309 (11th Cir. 2003)).

<sup>121</sup> *Id.* (quoting *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003)).

<sup>122</sup> *Id.* at 207.

<sup>123</sup> *Id.* (quoting *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005)).

<sup>124</sup> *Id.*

<sup>125</sup> *Id.* at 208.

suit by giving them permission to use the patent in return for assurances that the competitors would not price their product below a certain level.<sup>126</sup> The court admitted that there is something “on the face of [excessive reverse payment deals] that seem[s] ‘suspicious.’”<sup>127</sup> It concluded, however, that this suspicious behavior can be legitimately explained.<sup>128</sup> The Court reasoned that if patent litigation continued and the patent holder lost the suit, in addition to the brand-name manufacturer no longer being the sole producer of the drug on the market, the competition would force the brand-name manufacturer to lower prices, resulting in a further loss of profits.<sup>129</sup> Even though an excessive settlement may indicate that the manufacturer believed it had an invalid patent, the court found that this could not necessarily be concluded due to the inherent risk of loss in any suit.<sup>130</sup>

The court additionally considered a possible rule based on an alternate reading of the antitrust laws, which would outlaw nearly all settlements pertaining to the Hatch-Waxman Act.<sup>131</sup> Ultimately, the court found this reading to be contrary to established principles of law, which encourage settlement in order to obtain greater efficiency, even if it risked upholding monopolies based on weak or invalid patents.<sup>132</sup>

Specifically, the court held that

Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.<sup>133</sup>

Significantly, the Second Circuit applied the scope-of-the-patent test, which reads that “absent an extension of the monopoly beyond the patent’s scope . . . and absent fraud, . . . the question is whether the underlying infringement

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<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

<sup>129</sup> *Id.* at 209.

<sup>130</sup> *Id.* at 209–10.

<sup>131</sup> *Id.* at 212.

<sup>132</sup> *Id.*

<sup>133</sup> *Id.* at 213 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005)).

lawsuit was 'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.'"<sup>134</sup>

The Second Circuit concluded in *In re Tamoxifen Litigation* by holding that the exclusionary effects of the settlement agreement did not exceed the scope of the patent.<sup>135</sup> In support of this conclusion, the court noted that the agreement did not hinder the introduction or marketing of non-infringing drugs.<sup>136</sup> Additionally, the settlement agreement in question signified the conclusion of the litigation between Zeneca and Barr, therefore creating the opportunity for the Tamoxifen patent to be challenged by other generic drug companies (as Barr made it clear that it was not entitled to the 180-day exclusivity period) since the patent was not found to be invalid on appeal.<sup>137</sup> Finally, the Court concluded that the settlement agreement did not completely foreclose the competitive market for Tamoxifen because it still allowed Barr to market Tamoxifen for eight months following the execution of the agreement which, the Court argued, still provided the public with the positive benefits of competition.<sup>138</sup> In conclusion, the Court held that "[i]n the absence of any plausible allegation that the reverse payment provided benefits to Zeneca outside the scope of the [T]amoxifen patent, the plaintiffs have not stated a claim for relief with respect to the [s]ettlement [a]greement."<sup>139</sup>

2. *The Stance of the Third Circuit: In re K-Dur Antitrust Litigation*

a. *Facts and Procedural History.* *In re K-Dur Antitrust Litigation* (K-Dur) concerned a patent for the drug K-Dur 20 patented by the brand-name manufacturer Schering-Plough Corporation (Schering).<sup>140</sup> Upsher was the first generic pharmaceutical manufacturer to apply for the rights to distribute a generic version of K-Dur 20 under the ANDA, filing a Paragraph IV challenge, claiming that its patent did not infringe on Schering's patent because of a difference in the chemical make-up of the coating of its generic.<sup>141</sup> Schering subsequently sued Upsher in the district court of New Jersey, triggering a thirty-

<sup>134</sup> *Id.* (quoting *Proff'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993)).

<sup>135</sup> *Id.*

<sup>136</sup> *Id.* at 213–14 (citing *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 632 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003), *cert. denied, sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939, 125 (2004)).

<sup>137</sup> *Id.* at 214–15 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 200–01 (E.D.N.Y. 2003)).

<sup>138</sup> *Id.* at 215.

<sup>139</sup> *Id.* at 216 (citing *Twombly v. Bell Atl. Corp.*, 425 F.3d 99, 111 (2d Cir. 2005)).

<sup>140</sup> *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 202 (3d Cir. 2012).

<sup>141</sup> *Id.* at 205.

month automatic stay in the FDA's approval of Upsher's generic drug.<sup>142</sup> Just hours before the District Court was expected to rule on the case, the parties reached a settlement.<sup>143</sup> The agreement provided that Upsher, who did not concede that Schering's patent was valid, would nonetheless refrain from introducing its generic for approximately four years, after which it would receive a non-royalty non-exclusive license to market the generic. The agreement additionally provided that Schering would obtain licenses to sell several of Upsher's other products, including Niacor-SR, in exchange for a payment of \$60 million, in addition to other smaller sums based on Schering's future sales.<sup>144</sup> Schering similarly entered into an agreement with ESI Lederle (ESI) another generic company that was also seeking to market a generic version of K-Dur 20.<sup>145</sup> The agreement provided that Schering would provide ESI with a royalty-free license of the K-Dur drug beginning in 2004 in exchange for Schering to pay ESI \$5 million and an additional amount to be determined by the successfulness of ESI's ANDA claim.<sup>146</sup> The agreement further provided that ESI did not plan on developing any other similar drug.<sup>147</sup>

In March of 2001, the FTC filed a complaint against Schering, Upsher, and ESI alleging that they violated Section 5 of the Federal Trade Commission Act.<sup>148</sup> The *K-Dur* plaintiffs alleged that the sale of the license to market Niacor-SR was merely a pretext and that the \$60 million was in exchange for the promise to keep the generic drug off the market.<sup>149</sup> The FTC claimed that the settlement agreement between the parties delayed the introduction of the generic drug into the market and improperly extended Schering's monopoly of the K-Dur 20 patent.<sup>150</sup> In June of 2002, the Administrative Law Judge dismissed the FTC claim after a lengthy trial, finding that the licensing provision in the agreement were separately valued and the consideration was thus not a payment to delay generic entry.<sup>151</sup> In December, 2003, the FTC Commissioners, who are responsible for reviewing administrative law judge's opinions, reversed the judge's decision dismissing the FTC's complaint, holding that there was a "direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry" and that this agreement 'unreasonably

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<sup>142</sup> *Id.*

<sup>143</sup> *Id.*

<sup>144</sup> *Id.* at 206.

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*; 15 U.S.C. § 45.

<sup>149</sup> *In re K-Dur Antitrust Litig.*, 686 F.3d at 206.

<sup>150</sup> *Id.* at 197, 206–07.

<sup>151</sup> *Id.*

restrain[ed] commerce.’”<sup>152</sup> This decision was subsequently considered an appeal.

*b. The Rationale of the Third Circuit Court.* In its ruling, the Third Circuit rejected the scope-of-the-patent test.<sup>153</sup> It argued that the scope-of-the-patent test “improperly restricts the application of antitrust law and is contrary to the policies underlying the Hatch–Waxman Act as well as a long line of Supreme Court precedent on patent litigation and competition.”<sup>154</sup> The Third Circuit gave several reasons for refuting the scope-of-the-patent test.<sup>155</sup> First, the court claimed that the test had an “almost unrebuttable presumption of patent validity.”<sup>156</sup> The court noted that the test essentially resulted in a court enforcing a presumption that the patent holder would have won the suit, a policy which it found to be unsupported by patent law.<sup>157</sup> The court admitted that the same presumption exists when one challenges the validity of a patent, but argued that it was a procedural right, not a substantive right, and that it should not be used in this context.<sup>158</sup> Furthermore, the court noted that in patent infringement cases, as opposed to patent validity cases, “the patent holder bears the burden of showing infringement.”<sup>159</sup> Lastly, the court pointed out that such an unrebuttable presumption contradicts many of the actual outcomes of challenges under the Hatch–Waxman Act.<sup>160</sup> Indeed, it stated that a patent is simply a “legal conclusion reached by the Patent Office,”<sup>161</sup> and that under the Hatch–Waxman Act, Paragraph IV patent challenges have been successful “seventy-three percent of the time” (as of 2002).<sup>162</sup>

Second, the Third Circuit found fault with the Second Circuit’s reasoning that the subsequent challenges by other generic drug companies would effectively reject weak patents preserved by reverse payments.<sup>163</sup> The court noted that the first generic challenger had the greatest incentive because it alone

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<sup>152</sup> *Id.* at 207 (quoting *In re Schering–Plough Corp.*, Final Order, 136 F.T.C. 956, 1052 (2003)).

<sup>153</sup> *Id.* at 214.

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

<sup>156</sup> *Id.*

<sup>157</sup> *Id.*

<sup>158</sup> *Id.* (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983)).

<sup>159</sup> *Id.* (citing *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008)).

<sup>160</sup> *Id.* at 214–15.

<sup>161</sup> *Id.* at 215.

<sup>162</sup> *Id.* (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969) (citing Fed. Trade Comm’n, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* 17

16 (2002), available at [http://www.ftc.gov/os/2002/07/genericdrug\\_study.pdf](http://www.ftc.gov/os/2002/07/genericdrug_study.pdf))).

<sup>163</sup> *Id.*

would receive the 180-day period of exclusivity.<sup>164</sup> Also, the monopolistic nature of the drug marketing system provided sufficient revenue to “pay off” multiple generic companies, thereby preserving the patent’s validity (and its monopoly) despite its likely invalidity.<sup>165</sup>

The Third Circuit further claimed that Supreme Court precedent supported this argument.<sup>166</sup> The court noted that the Supreme Court recognized that “valid patents are a limited exception to a general rule of the free exploitation of ideas” and that it could therefore be reasoned that “public interest supports judicial testing and elimination of weak patents.”<sup>167</sup> The court claimed that this philosophy was supported by the Supreme Court’s holding in *Edward Katzinger Co. v. Chicago Metallic Manufacturing Co. (Katzinger)*.<sup>168</sup> *Katzinger* concerned an action for a declaratory judgment relating to the alleged invalidity and infringement of a patent.<sup>169</sup> The Court stated that a price-fixing provision in a contract based on an invalid patent would serve to violate antitrust law because the licensor would be estopped from bringing a challenge to the patent.<sup>170</sup> The *Katzinger* Court emphasized the great importance that the public interest plays in the patent system, highlighting the broad public interest in freeing our competitive economy from the trade restraints which might be imposed by price-fixing agreements stemming from narrow or invalid patents.” The court continued:

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<sup>164</sup> *Id.*

<sup>165</sup> *Id.* (“[D]rug manufacturer settled infringement suits by four generic firms, which agreed to delay market entry ‘in exchange for significant payments . . . for various licensing agreements, supply agreements and research and development deals.’” (citing *King Drug Co. of Florence*, 702 F. Supp. 2d at 521–22)).

<sup>166</sup> *Id.* at 215–16.

<sup>167</sup> *Id.* (explaining the “importance to the public at large of resolving questions of patent validity” and noting the danger of “grant[ing] monopoly privileges to the holders of invalid patents”) (citing *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 100–01 (1993)); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (noting that the patent laws embody “a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy”); *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) (“A patent affords no immunity for a monopoly not fairly or plainly within the grant. . . . [S]ince patents are privileges restrictive of a free economy, the rights which Congress has attached to them must be strictly construed . . . .”); *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234, 12 S. Ct. 632, 36 L. Ed. 414 (1892) (“It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly . . . .”).

<sup>168</sup> *In re K-Dur Antitrust Litig.*, 686 F.3d at 216.

<sup>169</sup> *Katzinger Co. v. Chi. Metallic Mfg. Co.*, 329 U.S. 394 (1947).

<sup>170</sup> *Id.*

It is the public interest which is dominant in the patent system and . . . the right to challenge [a patent] is not only a private right to the individual, but it is founded on public policy which is promoted by his making the defence, and contravened by his refusal to make it.<sup>171</sup>

The Third Circuit found this reasoning applicable to the reverse payment practice because the deals allow for a duopoly of competitors without a guarantee that the patent underlying the product is valid.<sup>172</sup> The court asserted that the scope-of-the-patent test failed to account for these principles of patent law previously outlined by the Supreme Court.<sup>173</sup>

The Third Circuit also addressed the Congressional intent for the Hatch-Waxman Act.<sup>174</sup> It recognized that Congress intended the Hatch-Waxman Act to strike a delicate balance between protecting intellectual property and allowing competition.<sup>175</sup> The Third Circuit concluded that the antitrust analysis of reverse payments under a rule of reason test was more in line with the balance that Congress sought to create with the Hatch-Waxman legislation than the scope-of-the-patent test.<sup>176</sup>

The Third Circuit admitted that the scope-of-the-patent test promoted settlements, which are judicially “laudable,” but found that the general preference for settlement is superseded in this instance by the countervailing public policy that was set forth by Congress: “that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers.”<sup>177</sup> The Third Circuit further argued that a rule of reason test did not diminish the parties’ ability to reach settlements concerning a negotiated entry date for marketing the generic.<sup>178</sup> The court made it clear that the ruling in this case pertained specifically to settlements involving a reverse

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<sup>171</sup> *Id.* at 401.

<sup>172</sup> *In re K-Dur Antitrust Litig.*, 686 F.3d at 216 (suggesting an agreement might be anticompetitive if it “give[s] potential competitors incentives to remain in cartels rather than turning to another product, inventing around the patent, or challenging its validity” (citing *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1136 (D.C. Cir. 1981))).

<sup>173</sup> *Id.*

<sup>174</sup> *Id.* at 216–17.

<sup>175</sup> *Id.* at 217 (citing 130 CONG. REC. 24,425 (Sept. 6, 1984)); H.R. REP. NO. 98-857, pt. 2, at 30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2713 (emphasizing that the bill achieves “what the Congress has traditionally done in the area of intellectual property law[.] balance the need to stimulate innovation against the goal of furthering the public interest”).

<sup>176</sup> *In re K-Dur Antitrust Litig.*, 686 F.3d at 217.

<sup>177</sup> *Id.*

<sup>178</sup> *Id.* at 217–18.

payment from the name brand manufacturer to the generic drug company, which, according to the FTC, would not affect the vast majority of pharmaceutical patent settlements.<sup>179</sup>

The Third Circuit then explained its proposal for use of the “quick look” rule of reason analysis.<sup>180</sup> This abbreviated rule of reason test would be “based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties.”<sup>181</sup> The court went a step further, insisting that courts find that any agreement involving a payment from the patent holder to the potential patent infringer for the purpose of delaying a generic’s entry into the market constitutes *prima facie* evidence of an unreasonable restraint on trade.<sup>182</sup> This *prima facie* presumption could be rebutted by showing that the payment “(1) was for a purpose other than delayed entry of a generic drug or (2) offers some pro-competitive benefit.”<sup>183</sup> The court explained that this exception allows for those “probably rare” situations where a reverse payment could serve to increase competition.<sup>184</sup> As an example, the court described a situation in which a small payment is made to a needy generic manufacturer so it can market a generic to avoid bankruptcy.<sup>185</sup> The Third Circuit agreed with the FTC that the court did not need to consider the underlying merits of the patent suit because “[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.”<sup>186</sup> In light of the above arguments and analysis, the Third Circuit reversed the decision of the District Court and became the first circuit court to reject the scope-of-the-patent test and find reverse payments *prima facie* evidence of an illegal restraint on trade.<sup>187</sup>

3. *Supreme Court Response.* The circuit split regarding treatment of reverse payment deals and corresponding appeals from various circuits created a rather unique set of options available to the United States Supreme Court when choosing which case it would hear on the issue. The procedural history and

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<sup>179</sup> *Id.* at 218 (citing FTC, Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2010*, 2 (2011) (showing that nearly 75% of Hatch–Waxman Act infringement suits that settled in 2010 did so without reverse payments)).

<sup>180</sup> *Id.*

<sup>181</sup> *Id.*

<sup>182</sup> *Id.*

<sup>183</sup> *Id.*

<sup>184</sup> *Id.*

<sup>185</sup> *Id.*

<sup>186</sup> *Id.* (quoting *In re Schering–Plough Corp.*, Final Order, 136 Fed. Trade Comm’n at 988).

<sup>187</sup> *Id.*



factual background of the underlying cases provided a myriad of related issues and varying party plaintiffs. In the end, it decided to grant certiorari to *Watson*, an FTC challenge to a reverse payment deal.<sup>188</sup>

*Watson* involved a prescription drug called AndroGel, a product developed by Besins Healthcare, S.A. (Besins) and distributed by Solvay Pharmaceuticals, Inc. (Solvay), to treat low testosterone in men.<sup>189</sup> Two generic manufacturers, Watson Pharmaceuticals, Inc. (Watson) and Paddock Laboratories, Inc. (Paddock) filed Paragraph IV challenges to the AndroGel patent.<sup>190</sup> In response, Solvay instituted a patent infringement action, which was ultimately settled by a reverse payment agreement.<sup>191</sup> In addition to several other terms, the agreement provided that the generic drug companies would refrain from marketing their generic versions of AndroGel until August 31, 2015 in exchange for multimillion dollar yearly payments from Solvay.<sup>192</sup> The FTC subsequently filed a complaint, alleging that the deal constituted an illegal restraint on trade.<sup>193</sup> The Eleventh Circuit adopted the scope-of-the-patent test and, in doing so, found that the FTC's complaint failed to state a plausible antitrust claim.<sup>194</sup>

The Supreme Court recently denied the petition of a case that dealt with the legality of reverse payment deals.<sup>195</sup> The case, decided as *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, held that reverse payment deals were presumptively legal and endorsed the scope-of-the-patent test, adding intrigue as to how the Supreme Court will rule on the legality of reverse payment deals in *Watson*. The denial of certiorari could indicate approval of the scope-of-the-patent test as the Court passed on this opportunity to reject it.<sup>196</sup>

Prior to granting certiorari to *Watson*, the U.S. Supreme Court could have chosen from two other petitions for writs of certiorari. In *In re K-Dur* (K-Dur), the successor-in-interest of the brand-name manufacturer filed for a writ of certiorari.<sup>197</sup> It was only after this filing that the FTC followed suit and appealed the ruling in *Watson* to the Eleventh Circuit.<sup>198</sup> It is also notable that

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<sup>188</sup> *Watson*, 677 F.3d at 1298.

<sup>189</sup> *Id.* at 1303–04.

<sup>190</sup> *Id.* at 1304.

<sup>191</sup> *Id.* at 1304–05.

<sup>192</sup> *Id.* at 1305.

<sup>193</sup> *Id.* at 1301.

<sup>194</sup> *Id.* at 1312.

<sup>195</sup> *Louisiana Wholesale Drug Co. v. Bayer AG*, 131 S. Ct. 1606 (2011).

<sup>196</sup> *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).

<sup>197</sup> *In re K-Dur*, 686 F.3d at 197.

<sup>198</sup> *Watson*, 677 F.3d at 1298; Alison Frankel, *FTC cert petition puts SCOTUS in pay-for-delay pickle*, THOMSON REUTERS NEWS & INSIGHT (Oct. 5, 2012), <http://newsandinsight.thomsonreuters.com>.

the Supreme Court did not decide to rule on both of these cases, a rare (but not unheard-of) circumstance.<sup>199</sup>

By filing the writ of certiorari for *Watson*, the FTC hopes to take control of the manner in which the Supreme Court rules on reverse payment deals. The FTC provided the Supreme Court with a rationale as to why it should grant the writ of certiorari for *Watson* instead of *K-Dur*, asserting several key points.<sup>200</sup> The FTC stated that the *K-Dur* case concerned private litigation, whereas *Watson* was brought by a federal agency given a mandate by Congress to investigate illegal restraints on trade.<sup>201</sup> Further, the FTC claimed that the Supreme Court would benefit from its expertise in the field of consumer protection litigation.<sup>202</sup> Furthermore, Thomas Rosch, a commissioner of the FTC, claimed that *Watson* provided a clearer presentation of the issue than *K-Dur* because it was decided on a motion to dismiss, which “presents a core issue of law,” rather than on a motion for summary judgment, as was the case in *K-Dur*.<sup>203</sup> Furthermore, the remedy sought in *K-Dur* is only retrospective in nature, while *Watson* involves a patent that has not expired yet and therefore presents the possibility of an injunction.<sup>204</sup> Perhaps most importantly, however, unlike *K-Dur*, *Watson* raises the question of both patent validity and infringement.<sup>205</sup> It is notable that the Supreme Court decided not to take up *K-Dur*, since it is the first case in which a federal circuit court has ruled that pay-for-delay deals are presumptively illegal.<sup>206</sup> The Supreme Court’s decision indicates that it does not believe that *K-Dur* provides a better vessel for addressing the arguments against the scope-of-the-patent test voiced by the Third Circuit.<sup>207</sup>

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com/Legal/News/ViewNews.aspx?id=58471&terms=%40ReutersTopicCodes+CONTAINS+'ANV'.

<sup>199</sup> Frankel, *supra* note 198.

<sup>200</sup> *Id.*

<sup>201</sup> *Id.*

<sup>202</sup> *Id.*

<sup>203</sup> Rosch, *supra* note 3.

<sup>204</sup> Frankel, *supra* note 198.

<sup>205</sup> *Id.*; Jillian Centanni, *Supreme Court to Examine Pay-For-Delay Settlements*, GIBBONS (Dec. 17, 2012), <http://www.iplawalert.com/2012/12/articles/patent-1/supreme-court-to-examine-payfordelay-settlements/>.

<sup>206</sup> *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 218 (3d Cir. 2012).

<sup>207</sup> Alison Frankel, *FTC cert petition puts SCOTUS in pay-for-delay pickle*, THOMSON REUTERS NEWS & INSIGHT (Oct. 5, 2012), <http://newsandinsight.thomsonreuters.com/Legal/News/ViewNews.aspx?id=58471&terms=%40ReutersTopicCodes+CONTAINS+'ANV'>.

## III. ANALYSIS

This section first provides for the necessary components for a successful test for judicial scrutiny of reverse payment deals, taking into account the judicial reasoning found in *Tamoxifen* and *K-Dur*. Secondly, a new test is proposed, called the “Modified Scope-of-the-Patent Test” (MSPT).

## A. THE INGREDIENTS OF A SUCCESSFUL SOLUTION TO THE REVERSE PAYMENT PROBLEM

The four components necessary for a successful reverse payment test are the: (1) protection of intellectual property, (2) promotion of competition, (3) assurance of patent validity, and (4) promotion of consumer interest.

The first two components, protection of intellectual property and the promotion of competition, in many ways oppose one another. Indeed, in *K-Dur* the Third Circuit stated that the optimal solution for the problem that reverse payment agreements pose should strike a delicate balance between the need for protection of intellectual property and the need for competition.<sup>208</sup> On the one hand, the Court must respect the wishes of pharmaceutical patent holders as owners of property, who have the right to use their property in the way they see fit to the exclusion of others. On the other hand, the protection of the pharmaceutical patent industry and consumers provides incentive to challenge invalid patents as they both hamper the pharmaceutical market and cost consumers a great deal due to legal monopolies or duopolies.<sup>209</sup> Furthermore, the effects on competition must be fully examined. Treating reverse payments as prima facie evidence of a restraint on trade has the potential to promote competition by ensuring that invalid patents do not lead to monopolies or duopolies in the pharmaceutical patent industry. However, the quick look rule of reason test may have unintended negative effects on competition as well. Reverse payment deals have become a fallback mechanism that brand-name manufacturers use to ensure continued profits on newly-developed drugs. If this fallback mechanism is taken away, brand-name manufacturers may be less inclined to spend the vast amounts of money and resources necessary to create new drugs. This lack of incentive could end up hurting competition more than helping it. Therefore, the first two necessary ingredients, protection of intellectual property and promotion of competition,

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<sup>208</sup> See *id.* at 216–17 (referencing 130 CONG. REC. 24425 (Sept. 6, 1984) (statement of Rep. Waxman underscoring the “fundamental balance of the bill”)); H.R. REP. NO. 98–857, pt. 2, at 30 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2713.

<sup>209</sup> *In re K-Dur Antitrust Litig.*, 686 F.3d at 216.

must be delicately balanced and must take into consideration the future consequences of the chosen test.

The third component is assurance of patent validity. When considering this component, it is important to keep in mind that the actual assessment of a patent's validity falls outside of the scope of a test that is related to reverse payment deals under a traditional antitrust analysis. However, the test that the Supreme Court ultimately accepts will have an impact on how many potentially invalid patents are allowed to survive. For instance, as the *K-Dur* court pointed out, the scope-of-the-patent test utilizes a presumption that the patent in question is valid, which may result in the preservation of patents that are actually invalid.<sup>210</sup> The quick look rule of reason test articulated in *K-Dur*, on the other hand, treats reverse payment deals as prima facie evidence of an illegal restraint on trade, thereby disallowing brand-name manufacturers from using reverse payment deals to protect invalid patents.<sup>211</sup> How the Supreme Court approaches the threat of patent invalidity will greatly influence which test it will choose to utilize. If it finds the threat of invalid patents to be a superseding issue, as the *K-Dur* court did, it may choose to adopt the quick look rule of reason test.<sup>212</sup> If the Supreme Court finds that the threat of invalid patents is superseded by another one of these components, however, it may endorse a test similar to the scope-of-the-patent test, which emphasizes preservation of intellectual property through its presumption of patent validity.<sup>213</sup>

Consideration of consumer interest is the final necessary component for a successful reverse payment test. In a pharmaceutical setting, consumers prefer low cost drugs in order to maximize their buying power. Consumer interest is served when the market is flooded with products, which then drives down the cost. The scope-of-the-patent test's presumption of validity allows monopolies and duopolies to form due to the dealmakers' agreement of exclusivity. This reduction of competition among manufacturers drives up prices for consumers. The Third Circuit's quick look rule of reason analysis is more beneficial for consumers in this respect because it views reverse payment deals as prima facie evidence of a restraint on trade. This prevents brand-name manufacturers from extending their exclusive license of their product by making deals with generic manufacturers, who would otherwise sell the product for a lower price.

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<sup>210</sup> *Id.* at 214.

<sup>211</sup> *Id.* at 218.

<sup>212</sup> *Id.* at 216 (citing *Edward Katzinger Co. v. Chi. Metallic Mfg. Co.*, 329 U.S. 394, 399 (1947)).

<sup>213</sup> *Id.* at 214.

## B. A PROPOSAL FOR A NEW TEST CONCERNING THE LEGALITY OF REVERSE PAYMENT AGREEMENTS

The *Tamoxifen* and *K-Dur* courts provide different rationales, which can be used to evaluate potential reverse payment tests. The scope-of-the-patent test has received the most widespread approval thus far, having been endorsed by the Second, Eleventh and Federal Circuits.<sup>214</sup> The Third Circuit utilized the less popular quick look rule of reason test. Considering the benefits and pitfalls of both tests, this Note proposes a test that may be better suited to meeting the underlying public policy needs of the pharmaceutical patent system.

The proposed model test is called the Modified Scope-of-the-Patent Test (MSPT). As its name implies, it is a variation on the scope-of-the-patent test. The decision to use the framework of the scope-of-the-patent test was a relatively simple one. The scope-of-the-patent test has been widely adopted in federal circuit courts, having been endorsed by the Second, Eleventh, and Federal Circuits.<sup>215</sup> Furthermore, the Supreme Court previously declined an opportunity to review the test in *Louisiana Wholesale Drug Co.*, indicating that it may favor the test,<sup>216</sup> and granted certiorari to *Watson* rather than *K-Dur*, providing further support of this conclusion. With this widespread implementation of the scope-of-the-patent test in mind, it seemed prudent to use it as a basis for a solution to the reverse payment issue.

However, the *K-Dur* Court articulated several valid criticisms against the scope-of-the-patent test. Specifically, two main arguments were made: (1) the test did not take into account the economic realities of the pharmaceutical patent industry; and (2) the test was overly protective of patents, and therefore protected potentially invalid patents.<sup>217</sup> Fortunately, a simple modification to the scope-of-the-patent test could address these concerns and provide a compromise among the positions of the Third Circuit and the Second, Eleventh and Federal Circuits. The MSPT proposes adding a fourth element to the scope-of-the-patent test in which a court would use a balancing test to decide whether the possible anti-competitive effect of the agreement outweighs the need for protection of intellectual property. The MSPT would be as follows: a reverse agreement is allowed as long as “(1) the exclusion does not exceed the patent’s scope, (2) the patent holder’s claim of infringement was not objectively

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<sup>214</sup> *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213; Fed. Trade Comm’n v. *Watson Pharm., Inc.*, 677 F.3d 1298, 1308 (11th Cir. 2012); Onoe, *supra* note 8, at 538.

<sup>215</sup> *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005); Fed. Trade Comm’n v. *Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012).

<sup>216</sup> *Louisiana Wholesale Drug Co. v. Bayer AG*, 131 S. Ct. 1606 (2011).

<sup>217</sup> *In re K-Dur*, 686 F.3d at 216–18.

baseless, [ ] (3) the patent was not procured by fraud on the PTO,” and (4) the possible anti-competitive effect of the agreement does not outweigh the need for protection of intellectual property.<sup>218</sup>

This method has several advantages over other choices. First, as mentioned above, it utilizes the pre-existing framework of the predominant reverse payment test. The Supreme Court could easily adopt such an approach in its *Watson* decision. This would avoid the uncertain results of a completely new test. The effects of the scope-of-the-patent test have already been observed; thus, it is easier to project the legal ramifications of modification of the scope-of-the-patent test than for a new test. In terms of the four essential ingredients of a successful reverse payment test ((1) protection of intellectual property; (2) promotion of competition; (3) assurance of patent validity; and (4) consumer interest), the test provides for a satisfactory response for each.

Considering the protection of intellectual property, the MSPT preserves the presumption of patent validity, used by the scope-of-the-patent test. This presumption provides a greater feeling of security to patent holders, and is in line with the general legal policy of protecting intellectual property.<sup>219</sup> Furthermore, greater patent security could serve to provide better incentives for brand-name manufacturers to invest in developing new pharmaceuticals because the presumption would allow them to be more confident in defending their patents.

The concern for the protection of intellectual property is often tempered by the concern for healthy competition in the marketplace. The MSPT accommodates both. The fourth element of the MSPT provides for a safety net where there is sufficient evidence to indicate that a reverse payment deal could be considered an illegal restraint on trade. This provides a clear protection for competition as it allows a court to engage in a quick look analysis of a reverse payment case, yet still accounts for the impact of the trade on competition. The *K-Dur* court criticized the scope-of-the-patent test for failing to take into account the “economic realities” of the cases in which it was used.<sup>220</sup> The fourth element of the MSPT does just that by providing an economic context for the analysis.

In terms of the assurance of patent validity, the MSPT does not provide any additional means to further examine patent validity. It does, however, filter out reverse payment deals that could have a significant effect on the pharmaceutical

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<sup>218</sup> *Id.* at 214 (citing *King Drug Co. of Florence v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 528–29, 533 (E.D. Pa. 2010)).

<sup>219</sup> Posner, *supra* note 1.

<sup>220</sup> *In re K-Dur Antitrust Litig.*, 686 F.3d at 218.

patent market. Thus, the fourth element of the MSPT “catches” any high-profile deals that might conceal a potentially invalid patent. The approach does allow for deals that conceal possibly invalid patents if the deal’s effect on competition is minimal. However, if a deal has only a minimal restraint on trade, then the public interest in revealing that invalidity may be mitigated in a case in which the deal has no substantial restraint on trade.

Finally, the MSPT is consistent with consumer interest. By catching deals that would result in a significant restraint on trade, the MSPT would prevent a market environment that naturally leads to monopolies and duopolies. On the other hand, the test allows for deals that would not result in a substantial restraint on trade. As mentioned above, this allows for brand-name manufacturers to have confidence in a means of protection for their patents, and therefore, in the resources they invest in developing a particular drug.

One potential criticism of the MSPT is that, accepting the reasoning of the FTC, almost every reverse payment deal is a restraint on trade.<sup>221</sup> Even if the Supreme Court does not accept the reasoning of the *K-Dur* Court, every reverse payment deal has characteristics of a restraint on trade: they are deals that essentially prolong a monopoly or duopoly.<sup>222</sup> This is a valid criticism. The MSPT will force courts to decide where to draw the line between a reverse payment deal that has a minimal impact on trade and deals that have a significant restraint on trade. With this in mind, it is recommended that courts take into account four different factors: (1) the amount of money or other consideration involved in the deal; (2) the potential market share of the drug; (3) how critical the need is for the drug (whether a monopoly could produce widespread harm); and (4) the potential of the drug being pursued and marketed by another generic company.

In closing, the MSPT provides for the protection of intellectual property, promotion of competition, assurance of patent validity, and protection of consumer interest. The test may not satisfy ardent supporters of the reasoning of the Second, Third, Eleventh, and Federal Circuits, but it is a solution that finds some middle ground, and has the ingredients necessary for a successful reverse payment test. Furthermore, the test is simply a modification of the prevailing test, and could thus be easily implemented. For these reasons, I recommend that the Supreme Court adopt the MSPT in its forthcoming opinion.

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<sup>221</sup> Rosch, *supra* note 3, at 13.

<sup>222</sup> Kesselheim et al., *supra* note 5, at 1440.

## IV. CONCLUSION

In conclusion, there is a controversy between the circuit courts about the legality of reverse payment agreements. The Second, Eleventh, and Federal Circuit Courts regard such agreements as presumptively valid as long as it does not violate the scope-of-the-patent test. The Third Circuit disagrees with this approach and finds the agreements *prima facie* evidence of a restraint on trade. The Third Circuit subjects the agreements to antitrust scrutiny by way of the quick look rule of reason analysis.

The Supreme Court heard arguments for and against the scope-of-the-patent test on March 25, 2013. The pending opinion will presumably rule on the appropriateness of the scope-of-the-patent test as opposed to the quick look rule of reason analysis.

This Note proposes that the Supreme Court should take into account four concerns when formulating a response to this issue. First, the protection of the intellectual property rights of patent holders must be preserved. Second, competition should be promoted within the pharmaceutical patent industry. Third, a test should provide assurance of pharmaceutical patent validity in order to promote competition. Finally, consumer interest and the cost of pharmaceuticals should be taken into account in order to provide access to needed drugs.

This Note also proposes a new test to analyze reverse payment agreements, called the Modified Scope-of-the-Patent Test. This test takes into account the aforementioned concerns and tries to find a middle-ground between the stances of the Second, Eleventh and Federal Circuits and the Third Circuit. It adds a fourth requirement to the existing scope-of-the-patent test, requiring courts to engage in a balancing test as to whether the possible anti-competitive effect of the agreement outweighs the need for protection of intellectual property. For the above reasons, I recommend that the Supreme Court adopt the Modified Scope-of-the-Patent Test.



