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I. INTRODUCTION

[1] Big Brand Name develops and files a patent for a drug that kills bacteria in an innovative way. The drug is groundbreaking and potentially marketable, so Big Brand Name incurs the enormous cost (estimated at $868 million) and time of drug discovery research and safety determinations of clinical trials to bring the drug to market.[1] Small Generic Company wants to sell the same drug but must wait until Big Brand Name's patent expires or, in the alternative, Small Generic Company can file an Abbreviated New Drug Application ("ANDA") with the FDA and allege Big Brand Name's patent is invalid or the patent does not cover Small Generic Company's Drug.[2] Filing an ANDA application is an attractive option for Small Generic Company because it can market and sell the same drug for a fraction of Big Brand Name's development

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[1] *See* Christopher Adams & Van Brantner, *Estimating the Cost of New Drug Development: Is it Really $802 Million?*, 25 HEALTH AFFAIRS 420, 420, 424 (2006).

[2] *See* Andrew A. Caffrey, III & Jonathan M. Rotter, *Consumer Protection, Patents and Procedure: Generic Drug Market Entry and the Need to Reform the Hatch-Waxman Act*, 9 VA. J.L. & TECH. 1, 6–7 (2004).

and clinical trial cost.[3] Thus, Small Generic Company files an ANDA application, stating the relevant patent (Big Brand Name's patent) is invalid or their drug does not infringe the relevant patent.[4] The ANDA application allows Small Generic Company to bypass the expensive clinical trials.[5]

[2] The ANDA application filed by Small Generic Company provides Big Brand Name with standing to sue for patent infringement.[6] Big Brand Name files suit.[7] Small Generic Company files a counter-claim asserting Big Brand Name's patent is invalid. Instead of risking Big Brand Name's patent and loss of its temporary monopoly on the drug and the accompanying large profits, Big Brand Name pays Small Generic Company nearly $400 million to drop their invalidity counter-claim and refrain from entering the market.[8] Big Brand Name would rather share some of its monopoly profits with Small Generic Company and keep competition at bay than risk the invalidity of its patent and the end of its monopoly profits. Interestingly, Small Generic Company may have only earned $200 million from marketing and selling the drug on its own.[9]

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[3] *See id.* at 6.

[4] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006); *see, e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1328 (Fed. Cir. 2008).

[5] *See* FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, 5 (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

[6] *See* 35 U.S.C. § 271(e)(2) (2006).

[7] If Big Brand Name does not file suit within forty-five days of the ANDA filing date, then Big Brand Name does not trigger the 30-month stay provision preventing FDA approval of Small Generic's ANDA application. *See* 21 U.S.C. § 355(c)(3)(C) (2006).

[8] *See, e.g.*, Petition for Writ of Certiorari, Louisiana Wholesale Drug Co. v. Bayer AG, 131 S. Ct. 1606 (2011) (No. 10-762), 2010 WL 5014323 *7-8; *In re Ciprofloxacin*, 544 F.3d at 1329 & n.5.

[9] *See* Petition for Writ of Certiorari, *Louisiana Wholesale Drug Co., Inc.*, 131 S. Ct 1606 (No. 10-762), 2010 WL 5014323 *7-8.

Therefore, Small Generic Company earned $298 million more by settling than it could from selling the drug.[10]

[3] This can result in an interesting predicament—a generic pharmaceutical company obtaining more money from a lawsuit settlement than the same company could stand to earn from manufacturing and selling the drug.[11] Scholars and practitioners call this a reverse payment because Big Brand Name originally sued Small Generic Company as the plaintiff.[12] In most litigation settlements, the defendant pays the plaintiff to drop the suit.[13] This is the reverse situation—the plaintiff, Big Brand Name, pays the defendant, Small Generic Company, to drop the counter-claim.[14] As part of the settlement, the generic company agrees to not enter the market with the drug until the brand name company's patent expires.[15]

[4] This type of settlement is troubling because Congress's purpose in enacting the ANDA legislation was to encourage competition in the pharmaceutical realm, not stifle it.[16] Generic drug companies are market competitors with brand name drug companies in the pharmaceutical

[10] *See id.*

[11] *See id.*

[12] *See* Christopher Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 494 (2007) (defining reverse payments as "a variety of diverse patent settlement agreements that involve a transfer of consideration from the patent owner to the alleged infringer . . . [T]he patent owner agrees to provide some compensation to the alleged infringer, and the alleged infringer agrees to delay developing or marketing a product").

[13] *See id.*

[14] *See, e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1328–29 (Fed. Cir. 2008) (explaining the patent owner paid the alleged infringer and generic company $398.1 million to drop its counter-claim and delay entry into the market).

[15] *See id.*

[16] H.R. REP. NO. 98-857(I), at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48.

market. Generic companies must enter the market to compete. Congress tried to encourage more generic companies to enter the market by providing two significant incentives: a faster approval system for pharmaceutical competitors marketing previously approved FDA drugs[17] and the reward of a temporary monopoly to the first generic filer that challenges a bad patent through this faster filing process.[18] However, Congress's competitive purpose is thwarted by the reverse payment settlements because it involves generic companies agreeing to not enter the market. Worst yet, when reverse payments are combined with the 180-day exclusivity provision, other potential competitors are prevented from entering the market.[19]

[5] This article identifies two problems with reverse payment settlements. One problem stems from Congress's well-intended, but incomplete, incentives from the Hatch-Waxman Act.[20] One incentive intended to encourage competition between brand name companies and generic companies may actually prevent competition when companies enter reverse payment agreements. The second problem is with the courts' analyses of reverse payment agreements. The courts' analyses of reverse payment agreements are inconsistent, and some are misguided.[21]

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[17] *Compare* 21 U.S.C. § 355(b)(1) (2006) (explaining that a drug under the new drug application must show, among many other things, full reports of investigations whether the drug is safe and effective), *with* 21 U.S.C. § 355(j)(2)(A) (stating that a drug under the abbreviated new drug application must show that it has the same active ingredient as a previously approved drug).

[18] *See* 21 U.S.C. § 355(j)(5)(b)(iv).

[19] *See* Holman, *supra* note 12, at 494.

[20] *See* C. Scott Hemphill & Mark A. Lemley, 77 ANTITRUST L.J. 947, 947–48 (2011) (describing why the Hatch-Waxman Act's quasi-exclusive rights are insufficient incentives for holders of generic patents).

[21] *See, e.g., In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 900 (6th Cir. 2003) (this author believes that the Sixth Circuit's holding that the plaintiff's decision to enter into a reverse payment agreement means the patent is *per se* invalid is not the right determination or analysis for reverse payment cases).

[6] To ensure that the proper balance of competition and innovation thrives in the pharmaceutical industry, Congress must address both problems. Congress must amend the Hatch-Waxman Act to provide proper incentives to qualifying generic companies, which would prevent many reverse payments from forming. Specifically, Congress needs to reward a second generic patent challenger with a temporary monopoly incentive if the first fails to utilize the incentive. In addition, Congress must detail a uniform reverse payment agreement analysis to properly determine whether reverse payment agreements are anticompetitive. Without an amendment to the Hatch-Waxman Act removing an unintended approval roadblock for generic drug competitors, many anticompetitive reverse payment agreements will continue to form. Without a proper uniform ex post court analysis, courts cannot appropriately police the reverse payment agreements that are anticompetitive. Thus, Congress must fix both.

[7] Section II describes the balance Congress struck between innovation and competition in the pharmaceutical industry. Specifically, this section describes the two Hatch-Waxman incentives aimed at encouraging competition and making available lower price drugs. Section III explains how companies enter reverse payment agreements and how these agreements undermine Congress's balancing act. Section IV examines how courts have analyzed the anticompetitive nature of reverse payments. Of the three primary modes, one court's reasoning is the most sound. However, even a proper court analysis or a new Senate bill codifying this analysis is ineffective alone in preventing anticompetitive reverse payments from forming. Section V proposes a legislative amendment to the 180-day exclusivity incentive for Congress to discourage companies from forming anticompetitive reverse payment agreements to start with. Only when Congress combines the amendment with the proper ex post analyses of these agreements by the courts can we have an effective solution to ensure the agreements are not anticompetitive.

II. CONGRESS'S DELICATE BALANCE: HATCH-WAXMAN INCENTIVES TO ENCOURAGE INNOVATION AND COMPETITION

[8] Congress believes that consumers need innovation delicately balanced with competition in the pharmaceutical industry because both are important.[22] Competition is needed to help reduce drug prices for consumers.[23] Innovation is needed to create new life saving drugs.[24] Unfortunately, without proper incentives, competition will take precedence at the expense of innovation, or vice versa. Competition in the pharmaceutical industry creates lower priced drugs, but it comes at the cost of less innovation.[25] Too much competition would stifle innovation and starve the world of new life saving drugs.[26] However, a lack of competition between drug companies would keep drug prices high, thereby making them inaccessible to many who need them the most.[27]

[9] Recognizing this, Congress enacted the Hatch-Waxman Act to encourage competition in pharmaceuticals without sacrificing innovation.[28] The Hatch-Waxman Act encourages innovation by allowing patent holders to extend the life of their patent monopoly beyond the

[22] *See* H.R. REP. NO. 98-857(I), at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48; Holman, *supra* note 12, at 513.

[23] *See* FTC STUDY, *supra* note 5, at 9.

[24] Albert Wertheimer &Thomas Santella, *The History and Economics of Pharmaceutical Patents*, *in* 16 RESEARCH IN HUMAN CAPITAL AND DEVELOPMENT, THE VALUE OF INNOVATION: IMPACT OF HEALTH, LIFE QUALITY, SAFETY, AND REGULATORY RESEARCH 101, 102 (Irina Farquhar et al. eds., 2008).

[25] *See* Carmelo Giaccotto, Rexford Santerre & John Vernon, *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195, 212 (2005).

[26] *See id.*

[27] *See* Patricia Danzon, *Making Sense of Drug Prices*, 23 REGULATION 56, 58 (2006), *available at* http://www.cato.org/pubs/regulation/regv23n1/danzon.pdf.

[28] *See* H.R. REP. NO. 98-857(I), at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647 (describing the purpose of the bill is to increase the number of generic drug); *id.* at 39 (explaining that new and important innovation should be rewarded).

normal patent life of twenty years.[29] The Hatch-Waxman Act encourages competition by creating a less expensive FDA approval process for generic drugs,[30] and providing the first generic patent challenger with a first mover advantage against other generics.[31] However, when Congress created the incentives to balance innovation and competition they failed to realize that the incentives encouraged pharmaceutical companies to enter into reverse payment agreements.[32] These reverse payment agreements between patent-holding pharmaceutical companies and ANDA filers upset Congress's competition-innovation balance.[33] One incentive, in particular the 180-day exclusivity, established a roadblock to the very competition that Congress intended to create.[34]

A. Innovation versus Competition

[10] Competition encourages lower prices for medicine, but in the pharmaceutical industry, it may decrease innovation.[35] The first company to create a new drug and file for a patent has a competitive advantage due to the inherent monopoly rights granted with the patent.[36] A second company, or generic company, invests a smaller amount of money than

[29] 35 U.S.C. § 156 (2006).

[30] *See* 21 U.S.C. § 355(j) (2006).

[31] *See id*; 21 U.S.C. § 355(j)(2)(A)(i)-(iv) (providing the first generic patent challenger with a 180-day exclusivity against other generics).

[32] *See* Hemphill & Lemley, *supra* note 20, at 947-48. *See generally* H.R. REP. NO. 98-857(I), *reprinted in* 1984 U.S.C.C.A.N. 2647.

[33] *See* Holman, *supra* note 12, at 506.

[34] Hemphill & Lemley, *supra* note 20, at 947-48.

[35] *See* Giaccotto, Santerre & Vernon, *supra* note 25, at 212.

[36] *See* Wendy H. Schacht & John R. Thomas, CONG. RESEARCH SERV., RL30756, PATENT LAW AND ITS APPLICATION TO THE PHARMACEUTICAL INDUSTRY: AN EXAMINATION OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 ("THE HATCH-WAXMAN ACT") 12-14 (2005).

the first, by copying the first company's drug through the ANDA process.[37] Therefore, the generic company can sell the same drug at a lower, but still profitable, price. A generic company's substantially lower drug development costs leads to an increase in the number of generic competitors in the market.[38] As generic competitors enter the market, the inventing company's market share declines resulting in fewer profits.[39] Because the inventing company makes fewer profits, it has less of an incentive to continue inventing new drugs, decreasing innovation.[40]

[11] Some commentators note, however, that companies with an established market presence have no incentive to truly innovate and instead pool resources to maintain their market dominance.[41] Thomas Piraino wrote that some economic studies show monopolists conduct less research and innovation than companies in competitive markets.[42] However, in the same article he states that economic studies conclude that competition in innovation is "more critical to long-term economic efficiency than is price competition."[43] He notes that continuous

[37] *See* Holman, *supra* note 12, at 511.

[38] *See id.* at 510–11.

[39] *See id*; *Generic Competition and Drug Prices*, FDA.GOV, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm (last visited Dec. 5, 2011).

[40] *See* CBO, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 45, *available at* http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf; *see, e.g.*, F. M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97, 105 (1993).

[41] *See* Thomas Piraino, *Identifying Monopolists' Illegal Conduct Under the Sherman Act*, 75 N.Y.U. L. REV. 809, 814-15 (2000); Douglass Ginsburg, *Antitrust, Uncertainty, and Technological Innovation*, 24 ANTITRUST BULL. 635, 649 (1979); Mark Green, *Have the Antitrust Law Promised Too Much and Accomplished Too Little? Answer: Yes*, 46 ANTITRUST L.J. 752, 755 (1977).

[42] *See* Piraino, *supra* note 41, at 815.

[43] *Id.*

innovation is important because it decreases prices of goods and expands the number of goods for consumers.[44] He provides the example of Microsoft, which used its market dominance to stifle innovation in operating systems and other similar software.[45]

[12] As Mr. Piraino states innovation provides more benefits to the market than price competition.[46] Mr. Piraino admits that innovation is more critical than price competition.[47] He is merely worried about companies who sit on their innovations without contributing to new ones.[48] He specifies that continued innovation is the highest level of importance to consumers because it increases the number of new products on the market.[49] Our market system should favor innovation because gains from innovation can be significantly greater than gains from competition.[50] Innovation can create jobs, new industries, and new products.[51] Patents encourage innovation and should be favored over

[44] *See id.*

[45] *See id.*

[46] *See id.*

[47] Piraino, *supra* note 41 at 815.

[48] *See id.*

[49] *See id.*

[50] *See* Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 833 (2002); Herbert Hovenkamp, *The Monopolization Offense*, 61 OHIO ST. L.J. 1035, 1045 (2000); Neelie Kroes, Op-Ed, *Why Microsoft Was Wrong*, WALL ST. J. EUR., Sept. 26, 2007 at 13 ("Where a well-established monopolist exploits its position to colonize neighboring markets, this can scare investors from funding competitors, undermine the incentive and ability of those competitors to invest and innovate, and drive out competitors who are as efficient as the monopolist. And monopolists exploiting their strategic position to conquer new markets are less likely to innovate than companies forced to compete for customers on the basis of the merits of their products.").

[51] *See A Strategy for American Innovation: Driving Towards Sustainable Growth and Quality Jobs*, NAT'L ECON. COUNCIL (Sept. 2009), *available at* http://www.whitehouse.gov/administration/eop/nec/StrategyforAmericanInnovation.

competition.[52] In addition to the benefits of innovation over competition, in medicine, innovation can save lives.[53] Thus, when balancing is not an option, Congress should err on the side of over-rewarding innovation.[54]

B. Hatch-Waxman Incentives for Generics

[13] The Hatch-Waxman Act provides, among other things, two incentives to generic drug manufacturers to compete with brand name manufacturers.[55] First, the Act creates the ANDA process, which permits generic manufacturers to forgo the onerous clinic trials required in typical new drug applications if the generic manufacturer can show the FDA its drug is bioequivalent to an existing approved drug. [56] Second, the Act provides a temporary 180-day monopoly to the first generic manufacturer to file an application challenging the brand name manufacturer's patent through the ANDA process.[57]

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[52] *But see* Berlin Packaging, LLC v. Stull Techs., Inc., 381 F. Supp. 2d 792, 796 (N.D. Ill. 2005) ("[I]n patent law, the purpose is to encourage innovation while inviting competition; the recipient of a patent is granted a monopoly for a limited time, after which the innovation passes to the public for copying and improvement.").

[53] *See* Brief for Pharmaceutical Research and Manufacturers of America as Amici Curiae Supporting Respondent, Mayo Collaborative Servs. v. Prometheus Labs. Inc., (U.S. 2011) (No. 10-1150), 2011 WL 5373698 at *22.

[54] *See id*. at *23 (describing pharmaceutical patents as "critical to spurring innovation that will save or improve countless lives. . . . [w]ithout the promise of protection that will enable recoupment of the enormous investment that goes into development of these processes, the development will not be undertaken").

[55] *See generally* 21 U.S.C. § 355(j) (2006) (providing the ways in which abbreviated applications may be filed).

[56] *See* 21 U.S.C. § 355(j)(2)(iv).

[57] *See* 21 U.S.C. § 355(j)(5)(B)(iv) (defining the 180 day exclusivity period and explaining that the Secretary shall approve or disprove an application within 180 days).

1. A Shorter Process: The Abbreviated New Drug Application

[14] One way Congress encourages competition is through the ANDA process.[58] Rather than going through the full-length approval process, generics can rely on brand names' approval and enter the market quickly and cheaper than their brand name counter parts.[59] This is obviously enticing for the competing drug companies because they can charge a lower price for a drug than the brand name and still earn a profit.

[15] A brand name must incur a high cost for drug development and approval and thus has to charge a high price to obtain a return on its investment.[60] First, the brand name spends money on discovering a drug.[61] Then brand name spends money on filing for a patent on the drug.[62] Then the company undergoes expensive clinical trials for the new drug as required by the FDA.[63]

[16] A patent holder likely files for a patent once the drug is discovered.[64] Once discovered, the patent holder must undergo arduous clinic trials to ensure that the drug is effective and safe for human consumption.[65] The FDA regulates and requires clinical trials as a part of

[58] *See* Holman, *supra* note 12, at 510.

[59] *See id.* at 510-11.

[60] *See* FTC STUDY, *supra* note 5, at 4.

[61] *See id.*

[62] *See generally* 21 U.S.C. § 355(b) (2006) (explaining the contents of a drug patent application).

[63] *See id.*

[64] *See* FTC STUDY, *supra* note 5, at 4.

[65] *See generally* 21 U.S.C. § 355(b)(1)(A) (2006) (describing the FDA's review requirements).

the new drug application ("NDA") process and requires many years to complete the testing.[66] After the research, clinical trials, and full FDA approval, the brand name places the drug on the market using its patent to exploit its monopoly with higher prices to recoup investment costs.

[17] In contrast, the ANDA filer has a shorter, less expensive route to market.[67] The ANDA filer does not have to perform research and development to discover the drug nor does the ANDA filer need to perform clinic trials to show the drug is safe and effective.[68] The ANDA filer may instead copy the patent holder's drug, show that the new drug is the same as the patent holder's, and file an ANDA application.[69] In the ANDA application, the ANDA filer claims that their drug is bioequivalent to the patent holder's drug.[70] A company may show a drug is bioequivalent if it has the same active pharmaceutical ingredient ("API") as an already FDA approved drug.[71] The FDA approves an ANDA application in a short period because the patented drug already underwent studies to ensure it is safe and effective; the ANDA filer simply must show the FDA that its drug is the same.[72] This shorter and less expensive process allows the ANDA filer to sell the same drug as the patent holder for a lower price because the ANDA filer incurred much lower costs to get to market.

2. The 180-Day Exclusivity Period

[66] *See* 21 U.S.C. § 355(b).

[67] *See* NPS, *Generic Medicines: Informing Patients About Multiple Brands*, http://www.nps.org.au/health_professionals/publications/nps_news/current/generic_medicines_informing_patients (last visited Apr. 18, 2012).

[68] *See* Holman, *supra* note 12, at 511.

[69] *See* 21 U.S.C. § 355(j)(2)(A)(ii)-(iv).

[70] *See* 21 U.S.C.§ 355(j)(2)(A)(iv).

[71] *See id.*

[72] *See* 21 U.S.C. § 355(j)(2)(A)(i)-(viii).

[18] Congress also provided a temporary monetary incentive through a first mover advantage to encourage competition, but only to an ANDA filer that challenges a patent.[73] An ANDA filer must make one of four certifications with respect to any related patents on the drug: (I) the related patent has not been filed on the drug; (II) the related patent has expired; (III) the related patent will expire soon; or, (IV) the related patent is invalid or will not be infringed by the new drug.[74] This framework rewards the ANDA filer that makes the fourth certification to encourage generic companies to compete with brand name companies by challenging the latter's patents.

[19] Congress grants the first ANDA filer making a paragraph (IV) certification with a 180-day exclusivity period, making it the only generic seller of the drug.[75] The first ANDA challenger is the only generic company in the market for a small period allowing it to maintain a high price and earning a high return on its drug manufacturing costs.[76] It is not until the second generic drug enters market that major price erosion begins.[77] In addition to the high short-term return on investment, the 180-day exclusivity rewards the first ANDA challenger with the first mover advantage.[78] This provides the challenger with the ability to establish itself in the marketplace, leading to more revenue opportunities for the generic company as the preferred generic alternative to consumers.[79]

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[73] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

[74] *See* 21 U.S.C. § 355(j)(5)(B)(i)-(iv).

[75] *See id.*

[76] *See Generic Competition and Drug Prices*, *supra* note 39.

[77] *See id.*

[78] Aidan Hollis, *The Importance of Being First: Evidence From Canadian Generic Pharmaceuticals*, 11 HEALTH ECON. 723, 732-33 (2002).

[79] Marvin B. Lieberman & David B. Montgomery, *First-Mover Advantages*, 9 STRATEGIC MGMT. J. 41, 44 (1988) (explaining that the first mover is able to preempt rivals to scarcities such as the shelf space in a pharmacy).

III. HOW CONGRESS GOT SICK: REVERSE PAYMENTS

[20] Through the Hatch-Waxman Act, Congress tried to balance innovation and competition in the pharmaceutical industry, reverse payments upset this balance.[80] Congress did not anticipate reverse payment agreements when drafting the Hatch-Waxman Act, particularly concerning its competitive incentives such as the 180-day exclusivity for the first ANDA challenger.[81] Thus, unexpected consequences occurred. When these unique agreements combine with the 180-day exclusivity incentive it actually hinders competition instead of encourage it as Congress originally intended.

[21] Reverse payment agreements result from a unique situation between a patent holder and a generic company. First, a brand name drug company discovers a new drug and files for a patent and for FDA approval.[82] The drug company receives a patent and eventually FDA approval.[83] The drug company and now patent holder sells the drug for a high price because of the large cost the patent holder had to incur in discovering the drug and seeking FDA approval through the new drug application.[84] Eventually a generic drug company decides to make the

[80] *See also* William H. Rooney & Elai Katz et al., *Review of Reverse-Payment Agreements: The Agencies, the Courts, Congress, and the European Commission*, 5 COMPETITION POL'Y INT'L 122, 122 (Apr. 17, 2012, 7:45 PM), *available at* https://www.competitionpolicyinternational.com/review-of-reverse-payment-agreements-the-agencies-the-courts-congress-and-the-european-commission/ *See generally* H.R. REP. NO. 98-857(I), *reprinted in* 1984 U.S.C.C.A.N. 2647.

[81] *See generally* Rooney & Katz et al., *supra* note 80 (describing how the Hatch-Waxman Act intended to foster innovation but resulted in the creation of reverse-payment agreements).

[82] *See* FTC STUDY, *supra* note 5, at 4.

[83] *See id.* at 5.

[84] *See generally* Hemphill & Lemley, *supra* note 20, at 951 (describing the testing and approval process required for the FDA is expensive and time consuming).

exact drug as the patent holder.[85] Since the drug is not new, the generic company files an ANDA to obtain FDA approval.[86] The ANDA filer must make a certified statement regarding why their drug will not affect related patents including the patent holder's.[87] The ANDA filer may state the related patent is invalid or that it does not infringe the related patent—a paragraph (IV) certification.[88] This provides the patent holder with a cause of action to sue the ANDA filer for patent infringement.[89] Once sued, the ANDA filer will typically assert a counter-claim stating the patent is invalid.[90] Instead of risking a judgment against that patent holder, invalidating or narrowing the patent's scope, the patent holder settles with the ANDA filer.[91] The patent holder has a larger risk—the end of highly lucrative monopoly profits—thus pays the ANDA filer to end litigation and refrain from entering the market with their generic drug.[92] Because the patentee pays the infringer to settle the lawsuit, this is called a reverse payment.[93]

[22] When the reverse payment is combined with the 180-day exclusivity incentive, a bottleneck for subsequent ANDA filers is formed and competition is hindered. The 180-day exclusivity hinders competition

[85] *See* FTC STUDY, *supra* note 5, at 4.

[86] *See* 21 U.S.C. § 355(j) (2006); FTC STUDY, *supra* note 5, at 4.

[87] 21 U.S.C. § 355(j)(2)(A)(vii).

[88] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[89] *See* 35 U.S.C. § 271(e)(2) (2006).

[90] *See, e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1328 (Fed. Cir. 2008).

[91] *See id.*

[92] *See id.* at 1329.

[93] *See id.*.

if the first ANDA challenger does not execute its exclusivity.[94] Competition is hindered because the FDA will not grant subsequent filers approval until the first ANDA challenger uses the 180-day exclusivity period.[95] This delay in approval discourages subsequent filers from filing an ANDA application or marketing a drug.[96] The 180-day exclusivity is triggered when the first ANDA challenger markets the drug.[97] Thus, when the ANDA challenger agrees to delay marketing in a reverse payment agreement, the challenger delays the start of the exclusivity period. [98] This delay blocks other generics from entering the marketplace until 180-days after the challenger begins to market the generic drug.[99] Through the agreement, the first ANDA challenger collects money from the patent holder and utilizes the 180-day exclusivity after the agreement concludes.[100] This works great for the first ANDA challenger because it is able to collect a large sum of money without entering the market.[101] In addition, once the agreement ends—usually many years later—the ANDA challenger may reap the benefits of the 180-day exclusivity period as a second payday.

[94] *See* Shashank Upadhye, *Triggering the 180-Day Exclusivity Clock Under the Post-MMA Rules*, GENERIC PHARMACEUTICAL PATENT AND FDA LAW, Feb. 2012, at § 13.9, *available at* WL GENPHARMA § 13:9.

[95] *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

[96] If a potential subsequent generic filer learns that a prior generic has an exclusivity period that could be prevent the subsequent filer from FDA approval for an unknown period, the subsequent filer would likely forgo investment in that drug for another.

[97] *See* Upadhye, *supra* note 94, at § 13:9.

[98] *See id.*

[99] *See id.*

[100] *See* Hemphill & Lemley, *supra* note 20, at 948.

[101] *See* Petition for Writ of Certiorari at 7-8, Louisiana Wholesale Drug Co. v. Bayer AG, 131 S. Ct. 1606 (2011) (No. 10-762), 2010 WL 5014323 at *7-8.

[23] Subsequent ANDA-filing generic drug companies have fewer incentives or no incentives because of the bottleneck to enter the market. Congress only provides the 180-day exclusivity provision to the first ANDA filer making a paragraph (IV) certification, regardless of whether or when the first filer utilizes the incentive.[102] Later ANDA filers do not have the benefit of the 180-day exclusivity and are, in fact, prevented from obtaining FDA approval until the first ANDA filer exercises its 180-day exclusivity right.[103] The main incentive for subsequent generic companies is the faster ANDA process, compared to the new drug application process.[104] However, even this incentive is unavailable if a previous filer has the right to 180-day exclusivity.[105] Without the first mover benefit and more importantly the delay of FDA approval due to prior filers with the 180-day exclusivity, subsequent filers have less incentives and a higher risk to enter the market.

IV. TREATING THE SYMPTOMS: CURRENT APPROACHES

[24] Courts do not agree whether reverse payment agreements are anticompetitive and illegal, causing uncertainty about the validity of the agreements.[106] Three different analyses have emerged.[107] The Sixth Circuit views a reverse payment as evidence that a patent is not strong enough for the patent holder to exclude others, and thus, is per se anticompetitive.[108] The Second Circuit relies on the presumption that a

[102] *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

[103] *See id.*

[104] *See id.*

[105] *See id.*

[106] *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212-13 (2d Cir. 2005); *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 915 (6th Cir. 2003); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1309 (11th Cir. 2003).

[107] S*ee In re Tamoxifen*, 466 F.3d at 212-13; *In re Cardizem*, 332 F.3d at 915; *Valley Drug*, 344 F.3d at 1313.

[108] *See In re Cardizem*, 332 F.3d at 915.

patent is valid unless fraud was committed on the patent office.[109] Because reverse payment agreements are based around the exclusionary right of a patent, they are presumptively valid and not anti-competitive.[110] The Eleventh Circuit uses a two-step process.[111] The court determines the scope and strength of the disputed patent first and then analyzes whether the reverse payment settlement is anticompetitive based on the patent.[112]

[25] Congress needs to supply the courts with the best approach. Once the ANDA filer and patent holder reached an agreement, following an ANDA initiated patent infringement suit, the companies depend and plan future investments based on the agreement. Companies cannot plan for the uncertainty surrounding validity of these agreements since the courts do not agree on which type of reverse payments are valid. Companies are hesitant to invest in innovation when they have uncertainties in a significant portion of their budgets.[113]

A. Reverse Payments are Per Se Anticompetitive

[26] The Sixth Circuit in *In re Cardizem CD Antitrust Litigation* held that the reverse payment agreement at issue was anticompetitive and per se illegal.[114] The court determined that it must consider the strength of the patent when considering whether the reverse payment agreement is anticompetitive.[115] The court reasoned that if the brand name's patent

[109] *In re Tamoxifen*, 466 F.3d at 212-13.

[110] *See id.*

[111] *Valley Drug*, 344 F.3d at 1313.

[112] *Id.*

[113] *See* Samuel Brittan, *Question 1: Recovery*, FIN. TIMES, (Jan. 2, 2012), http://www.ft.com/intl/cms/s/0/ab493aa2-353e-11e1-a4ab-00144feabdc0.html#axzz1iLiTIsAX.

[114] *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 900 (6th Cir. 2003).

[115] *See id.* at 915.

were strong enough then it would not have paid the generic company to stay out of the market when the patent alone could have accomplished the same.[116] Thus, the court ruled that the reverse payment, of nearly ninety million dollars, was so anticompetitive, it was per se illegal.[117] The court also noted the agreement was anticompetitive because the ANDA filer held onto the 180-day exclusivity benefit without ending litigation between the companies.[118] This prevented subsequent ANDA filers from obtaining FDA approval. [119] Without FDA approval, other generic companies could not enter the same drug market and led the court to determine the agreement was anticompetitive.[120]

[27] The Sixth Circuit properly recognized a problem with reverse payment agreements, but erred in their analysis on why the agreements are anticompetitive. The court, noticing the anticompetitive nature of the agreement, created a presumption that reverse payment agreements are per se anticompetitive because the patent holder made a payment to the generic to delay its market entry.[121] The court was correct to find the agreement anticompetitive, but only because litigation between the companies continued. [122] The continued litigation allows the generic company to hold onto the 180-day exclusivity, preventing additional generic companies from entering the market.[123] Because at that time a court decision triggered the 180-day exclusivity, and a reverse payment

[116] *See id.*

[117] *See id.* at 905.

[118] *See id.* at 907 n.12, 908.

[119] *See In re Cardizem*, 332 F.3d at 907 n. 12, 908.

[120] *See id.*

[121] *See id.* at 910.

[122] *See id.* at 907 & n.12.

[123] *See id.*

agreement with continuing litigation prevented all other generic companies from entering the market.[124]

B. Reverse Payments are Presumed Valid and Not Anticompetitive

[28] Expressly rejecting the Sixth Circuit's analysis, the Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation* held that a reverse payment agreement is presumed valid and not anticompetitive.[125] The court reasoned patent holders have a lawful monopoly and thus no competition would result between the companies because of the patent.[126] The court presumed the reverse payment was not anticompetitive unless the patent was obtained through fraud or sham on the patent office.[127] The court also determined that the presumption may be overcome if the agreement extends beyond the exclusionary scope of the patent at issue.[128] Here, the settlement agreement between the patent holder and the ANDA filer ended the ongoing litigation and did not extend beyond the life of the patent.[129] Thus, the agreement was presume not to violate antitrust laws.[130]

[29] The Second Circuit places a high priority on a patent's presumption of validity without addressing the scope of the patent.[131] The Second Circuit bases the presumption that the reverse payment agreements are not anticompetitive because a patent is involved and patents are

[124] *See In re Cardizem*, 332 F. 3d at 907 & n.12.

[125] *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2006).

[126] *Id.* at 212-13.

[127] *See id.*

[128] *Id.* at 213.

[129] *See id.*.

[130] *See In re Tamoxifen*, 466 F.3d at 218.

[131] *See id.* at 211.

presumed valid.[132] The problem is that a patent's claim may be valid but too narrow to exclude a particular product.[133] To determine whether the patent covers the generic drug, the court must define the claim, determine scope of the claim, and find whether the generic drug infringes the claim. [134] This is the only way to determine if the reverse payment agreement is a lawful extension of the patent. The court must move through the patent claim construction before deciding the anticompetitive nature of the agreement.

C. Look to the Patent's Exclusionary Scope First

[30] The Eleventh Circuit in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* reversed a district court's holding that a reverse payment agreement was per se anticompetitive.[135] The court remanded the district court to incorporate in the anticompetitive analysis a patent holder's rights and protections granted by the constitution.[136] The Eleventh Circuit reasoned that reverse payment agreements are not per se anticompetitive, so long as the agreement is not broader than the exclusionary effects of the disputed patent.[137] The court recognized that patents are a general exception to antitrust liability, but the exception is limited to the scope of the patent.[138] The Eleventh Circuit instructed the

[132] *See id.*

[133] 21 U.S.C. §355(j)(2)(A)(iv) (2006) (certifying that the related patent is invalid *or* the generic drug will not infringe the related patent). *See generally* 35 U.S.C. § 271 (2006) (discussing patent infringement).

[134] *See In re Tamoxifen*, 466 F.3d at 212-13 (stating that competition can only be restrained "within the scope of the patent", implying that the scope of both patents needs to be examined to determine infringement).

[135] *See* Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1304 (11th Cir. 2003).

[136] *See id.* at 1312.

[137] *See id.* at 1309.

[138] *See id.* at 1312.

lower court to analyze the scope of the disputed patents before determining the anticompetitive nature of the agreement.[139] Once a court determines the metes and bound of the patent, the court can determine whether the settlement agreement extends beyond it.[140] On remand, the lower court addressed the exclusionary scope of the patent and found that the agreement was per se illegal because the patent was likely invalid.[141]

[31] Congress should adopt the Eleventh Circuit's analysis. It properly takes into account the legal monopolistic effects of patents, without over emphasis on the presumed validity or scope of the patents. The Sixth Circuit is at one extreme—it assumes that a payment from a patent holder to a generic company to delay entry is proof that the patent alone is not strong enough to exclude the drug.[142] The Second Circuit is at the opposite end of the spectrum—it assumes that the patent is valid and that its scope covers the drug unless fraud was committed on the patent office.[143] The Second Circuit relies on the presumption of a patent's validity without determining the scope of the patent claims.[144] The Eleventh Circuit takes the middle-ground approach by determining the scope and validity of the patent at issue and using it to determine whether the reverse payment agreement is a lawful extension of the patent.[145] In analyzing these agreements, Congress should adopt the Eleventh Circuit approach for similar determinations because it properly takes a patent's exclusionary effect without giving over emphasis to its presumed validity of the its scope.

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[139] *See id.*

[140] *See Valley Drug*, 344 F.3d at 1312-13.

[141] *See In re* Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1298, 1306–07 (S.D. Fla. 2005).

[142] *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 915 (6th Cir. 2003).

[143] *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212-13 (2d Cir. 2005).

[144] *See id.* at 212-13.

[145] *See Valley Drug*, 344 F.3d at 1312-13.

[32] A proper analysis helps courts determine whether the reverse payment is anticompetitive once entered into, but does not prevent them from occurring. Pharmaceutical companies' incentives to create these agreements and delay subsequent ANDA filers from entering the market remain. Patent holders still have an incentive to retain monopoly profits and pay generic companies to postpone entry in the market. Generic companies have an incentive to collect money from the patent holder to retain more money than companies would manufacturing and selling the generic drug. Because two parties to the underlying suit have the same objective—keeping the reverse payment agreement intact—Congress needs take the initiative to amend the Hatch-Waxman Act to discourage future anticompetitive agreements.

D. Senate Bill S. 27 Addresses the Symptoms Instead of the Sickness

[33] Congress's recent proposal falls short of addressing the real issue with reverse payment agreements: the misbalanced incentives in the Hatch-Waxman Act. In addition, the bill attempts to codify an incorrect analysis in determining whether the agreements are anticompetitive. As a first priority, Congress should focus its efforts on correcting and amending the incentives in the Hatch-Waxman Act to discourage anticompetitive reverse payment agreement from forming by amending the 180-day exclusivity provision. As a second priority, Congress should mandate how courts analyze the anticompetitive nature of the agreement.

[34] Congress needs to change the incentive encouraging generics to challenge brand name patents. The 180-day exclusivity provides this incentive, but when combined with a reverse payment acts as a blockade to additional generic companies entering the market. The first ANDA challenger may prevent other generics from obtaining FDA approval until the ANDA challenger markets its drug.[146] The reverse payment delays the generic's market entry, the 180-day trigger, and thus all other generics are

[146] *See* Upadhye, *supra* note 94, at § 13:9.

prevented from entry until 180-days after the ANDA challenger's exclusivity period begins.[147] As discussed in the next section, Congress can by creating an additional triggering event—entering into a reverse payment—to encourage generics to challenge brand patents without blocking all generic competition. This would effectively prevent reverse payment agreements from forming.

[35] Congress, in Senate Bill S.27, proposes a new process for analyzing reverse payment agreements.[148] The bill creates a presumption that reverse-payment agreements are anticompetitive.[149] The bill grants the Federal Trade Commission ("FTC") the ability to police these agreements with its own proceedings using this presumption.[150] To overcome the presumption, the parties to the agreement must show the agreement has more beneficial effects than harmful anticompetitive effects.[151] The parties must prove this by a clear and convincing standard.[152]

[36] The bill proposes an incorrect anticompetitive determination. The bill's analysis and presumption is almost identical to the Sixth Circuit's presumption against the agreements.[153] It disregards the legal

[147] *See* Ankur N. Patel, *Delayed Access to Generic Medicine: A Comment on the Hatch-Waxman Act and the "Approval Bottleneck,"* 78 FORDHAM L. REV. 1075, 1095 (2009).

[148] *See* Preserve Access to Affordable Generics Act, S. 27, 112th Cong. § 3(a) (2011), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-112s27rs/pdf/BILLS-112s27rs.pdf.

[149] *See id.* (explaining that an agreement is presumed anticompetitive if the ANDA filer receives anything of value and agrees to limit research or other necessary steps to get the drug to market).

[150] *See id.*

[151] *See id.*

[152] *See id.*

[153] *Compare* Preserve Access to Affordable Generics Act, S. 27, 112th Cong. § 3(a) (2011), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-112s27rs/pdf/BILLS-112s27rs.pdf, *with* In re Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003).

exclusionary scope of disputed patents.[154] Patents provide the owner the ability to exclude others from making, using, or selling a product covered by the patent.[155] This is an express exception to antitrust laws granted by the Constitution and must be incorporated into the analysis.[156]

[37] Congress should follow the Eleventh Circuit's analysis. The Eleventh Circuit looked at the exclusionary effects of disputed patents before determining whether a reverse payment agreement is anticompetitive.[157] The court reasoned that a patent is a constitutional exception to antitrust law.[158] A patent holder may exclude others from the market so long as their patent rightfully grants the right.[159] Here, the bill unconstitutionally ignores a patent holder's rights by creating a presumption against reverse payment agreements.[160] Congress should remove the presumption against reverse payment agreements and look at the disputed patents first to take into account this express exception to antitrust laws. In addition, instead of having the FTC making the determination, Congress should leave it to the courts to decide as an impartial decision maker unaffected by administration change.

VI. THE VACCINE APPROACH: LONG TERM PREVENTATIVE AND PROACTIVE LEGISLATIVE PROPOSALS

[154] Preserve Access to Affordable Generics Act, S. 27, 112th Cong. § 3(a) (2011), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-112s27rs/pdf/BILLS-112s27rs.pdf.

[155] 35 U.S.C. § 271 (2006).

[156] *See* U.S. CONST. art. I, § 8, cl. 8.

[157] Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003).

[158] *See id.* at 1309.

[159] *See* 35 U.S.C. § 271 (2006).

[160] *See* Preserve Access to Affordable Generics Act, S. 27, 112th Cong. § 3(a) (2011), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-112s27rs/pdf/BILLS-112s27rs.pdf.

[38] To rid consumers of the anticompetitive illness, the courts have to utilize the proper anticompetitive analysis and Congress must pass working incentives. Two solutions are proposed. The first proposal transfers one of Congress's original competitive incentives to the next in-line ANDA filer to encourage competition beyond the first generic company. The second proposal is for Congress to mandate the Eleventh Circuit approach to properly analyze whether reverse payment agreements are anticompetitive.

A. 180-day Exclusivity Pass-Through

[39] Congress originally created the 180-day exclusivity period to incentivize generic companies to challenge brand name patents by providing the first mover advantage.[161] However, the 180-day exclusivity blocks other generic companies from FDA approval until the first generic filing a paragraph IV certification commercially markets its drug.[162] In the reverse payment agreement, the generic agrees to delay marketing its drug preventing it from triggering the 180-day exclusivity.[163] Until the 180-day exclusivity is transferred, all other generics are blocked from obtaining FDA approval.[164] Only the first generic filing an ANDA with a paragraph IV certification is able to use the right.[165] Thus, Congress should allow the 180-day exclusivity transfer to the second ANDA filer upon a triggering event by the first ANDA filer to ensure that generic competition is not harmed.

[40] Congress should make the 180-day exclusivity incentive transferrable to the next ANDA filer based on a reverse payment-

[161] *See* H.R. REP. NO. 98-857(I), at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

[162] *See* Upadhye, *supra* note 94, at § 13.8.

[163] *See id.* at § 13.9.

[164] *See id.*

[165] *See* 21 U.S.C. § 355(j)(5)(D)(iii) (2006).

triggering event. The current legislation provides the exclusivity only to the first ANDA filer that makes a paragraph IV certification.[166] Congress should allow the exclusivity incentive to pass from the first ANDA challenger to the second ANDA challenger, once the first has entered into a reverse payment agreement.[167] This would encourage patent holders and the first ANDA challenger to weigh the cost of entering into reverse payment agreements against manufacturing the drug without compromising the competitive generic market. The transfer of the exclusivity would remove the FDA approval barrier because the second ANDA challenger now wields the barrier for the other generic's entry into the market.

[41] In order to determine whether the 180-day exclusivity has transferred, Congress must require pharmaceutical companies to register all reverse payment agreements with the FDA. This will provide notice to the FDA providing it the ability to inform the next ANDA paragraph IV challenger of its new rights.

[42] The exclusivity pass-through should transfer only to the first three paragraph IV ANDA challengers and then open the availability of FDA approval to all generics. If the second ANDA challenger enters into a reverse payment agreement, then it would trigger the transfer of the 180-day exclusivity to the third ANDA challenger. If the third ANDA challenger enters into a reverse payment, then the exclusivity would not transfer, opening the FDA approval roadblock to all subsequent ANDA filers.

[43] It is important to limit the exclusivity pass-through to the first three challengers otherwise pass-through exclusivity would act as a continuous

[166] *See id.*

[167] *See* Henry Butler & Jeffrey Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 124 (2010). Mr. Butler and Mr. Jarosch provided this as an afterthought solution to their article. Here, we will explore this idea more in depth. Later in this section we will explore this in conjunction with a proper court analysis of reverse payments.

blockade. In theory, if the exclusivity pass-through was not limited it could delay generic competition further. Imagine the 180-day exclusivity transferring through the first nineteen ANDA challengers because the first eighteen challengers entered into reverse payment agreements. Each ANDA challenger would receive the 180-day exclusivity when the ANDA challenger before it entered into a reverse payment. This would block generic market from other generics until 180-day after one generic uses the exclusivity. This could prevent generic market entry longer than the current process.

[44] Congress has contemplated a similar idea in 2009, but Congress has yet to approve the proposed bill.[168] The 2009 bill suggested that a subsequent ANDA challenger may *share* the exclusivity period with the first challenger if the subsequent ANDA challenger succeeds in its challenge against the patent holder. [169] Alternatively, if the patent holder does not initiate a lawsuit against a subsequent ANDA challenger, then that ANDA challenger may earn exclusivity.[170] Since multiple challengers may succeed against the patent holder, multiple challengers may earn and share the 180-day exclusivity.[171] When multiple companies share the exclusivity period, the companies lose the first mover advantage over the entire 180-day period. More importantly, it creates multiple market participants lowering the price of the drug more than if there were only the patent holder and one generic in the market.[172] A lower price of the drug means that the multiple generics earn less than if only one generic

[168] *See* Drug Price Competition Act of 2009, S. 1315, 111th Cong. (2009); Butler & Jarosch, *supra* note 166 at 122.

[169] *See* Drug Price Competition Act of 2009, S. 1315, 111th Cong. (2009); Butler & Jarosch, *supra* note 166, at 123.

[170] *See* Drug Price Competition Act of 2009, S. 1315, 111th Cong. (2009); Butler & Jarosch, *supra* note 166, at 123.

[171] *See* Drug Price Competition Act of 2009, S. 1315, 111th Cong. (2009); Butler & Jarosch, *supra* note 166, at 123.

[172] *See Generic Competition and Drug Prices*, *supra* note 39.

was in the market, which lowers the generics potential profits.[173] This weakens the generic drug companies' incentive to challenge the brand name in the first place.[174]

[45] In contrast, the pass-through exclusivity proposal is triggered upon the first ANDA challenger entering into a reverse payment agreement. The pass-through exclusivity option ensures only one generic manufacturer may use the exclusivity period. It allows a generic filer to reap the maximum benefit from being the sole generic drug in the market for 180-day period providing it with the ability to sell the generic drug at a higher price. In addition, it provides the sole generic drug company with the first mover advantage. The incentive for a generic drug company to challenge the brand name's patent must be strong to encourage generic drugs to file for approval and lower its risk for market entry.

[46] The pass-through proposal provides flexibility to patent holders and the first ANDA challenger with limited harm to competition. The solution does not eliminate the ability for brand and generic companies' to enter into reverse payment agreements. It provides the companies the option of using these agreements as effective solutions to their patent disputes. In addition, Congress would incentivize subsequent generic filers to enter the market, when previously they were prevented or discouraged. Previously, if the first ANDA challenger did not use the 180-day exclusivity then neither could a subsequent challenger. The pass-through proposal ensures that the 180-day exclusivity is accessible to other generics companies if the first does not use it. Since the incentive is accessible to a subsequent challenger, it provides an incentive to a subsequent challenger to file an ANDA application and enter the market.

B. A Proper Court Diagnosis System

[47] Congress should mandate the Eleventh Circuit's approach in analyzing reverse payments. This mandate would ensure that the courts

[173] *See id.*

[174] *See id.*

have a uniform and proper analysis of reverse payments. It is important that Congress provide this mandate to analyze anticompetitive agreement that the first proposal does not prevent.

[48] The courts must look at the exclusionary scope of the patent before making the determination of the anticompetitive nature of a reverse payment agreement.[175] Courts must presume the patent is valid and cannot discard its exclusivity. But a valid patent is far different than a valid reverse payment agreement. A court must compare the patent's claims to that of the ANDA filer's drug to determine whether drug falls within the scope of the patent claims. If ANDA drug falls directly within the scope of a valid patent claim then the reverse payment agreement has a high likelihood of being a valid extension of the patent. If the ANDA drug does not fall within the scope of a patent claim, then the reverse payment has a low likelihood of being a valid extension of the patent. The court then must weigh the strength and scope of the patent in with the traditional antitrust analysis.

[49] It is critical that Congress establish a pass-through 180-day exclusivity and mandate the Eleventh Circuit's reverse payment analysis. The pass-through exclusivity proposal ensures generic filers are incentivized to challenge brand name patents encouraging competition in the market and removing the drug approval bottleneck for future generics. The pass-through exclusivity proposal prevents anticompetitive reverse payments by removing the approval bottleneck. Under the new proposal, if the first three generic challengers enter into reverse payments, then the approval bottleneck is removed for all other generic companies.

[50] However, the pass-through proposal does not prevent all reverse payment agreement. It only removes the 180-day exclusivity bottleneck to reduce the number of reverse payment agreements that are anticompetitive. In order to discourage anticompetitive reverse payments

[175] Paolo Morante, Stuart E. Pollack & Jarod M. Bona, *Does My Reverse-Payment Settlement Violate the Antitrust Laws?*, Pharmaceutical Law & Industry Rep. (BNA), at 3 (June 4, 2010).

that the pass-through proposal fails to prevent, Congress must mandate the analysis set forth by the Eleventh Circuit.

VI. CONCLUSION

[51] Encouraging innovation over competition provides more value to society than the other way around. Both are important and so Congress must implement a proper balance to ensure one does not overwhelm the other. Congress attempted to implement a balance between competition and innovation in the pharmaceutical industry with the Hatch-Waxman Act.[176] Congress rewarded the first generic with a 180-day exclusivity to obtain a first mover advantage.[177] But Congress drafted the generic exclusivity legislation in a way that harmed the subsequent generic filer from competition. The first generic filer to challenge the patent holder could enter into an agreement and not trigger its 180-day exclusivity.[178] Until the challenger triggered the exclusivity by marketing the drug, a subsequent filer could not gain approval from the FDA to market its own version.[179] Forcing the first generic challenger to pass the exclusivity right to the next generic challenger increases competition and provides the second generic challenger with greater incentive to make the drug. The most important change Congress can make is to remove the generic exclusivity bottleneck through a legislative amendment to prevent companies from forming reverse payment agreements that are anticompetitive. Secondly, Congress needs to mandate the Eleventh's Circuit approach in analyzing whether reverse payment agreements are

[176] Martha M. 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-hatchwazman-0809/.

[177] William J. Newsom, *Exceeding the Scope of the Patent: Solving the Reverse Payment Settlement Problem Through Antitrust Enforcement and Regulatory Reform*, 1 HASTINGS SCI. & TECH. L.J. 201, 237 (2009).

[178] *See id.*

[179] *See id.*

anticompetitive to analyze reverse payment agreements that the first proposal fails to prevent.