Additive Manufacturing, Pay-for-Delay, and Mandatory Care: Is There Space for Positive Reform?

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NOTES

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Jordan L. Jackson

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I. INTRODUCTION

The Supreme Court of the United States decided Federal Trade Commission v. Actavis, Inc.\(^1\) in the summer of 2013. The case opened up pharmaceutical developers with reverse payment settlements (pay-for-delay agreements) to potential antitrust liability. This decision resolved a circuit split and had many declaring the judgment a legal victory.\(^2\) The Federal Trade Commission (FTC) reported that just one year after the ruling, “pharmaceutical companies entered into substantially fewer potential pay-for-delay patent dispute settlements,” effectively ending a consistent increase in these types of settlements.\(^3\) Pay-for-delay agreements almost exclusively involve drug manufacturing,\(^4\) and it is generally thought that pay-for-delay agreements in this context harm American consumers.\(^5\)

Pay-for-delay agreements outside of pharmaceutical manufacturing arrangements have merits that potentially outweigh the costs. There are markets where pay-for-delay agreements can fulfill their specific goals while also benefiting the consumer, specifically, generic medical-devices manufactured by emergency care hospitals. Generic medical devices are now possible with the rise of 3-D printing technology, and American hospitals are uniquely equipped to enter into the market. As the technology infiltrates this particular market, regulators will have to decide if reverse payment settlements will fall under the Actavis umbrella.

It is important that these regulators consider the function of reverse payment settlements and the law that governs them. Reverse payment settlements teeter between two areas of federal law: (1) patent protection through the Patent and Trademark Office (PTO) and (2) the Sherman Antitrust Act policed by the FTC. Both areas of law have conflicting goals and must be

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1 133 S. Ct. 2223 (U.S. 2013).
4 Actavis, 133 S. Ct. at 2227.
understood separately before exploring their overlap. It is also important to review the current climate of both the medical device and hospital provider industries in the United States. It is the intersection of these four distinctive areas, patent law, antitrust law, the medical device industry, and medical providers, that creates an interesting problem. If it is possible that reverse payment schemes are beneficial to both the consumers and the providers while also falling within the tolerable boundaries of both patent and antitrust law, should the Supreme Court revisit reverse payment patent settlements for medical devices for hospitals? Is it possible that these settlements can be consumer friendly outside of the pharmaceutical industry, thereby allowing name brand medical device developers with reverse payment settlements to be shielded from antitrust litigation?

II. BACKGROUND

A. HISTORY OF PATENT PROTECTION

Under Article I, Section 8 of the United States Constitution, Congress has the authority to create legislation to promote production and protect the work product of inventors by granting individuals temporary exclusive rights over their inventions. The right to a product monopoly serves as a potential financial incentive for inventors not only to create, but also to share how the invention functions. The exclusive right is a tradeoff for the knowledge—the patent will eventually expire and be a part of the public collective knowledge. Patent rights are codified under Title 35 of the United States Code and

6 Michele M. Kang, ANDA Reverse Payments and the Post-Actavis Landscape, 8 HASTINGS SCI. & TECH. L.J. 73, 80 (2016) (examining the patent law’s conflicts with antitrust goals and antitrust rulings on patent settlements).
7 U.S. CONST. art. 1, § 8, cl. 8.
8 See Kang, supra note 6; contra Duffy et al., supra note 5, at 524 (Professor J.F. Duffy expresses concerns for viewing the U.S. patent system as a monopoly granting authority). With no codified legal definition provided in the Sherman Antitrust Act, 15 U.S.C. §§ 1–7 (2012), the colloquial definition of monopoly will be relied upon here: “exclusive ownership through legal privilege, command of supply, or concerted action.” Monopoly, MERRIAM-WEBSTER (11th ed. 2003). It should be noted, however, in line with Professor J.F. Duffy’s argument, that under the formal legal test used by the FTC to determine illegal monopolies, patent rights might not be considered squarely monopolies. Antitrust Laws and You, U.S. DEP’T OF JUSTICE, https://www.justice.gov/atr/antitrust-laws-and-you (last updated Jan. 5, 2017).
Valid patents grant the holder exclusive rights to produce the good protected within its claims. Patent holders were historically not given free rein in the market of their legal monopolies. In the past, patent-misuse occurred when a patent holder behaved in a manner that was considered outside the scope of the patent grant or had substantial market effects, like monopolization. Critique of patent holders’ market activity has a significant case history that has helped build current patent-misuse law. Like antitrust litigation, the revisions in statutory interpretations by the Court create a clearer vision of current law. Initially, a patent’s exclusive rights granted the holder wide berth from market-behavior regulation. This broad protection was introduced in the 1912 Supreme Court case, Henry v. A.B. Dick Co. Decided during possibly the most restrictive time in patent infringement litigation, this decision resulted in exaggerated respect for patent holders’ rights. Henry v. A.B. Dick Co. barred an affirmative defense that a patent holder’s market activity overstepped the rights of the patent monopoly. The Court actively reexamined the holding, and the doctrine was subsequently jettisoned only two years later in Motion Picture Patents Co. v. Universal Film Mfg. Co. by the Supreme Court. Notably, however, formal patent misuse laws remained in neither judge-made law nor legislation until the 1942 case, Morton Salt Co. v. G.S. Suppiger Co. Patent-infringement cases continued to be met with misuse affirmative defenses despite legislative action recognizing misuse as an exception to the patent monopoly. The courts took steps to limit patent holders’ behavior by formally introducing “patent-misuse” in Morton Salt Co. v. G.S. Suppiger Co. At the same time, the legislature took steps to limit these defenses with the 1952 Patent Act, which included defining infringement for the first time.

14 224 U.S. 1, 49 (1912).  
16 243 U.S. 502, 518 (1917).  
steps did not quell the patent-misuse allegations, and the frenzy to regulate patent holders' market behavior reached an all-time high with the Deputy Assistant Attorney General, U.S. Department of Justice, Bruce B. Wilson’s infamous “Nine No-Nos.”20 The list, which was proposed and supported by the Justice Department, enumerated the per se misuse practices. At the height of widespread patent regulation, patent holders risked their licensing rights by participating in "behavior that arguably constitutes an attempt to 'extend' the patent monopoly.”21 Courts continued to interpret qualifications for patent misuse, which created circuit splits until Congress passed the Patent Misuse Reform Act of 1988.22 Within the Act, Congress codified a set of “safe harbors” within 35 U.S.C. § 271(d) to clarify what qualifies as an overextension of patent protection that would be open to a misuse affirmative defense.

B. CURRENT STATE OF PATENT PROTECTION

Prior to the passage of the Leahy-Smith America Invents Act (AIA), the U.S. had a first-to-invent system—awarding patents to the inventor who established proof of the concept first. AIA, which only affects patents filed after March 16, 2013, brought a significant change to the United States patent system. The United States is now a first-to-file system,23 but the Act also opened up issued patents to a new and more extensive reexamination process. Now, the only way to legally enter the market of a patented good is to bring a successful federal suit or reexamination request challenging the validity of the patent.24 Challenges are primarily brought by competitors in district courts, but competitors can also enter a request for reexamination25 by the PTO under 35 U.S.C. § 282(b)(2) or (3).26 While the court can hear any invalidity case, there

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21 Homiller, supra note 18, ¶ 14.
22 Id. ¶ 18.
are limits to these administrative reexaminations because “the only issues the Board is allowed to consider in inter partes review (IPR) proceedings are novelty and obviousness.”

It is important to note that the American Intellectual Property Law Association estimates that the “all-in” cost for an IPR is around $300,000. This review is still staggeringly less expensive than the average cost to litigate a patent invalidity claim in district court, which can rise well into the millions. These costs are correlated to, if not caused by, a record high in documented settlements in the pharmaceutical industry in 2014. While these entry barriers are all protected under Title 35 of the United States Code, the difficulty and overhead cost of challenging existing patents hindering market entry is a flag indicating a potential Sherman Antitrust Act dispute.

Once an individual has a valid patent, there are restrictions to its use in the market. After the enactment of the Patent Misuse Reform Act of 1988, the popularity of misuse as a defense has been on a steady decline. This trend is important; it demonstrates the growing strength of patent protection and the widening range of rights patent holders are gaining to control the market space granted to them by the PTO. While patent holders are not immune from certain public policy concerns when engaging in practices that could be considered misuse, there is substantial expansion of tolerable behavior since the

placing a limit the time frame of reexamination request under the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011)); see also Duffy et al., supra note 5, at 694 (noting an upward trend in reexamination filings).


29 Duffy et al., supra note 5, at 701.


Behavior is monitored, but there are no longer per se offenses. The safe harbors under 35 U.S.C. § 271(d) help guide patent holders, but courts retain considerable control to balance private and public interests in misuse cases.

C. HISTORICAL CONTEXT OF ANTITRUST LAW

To decipher when patent protection might not shield an inventor from monopolistic practices, it is important to unravel the statutory provisions and case law that has led to the current understanding of the Sherman Antitrust Act and its companion, the Clayton Act. While many articles and case holdings on reverse payment plans have given a proportionally brief background understanding on the statute, it might help to delve a bit more into the contours of the law to create a complete picture before integrating it with patent protection law.

Enacted in 1890, the Sherman Antitrust Act is codified in 15 U.S.C. §§ 1–7. The statute derives from the Commerce Clause which grants Congress the authority to regulate interstate commerce. The Act’s primary purpose is to delegate “the Federal Government to institute proceedings against trusts in order to dissolve them” for the explicit benefit of the consumer. There is not a single instance of the words ‘promote,’ ‘protect,’ ‘fair,’ ‘market,’ or ‘competition’ in the Sherman Antitrust Act. Most colloquial, not to mention scholarly, understandings of antitrust goals are articulated consistently as “promoting fair market competition.” The original drafted language of the Act directly asserted the promotion of competition goal, but the language was

34 Kenneth M. Frankel & Mark S. Zhai, A Return to the DOJ’s “Nine No-No”?, FINNEGAN (Jan. 2013), http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=9324c489-94fe-4b0a-499-8a817794e44.
35 Lim, supra note 33, at 308–09.
38 See generally Kang, supra note 6; Taylor Burke & Sara Rosenbaum, Aligning Health Care Market Incentives in an Information Age: The Role of Antitrust Law, 5 J. HEALTH & BIOMED. L. 151, 164 (2009).
40 Id.
43 See Burke & Rosenbaum, supra note 38, at 163; Lim, supra note 33, at 299, 310 (direct quote supporting assertion that “the antitrust laws promote vigorous competition” as an accepted overview of antitrust law).
intentionally removed from the final passed text. This omission caused disagreement within the courts: should the elimination of trust be motivated for the good of competition or the good of the consumer? The Court never clarified the goal of the legislation and artfully danced around the conflict between competition-driven versus consumer-interest-driven legislative intent. Yet, the beginning of the 1900s saw this un-codified interest in protecting competition to be a prevailing sentiment that was punctuated in the majority opinion of Standard Oil Co. of New Jersey v. United States. It was not until 1914 when Congress enacted the Clayton Act that the U.S. antitrust legislation officially included 'competition' in the legal vocabulary.

The Clayton Act formally codified the role of competition in antitrust laws. While the Act has seen several amendments, it introduced the “may tend” standard when assessing anticompetitive effects. This change is considered a softening and not “nearly so rigorous an analysis in determining the outlook for anticompetitive effects” as previously codified. The direct results of this change are seen in the current state of antitrust law.

D. CURRENT STATE OF ANTITRUST LAW

United States antitrust law is now controlled by a combination of legislation, common law, and regulatory agencies. The motives behind antitrust law has moved from strictly consumer centric to understanding the totality of the market economy. When assessing the legality of a monopoly, courts now

46 See Orbach, supra note 44, at 2268 (noting that the Supreme Court never commented on the implications of the Sherman Antitrust Act nor mentioned its ramifications on competition in the market place).
47 221 U.S. 1 (1911).
52 Justin (Gus) Hurwitz, Administrative Antitrust, 21 GEO. MASON L. REV. 1191, 1192 (2014).
53 Id. at 1198.
apply a rule of reason instead of a per se analysis. The rule of reason does not prohibit any particular action, but instead employs a balancing test asking three questions: "(1) What harm to competition results or may result from the collaborators' activities?" (2) Are the motivations behind the actions legitimate? (3) Are there less intrusive options? The court uses these questions to decide if the activity in question violates antitrust laws. The rule of reason lends itself to inconsistent holdings, and the case holdings often reflect the economic climate of the case in question. Therefore, the legality of cooperation activity is often best predicted by recent precedent. Antitrust scrutiny was on the rise in 2008 culminating with the inauguration of President Obama who expressly campaigned for increased "review of merger activity." Antitrust agencies saw significant wins in 2015 with threats of antitrust litigation terminating major merger deals. The most notable of these are the Department of Justice (DOJ) threatening and effectively stopping the Comcast/Time Warner Cable merger, and the DOJ filing a complaint and terminating the General Electric/Electrolux merger. Yet, 2016 had a slightly different narrative, with the Federal Communications Commission and the DOJ approving the merger of Time Warner Cable and Charter consummated in May 2016. The DOJ and the FTC are not the only actors terminating major mergers. The largest pharmaceutical merger between Pfizer and Allergan ended in 2016 by an

54 Lim, supra note 33, at 370; see Phillip Areeda, The "Rule of Reason" in Antitrust Analysis: General Issues, FEDERAL JUDICIAL CENTER 1 (June 1981), https://www.fjc.gov/sites/default/files/materials/2017/antitrust.pdf (noting that the distinction, while present, is a relatively simple concept).
55 Areeda, supra note 54, at 2.
56 See Lim, supra note 33, at 370.
57 Areeda, supra note 54, at 26.
58 Jacqueline Grise et al., Top 10 Antitrust Developments And Trends To Watch This Year, LAW360 (Jan. 12, 2016, 4:00 PM), https://www.law360.com/articles/745809/top-10-antitrust-developments-and-trends-to-watch-this-year.
extremely unfavorable taxation regulation passed by the U.S. Treasury before
the FTC could officially stop the merger itself.63

All monopolies are not illegal, however. Legislators have taken special efforts
to ensure that some markets remain under the control of a single corporation or
refined group. Legal monopolies exist in multiple forms such as public service-
providers, like water and waste management, or intellectual-property protection,
like copyright to a novel. This selective tolerance of monopolies is motivated
by an understanding that the benefits incurred by allowing market control outweigh
the concerns.64 Sometimes called natural monopolies, these types of single
market controlled entities are characterized as “industries where capital costs are
especially high and unusually high barriers to entry for other firms exist. Thus,
large economies of scale make it socially optimal to only have one supplier in the
industry.”65 These monopolies have limits; public service providers are restrained
by price requirements66 while intellectual property rights are restrained by time
(patents),67 specificity of use (copyright),68 or a continuation of market strength
(trademark).69 However, these natural monopolies are not without considerable
legal questions. Many politicians advocate for the lessening of state regulated
community resources in attempt to open up suppliers to free market price
demands.70 This fear of price collusion and the role state-granted monopolies
play in unnatural market costs are most hotly contested in the energy providers
sector.71 So while these types of government agreements do exist for service
providers, they are not without staunch opposers. Whether or not the same
opposition exists for intellectual property rights seems to be strongly based on the
industry where the monopoly exists.

63 David McLaughlin, Pfizer-Allergan Deal Faces In-Depth Antitrust Probe by U.S., BLOOMBERG
n-deal-faces-in-depth-antitrust-probe-by-u-s.

64 Richard A. Epstein, Justified Monopolies: Regulating Pharmaceuticals and Telecommunications, 56

65 Steven G. Calabresi & Larissa C. Leibowitz, Monopolies and the Constitution: A History of Crony

66 Id. at 1093.

67 Chapter 2: Fields of Intellectual Property Protection, WIPO INTELLECTUAL PROPERTY HANDBOOK:
m/pdf/ch2.pdf.

68 Id. ¶ 2.164.

69 Id. ¶ 2.796.

70 FIONA M. SCOTT MORTON, The Problems of Price Controls, CATO REV. OF BUS. & GOV’T, 24
controls.

71 Sandeep Vaheesan, Market Power In Power Markets: The Filed-Rate Doctrine and Competition In
III. PATENTS AND ANTITRUST LAW

Patent misuse and antitrust policies are not inherently the same. While there is some overlap, it would undercut both policies to assume both had the same coverage and exceptions. Many legal sources state in some manner that under the Sherman Act, the antitrust analysis for patent antitrust claims is complex because the purpose of patent law—to grant a legal monopoly—contradicts the purpose of antitrust law—to prevent a monopoly. But with both areas of law being particularly malleable by the courts, they could fit together without aversion. Patent misuse, as discussed above, is an overreaching policy concern when the patent holder acts in a way that regulatory boards and courts see as noxious to the market. The patent misuse claim, therefore, lacks steady outcomes in U.S. litigation. Currently downtrending in litigation, patent misuse claims are governed by the U.S.C.’s enumerated Safe Harbors that leave courts with much deference. Antitrust law also follows this amorphous state, but with a richer legislative history to form rational conjectures. The government is actively concerned with the anticompetitive effects of business activity, the interest of the consumer is no longer the singular concern in the analysis of these cases which are, instead, governed by the rule of reason, and certain state-granted monopolies are permissible if advantageous to public policy. Therefore, it is possible from the legislative and case study background of both patent and antitrust law that the popular assumption that the motivation driving these two areas of law contradict is not accurate.

Patent protection and anti-trust law come together then in the area of tolerated monopolies. This is where the two do not conflict. The case law surrounding the intersection of the two however is exceedingly narrow. Most commonly, problems arise around the time of patent expiration. The Supreme Court established unlawful extension of patent protection in Brulotte v. Thys Co., a case involving a licensing contract that extended past the statutory patent protection period. The court in this case was clear: any attempt to extend the

73 Burchfiel, supra note 31.
74 Lim, supra note 33.
75 See supra text accompanying note 50.
76 See supra text accompanying note 53.
77 See supra text accompanying note 56.
78 See supra text accompanying note 65.
80 379 U.S. 29, 30 (1964).
This case was not decided under an antitrust theory, but a patent misuse affirmative defense. The backlash of this decision was swift. Scholars argue that the decision lacked economic sophistication, the limited marketplace effects, and overreaching by the courts that could actually adversely affect competition. Even with extended licensing agreements, the expiration of patent protection will allow other third-party manufacturers to enter the market that are not tied up in licensing agreements. These marketplace concerns are not rooted in patent law however; these are clearly antitrust concerns seeping into patent litigation. The convergence is elegant here. The court interweaves patents, monopolies, bargaining power, and free-market terminology without the tension scholars have assumed was inherently present. Perhaps more telling is despite the backlash, the Court has upheld this ruling within the last year.

The Supreme Court refused to succumb to decades of scrutiny and upheld the Brulotte decision in the 2015 case, Kimble v. Marvel Entertainment, LLC. The court held that if patent holders want extended protection past the protection period, they “must seek relief not from this Court but from Congress.” The case silences the concerns of Brulotte; despite the possibly incorrect economic theory assumed, “there was no empirical evidence showing that Brulotte has decreased innovation.” While the court does recognize that Brulotte concerns both patent and contract law, it still fails to recognize the importance of the third, and possibly more controlling, area of law present in the cases: antitrust. The court in fact goes as far as denouncing its application—

Recall that he wants courts to employ antitrust law’s rule of reason to identify and invalidate those post-expiration royalty clauses with anticompetitive consequences. But whatever its
merits may be for deciding antitrust claims, that “elaborate inquiry” produces notoriously high litigation costs and unpredictable results. Arizona v. Maricopa County Medical Soc., 457 U.S. 332, 343 (1982). For that reason, trading in Brulotte for the rule of reason would make the law less, not more, workable than it is now. 91

In attempt to keep the two areas of law separate, the court effectively creates a new per se rule: if a patent expires and the patent holder attempts to extend his rights, the patent holder is subjected to not only patent misuse affirmative defense, but also antitrust litigation.

A. PAY-FOR-DELAY AGREEMENTS

Reverse payment settlements primarily occur in the pharmaceutical industry 92 and serve as a mechanism for delaying generic drugs from entering the market of a patented drug. 93 They are a natural extension of Brulotte and Kimble. Pay-for-delay agreements not only extend the patent-protection period by incentivizing certain generic manufacturers to not enter the market, they also can impose a duty of no contest to the validity of the original patent. 94 These agreements are unicorns in industry; they are one of the few corporate contracts that result in increased net profit for both the generic and patent holding manufacturers. The FTC has declared fighting these agreements is a “top priority” and predicts that they are responsible for a $3.5 billion excess for consumers. 95 While the FTC may have painted pay-for-delay agreements as an exaggerated villain, it is important to understand how the economics and recent policy changes converge to make these plans profitable.

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, eased the pathway to FDA approval for generic drug manufacturers. 96 The act created the Abbreviated New Drug Application (ANDA) for generics seeking FDA approval for substantially similar to a FDA approved brand-named counterpart. Similarity is determined by the same “dosage form, strength, route of administration,

91 Id. at 12 (citation omitted).
93 Kang, supra note 6, at 78.
94 Id.
96 Kang, supra note 6, at 76.
quality, performance characteristics and intended use." This approval process is a race similar to development—the first to file for a generic is granted specific rights without any agreement with the original patent holder. With just forty-five days to bring suit against the generic, the original inventor is left out of the rights process for the generic. This is intentional. The goals of the Act are to reduce consumer cost and increase competition in the marketplace. The Act grants many rights to the first to file generic—most notable is a 180-day monopoly over generic sales once the patent has expired. It is this provision of the Act that motivates most pay-for-delay agreements and sparked the current trend to form these agreements. These types of settlement agreements rose to the forefront of political concern when the Supreme Court decided FTC v. Actavis, Inc in 2013. This case disputed the legality of the FTC bringing antitrust litigation against the parties to a reverse payment settlement. Historically, pay-for-delay agreements were viewed as legal settlements as opposed to business ventures. Because the patent holder has the right to file a dispute under the ANDA, a reverse payment plan was the response to this disagreement. The courts have no legal right to force civil litigation if the parties opt for a settlement. The court dismissed this distinction, deciding that if the settlement has monopolistic effects outside the grant of the legal patent monopoly, then the settlement could be open to FTC antitrust litigation. While this seems like an obvious conclusion, the court has a historic rule to not interfere with settlement agreements, even those that end with the suing party paying the defendant (which is the form reverse payment settlements take). Nonetheless, the majority believes the dissent is incorrect in its assumption that these agreements are the same and agrees to allow antitrust

99 Id. at 691.
101 Kang, supra note 6, at 85.
104 Id. at 2230.
105 Id. at 2233.
concerns to stand with the simple "we think, [reverse payment settlements] is something quite different" as an explanation.106

The Court held that pay-for-delay agreements are more than settlements on patent litigation rights, but the Actavis case holding is highly specific in scope. The Court takes considerable efforts to articulate the decision around the pharmaceutical industry, outlining "four key features of the relevant drug-regulatory framework" that control generic and name brand drug manufacturing on the first page of the opinion.107 This focus might indicate that the holding's legal arguments will not be applied to these types of agreements outside of the drug industry.

The Supreme Court broadly interpreted the Hatch-Waxman Act in Eli Lilly & Co. v. Medtronic, Inc.108 only five years after the Act was initiated. The holding was significant. The Court interpreted the Act to apply not only to drug companies, but also to medical devices.109 This inclusion was not a passive decision. The Federal District in Philadelphia had specially dismissed the defendant's affirmative defense on the grounds that the Hatch-Waxman Act only applied to pharmaceuticals. The medical device in question was not a drug dispensing device that could be considered within the framework of the law. It instead centered around a cardioverter defibrillator that works as an electromechanical signaling device on the heart; no pharma-tech was involved with its function.110 The consequence of this case is that generic device manufacturers are now under the umbrella of protection of the Hatch-Waxman Act despite the common rhetoric that the Act applies only to pharmaceuticals.111 Therefore, to be consistent with stare decisis, the legal argument for Actavis must rely more heavily on the nature of the pharmaceutical industry and not the legislation of the Hatch-Waxman Act.

IV. GENERIC DEVICES AND 3-D PRINTING

Additive manufacturing, also known as 3-D printing, is a process that marries computer automated design (CAD) directly with the physical world.

106 Id.
107 Id. at 2230.
109 Id. at 669.
111 See Troy, supra note 100 (making no mention of the Act's application outside of the pharmaceutical industry).
With the market flooding with affordable home 3-D printers costing less than the average laptop, their commercial counterparts rival the cost of a high-end MRI machine. The market disruption potential for the technology in the medical field is apparent. The possibility of 3-D printing medical devices is moving from theory to practice. The end of 2015 saw eighty-five FDA-approved 3-D printed medical devices. From teeth straightening to portal veins, the industry is booming because the only barrier to entry is purchasing power—“allowing every individual with the means to buy one, the ability to become a manufacturer.” The major difference in pharmaceuticals and medical devices is the generic market. Currently, there are minimal to no generic device manufactures, but instead, developers add “upgrades” to the devices currently on the market. Additive manufacturing 3-D printing is expected to change this, potentially forcing regulatory agencies, courts, and industry to shift current practices with generic pharmaceuticals to a generic device industry.

What the Supreme Court failed to recognize in Actavis is that a similar FDA expedited approval exists for medical devices outside of Hatch-Waxman. While the court in Eli Lilly applied the Hatch-Waxman Act to medical devices, it did so on a narrow scope. In practice, medical device manufacturers primarily employ 510(k) for an expedited approval of a substantially similar device. The 510(k) Premarket Notification program was established under

113 Jerome Groopman, Print Thyself, NEW YORKER (Nov. 24, 2014), http://www.newyorker.com/magazine/2014/11/24/print-thyself (pricing a medical grade 3D printer at $250,000).
116 Letourneau et al., supra note 114, at 3.
121 Letourneau et al., supra note 114, at 8.
the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act.\textsuperscript{122} One primary differences between 510(k) and Hatch-Waxman is the classification system based on the safety and effectiveness characteristics of the device.\textsuperscript{123} Different regulations apply for each of the three classes, with the lowest in Class I\textsuperscript{124} up to Class III.\textsuperscript{125} Mirroring the Hatch-Waxman Act's ANDA, 510(k) has a Premarket Approval (PMA) that grants FDA clearance to devices that pass much less rigorous testing compared with its already approved parent. When generic devices come to the market, this scheme along with the Hatch-Waxman Act 180-day generic monopoly could persuade brand name device manufacturers to negotiate pay-for-delay agreements with the generics.

A. HOSPITAL ECONOMICS

The United States healthcare industry is a highly complex system with a multitude of actors. Hospital conglomerates (such as Hospital Corporation of America) own and operate 3,183 of the 5,627 hospitals in America. The number of not-for-profit and for-profit is near evenly split.\textsuperscript{126} Five thousand nine hundred and thirty private domestic healthcare insurance providers collected two trillion dollars in domestic premiums in 2015 alone.\textsuperscript{127} However, public health insurance (including Medicaid, Medicare, and Military healthcare) is held by 37.1%\textsuperscript{128} of the population. The government pays a notably disproportionate 47%+ of the total healthcare costs in America for these services.\textsuperscript{129} Public health insurance therefore plays a substantial role in the industry. For a hospital to accept public health insurance, it must comply with numerous and onerous regulations.

\textsuperscript{125} Id. § 360e(b)(1).
The argument in support of shielding hospitals from anti-trust litigation if a member of a pay-for-delay agreement relies on the government's regulation over their specific market. Regulated by the Department of Health and Human Services in conjunction with by state health administrations, hospitals are one of few businesses where performance in certain circumstances is mandatory despite the economic status of the consumer and the hospital's ownership. These federal and state regulations control both public and private hospitals. On the federal level, Section 1867 of the Social Security Act, also referred to as Emergency Medical and Treatment Labor Act (EMTALA), was enacted in 1985 as part of the Consolidated Omnibus Budget Reconciliation Act (COBRA). EMTALA only applies to Medicare-participating hospitals with emergency services. These hospitals are required to provide a medical screening examination for all emergency medical condition, regardless of a patient's ability to pay. EMTALA applies to every patient at the participating hospital, not just the Medicare-covered.

The passage of the Medicaid Anti-Kickback Statute in 1987 greatly restricted alternative forms of income for physicians and health care providers outside of direct payment for services. Kickbacks from pharmaceutical and device companies had become popular—the physician or group would accept a return for patient referrals. The statute was extremely broad and systematically ended "kickbacks, bribes, and rebates made directly or indirectly, overtly or covertly, or in cash or in kind." It is important to note that this statute was passed in 1987, over twenty years prior to Affordable Care Act that greatly increased the number of government-insured patients. These patients are even further protected under Stark Law (I and II). 42 U.S.C.S. § 1395nn protects Medicaid and Medicare patients from financially self-interested referring physicians. All of these laws are centrally focused on healthcare consumer protection, but take little interest in the financial state of the physicians and groups.

Under the Affordable Care Act, healthcare insurance is now legally mandatory with the federal government stepping in to provide public insurance
for income and age qualified citizens.136 The Act has dramatically changed the percentage of publicly covered individuals with “20 million people gaining health insurance coverage under the Affordable Care Act between the passage of the health reform law in 2010 and early 2016.”137 With the current political climate in the United States, the future of this legislation is unknown.138 Because of this uncertainty, it is important that the argument is not substantiated by its implementation. It has affected the percentages and statistics, however, it is unlikely that these trends are to dramatically change in the upcoming years.139

The failure of the American Health Care Act of 2017140 further supports this supposition. The American Health Care Act of 2017 dominated the newsstands and social media outlets over the summer.141 The bill was politically polarizing as it attempted to greatly cut back from the Affordable Health Care Act passed under President Barack Obama.142 The bill was passed by the House of Representatives by a 217–213 margin on May 4, 2017, after being introduced on March 20, 2017.143 Within the House, the bill only saw minor amendments including the MacArthur Amendment and a direct Committee Report.144

139 Id.
The Senate attempted to revise the bill three times. The revised—"skinny"—version of the bill was still ultimately rejected.\textsuperscript{145} Currently, the bill is not dead per se. The bill could see even more revisions, or possibly a redrafting. It is likely that a total repeal/replace of the Affordable Health Care Act will not pass, instead an amendment package might have a higher chance of bicameral approval.\textsuperscript{146}

The numbers can be overwhelming, but they are important in understanding the current shifting landscape. The financial stability of the industry is hotly debated due to ever-increasing government regulation.\textsuperscript{147} While healthcare services is one of the nation’s leading industries in gross profits,\textsuperscript{148} regulations have cut deeply into the pockets of healthcare organizations (HCOs) resulting in uncertain financial future for the market.\textsuperscript{149} Hospitals’ primary consumer is the patient, and patients are currently required by law to carry health insurance.\textsuperscript{150} The insurance provider is responsible for payments outside of a decided deductible to the hospital. These price agreements between the hospital (or hospital group) and the insurance provider allow for a more streamlined bargaining process for cost of services.\textsuperscript{151} It is when the insurance companies fail to pay the coverage that loss occurs; this is called bad debt loss.\textsuperscript{152} This loss is not from pro-bono work, charity, or indigents, but from under or negligent reimbursement from a debtor who is capable of payment.\textsuperscript{153} Medicare and Medicaid are currently accepted at 4,788 hospitals\textsuperscript{154} yet “the ability of government payers to adequately reimburse providers leads the list of...
[bad debt loss] concerns. While hospital enrollment in Medicare and Medicaid coverage is not mandatory, it is economically infeasible not to accept the government insurance. Remember that government payment makes up more than 47% of the total healthcare costs in America, and thus, too great a market margin to make refusal of government insurance economically possible. This percentage, coupled with EMTALA, COBRA, anti-kickback statutes, and other regulatory laws, guarantees the healthcare industry is particularly positioned as both a public and private service.

Hospitals are uniquely equipped to develop 3D-printed generic alternatives to brand named devices. Additive manufacturing technology is most impressive for its ease of adaptability for customized patient fittings. It relies on scanning technology, most commonly MRI machines, present in all hospitals. Hospitals already utilize the technology to prepare for complicated surgeries with exact copies of patient defects and have the proper medical and engineering professionals on staff to ease into the emerging market with little to no cost.

V. THE ARGUMENT

There is a strong argument for allowing reverse payment settlements in the medical device industry for hospitals creating generics instead of purchasing from name brand manufacturers. Reverse payment settlements in this context should be tolerated and shielded from antitrust litigation. The argument relies on two fundamental conclusions from the research:

(1) Anti-trust laws are now motivated by preventing unfair competition instead of strictly centered on consumer protection interest. The rich historical case law and legislation outlined above highlight the current weight courts place on anticompetitive effects on the market. The reality of this less focused locus of consideration and the

155 GAPENSKI, supra note 148, at 18–19.
159 See supra text accompanying notes 38–53.
rule of reason analysis applied to anti-trust cases are inconsistent judgments that often reflect the political climate.\(^6\) While under the Obama administration America saw a rise in antitrust scrutiny\(^1\) and the adoption of the patient/consumer friendly Affordable Care Act.\(^2\) The political goals of the current Trump administration are less clear. While recent health insurance mergers have been blocked for antitrust public policy concerns,\(^3\) economists speculate that the Trump Administration will take a more light-handed approach to antitrust litigation than its predecessor under President Obama.\(^4\) If President Trump’s executive branch is open to more mergers and acquisitions, pay-for-delay agreements outside the pharmaceutical context could be tolerated from an antitrust perspective if the agreements are not against public policy.

(2) The Court and legislation indicate that very little market activity qualifies as patent misuse in the form of unfair competition. One must conclude Actavis should be construed strictly and not apply outside of its narrow field of interest so that the two laws [patent law and antitrust law] do not contradict each other.

(3) Hospitals are bound by government regulations to provide treatment without promise of compensation and often face under-reimbursement from the government controlled insurance companies. Therefore, hospitals should be given an alternative means of income by the government to offset the costs imposed on the industry.

If the three statements are true, it is fair and equitable to allow hospitals to enter into reverse payment settlements with medical device manufacturers without threat of antitrust litigation. The history and current state of the law call for the

\(^{16}\) See supra text accompanying note 53.

\(^{161}\) See supra text accompanying note 58.

\(^{162}\) See supra text accompanying notes 130–37.


Supreme Court to revisit reverse payment settlements. The law should be amended to shield hospitals from antitrust litigation regarding generic device manufacturing reverse payment settlements.

A. POSSIBLE SHORTCOMINGS

First, if the federal courts apply *Actavis* to generic devices by an *Eli Lilly* interpretation of the Hatch-Waxman Act, the Supreme Court should revisit the pay-for-delay scheme outside of the context of the pharmaceutical industry and reevaluate its economically based arguments for opening the agreement to costly antitrust litigation. This move would not be unprecedented. The "narrowest ground" doctrine, formally introduced in *Marks v. United States*, would surely apply here. Under this doctrine, the Supreme Court will, in cases of split decisions such as *Actavis*, "be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds." Therefore, the scope of *Actavis* should be construed to involve only the particular industry in which the case is held under a *stare decisis* rationale.

Second, the concern that the anti-kickback statute might cover pay-for-delay agreements between hospitals and medical device developers is not unfounded. The counter argument for this concern is that the patent holder has a legal monopoly over the market. The court could find that with no alternative outside of a hospital produced generic device, there is no kick-back for failing to produce in house. Finally, offsetting the costs of more expensive devices might not be absorbed by insurance companies but rather spread to consumers. The cost might outweigh the benefit of offsetting failing healthcare financials.

IV. CONCLUSION

After *Actavis*, it seemed the Supreme Court effectively ended pay-for-delay agreements. The holding allowed FTC antitrust intervention when patent terms were expanded to limit generic pharmaceutical manufacturing. However, the holding was clear—this bar would be specifically applied to the pharmaceutical industry due to its complex structure and public policy implications. There is a strong argument that the negative impact of these agreements could not exist outside of the narrow pharmaceutical market. Reverse payment plans might be beneficial in other industries that *Actavis* might not limit.

Currently, there is heavy regulatory control over hospital care and health insurance through the Affordable Care Act. Hospitals are mandatory providers of emergency services, citizens are required to carry health insurance, and federal health insurance providers are responsible for a large percentage of hospital bad debt. The government is requiring performance yet failing to adequately compensate for those services. This issue could be, at least partially, remedied if the government afforded hospitals a financial incentive for compliance. The incentive possibilities are numerous, however one might be to tolerate reverse payment plans between medical device manufacturers and hospitals despite limiting hospital production of generic devices (though 3D printing). Outside the scope of Actiniis, these agreements might not have the negative public policy effects that worried the Court—instead, tolerating the agreements might mitigate some of the economic burden imposed on hospitals from the Affordable Care Act.