2015

Regulatory Responses Against Reverse Payment Agreements in the Pharmaceutical Industry

Njideka Chukwu
Northeastern University

Follow this and additional works at: https://digitalcommons.wcl.american.edu/ipbrief

Part of the Intellectual Property Law Commons

Recommended Citation
Available at: https://digitalcommons.wcl.american.edu/ipbrief/vol6/iss2/3

This Article is brought to you for free and open access by the Washington College of Law Journals & Law Reviews at Digital Commons @ American University Washington College of Law. It has been accepted for inclusion in Intellectual Property Brief by an authorized editor of Digital Commons @ American University Washington College of Law. For more information, please contact kclay@wcl.american.edu.
Regulatory Responses Against Reverse Payment Agreements in the Pharmaceutical Industry

This article is available in Intellectual Property Brief: https://digitalcommons.wcl.american.edu/ipbrief/vol6/iss2/3
REGULATORY RESPONSES AGAINST REVERSE PAYMENT AGREEMENTS IN THE PHARMACEUTICAL INDUSTRY

NJIDEKA CHUKWU*

I. Introduction..............................................................................................................162
II. Patent and Drug Regulatory Regimes and the Pharmaceutical Industry
   A. Regulation Through The Federal Food, Drug, and Cosmetic Act.................................164
   B. Patent Law..............................................................................................................164
   C. Hatch-Waxman Act...............................................................................................166
      History and Purpose ................................................................................................166
      Abbreviated New Drug Application Litigation .........................................................168
III. Pay-For-Delay Scheme In The Pharmaceutical Industry.................................................170
   A. Antitrust Implications In The Pay-For Delay Scheme ..............................................170
      Scope of Patent Test vs. Quick Look Test ...............................................................172
   B. Government Antitrust Lawsuits ............................................................................173
      Government Antitrust cases .................................................................................173
      Private Antitrust Actions Post Actavis .....................................................................176
   C. Future of Reverse Payment Agreements ................................................................179
IV. Comparative Analysis Of Dealing With Reverse Payment Agreements ..............................180
   A. European Union ....................................................................................................180
   B. United Kingdom ....................................................................................................183

* Candidate for Juris Doctor, May 2015, Northeastern University School of Law. The author would like to thank Brook K. Baker, Professor of Law at Northeastern University, for his invaluable support, always being available to discuss the newest developments concerning this article’s subject matter, and providing feedback throughout the writing process. The author would also like to thank Michael G. Bennett, former Associate Professor at Northeastern University, for his encouragement and support.
I. INTRODUCTION

The pharmaceutical industry is a trillion dollar industry where “innovators” and “generic drug companies” compete for market shares.1 Generic companies in the United States had difficulty entering the market until the 1980s when there was a major revision to the drug laws that allowed generics to obtain marketing approval from the Food and Drug Administration (“FDA”) for their generic equivalents without redoing time-consuming and expensive clinical trials. Any company that wanted to sell drugs had to first have their drugs approved for human consumption by the FDA. Competition between generic and innovator companies benefits consumers because it leads to lower drug prices and an increased emphasis on ongoing innovation for major pharmaceutical companies that lose their exclusivity for older products. Innovator companies are aware that absent any differences in the quality of products, consumers will buy the cheapest market on the product. The desire to hold onto their high market shares incentivizes innovator companies to either keep the prices of their products aligned with similar products on the market or develop new products with new qualities that will justify consumers paying an increased price for the newly developed products. When multiple pharmaceutical producers compete in the

1. See David M. Dudzinski, Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics and Monoclonal Antibodies, 60 FOOD & DRUG L.J. 143, 156 (2005) (“[T]he combined market capitalization of the ten largest pharmaceutical companies trading on the New York Stock Exchange exceeds $1.1 trillion, and for the year 2002, the American pharmaceutical industry accounted for slightly more than half of the net profit of the Fortune 500.”); see also A Global Pharma Boom Is Coming... Here’s How To Profit, YAHOO FINANCE (July 11, 2014, 2:00 PM), http://finance.yahoo.com/news/global-pharma-boom-coming-heres-180000860.html (“Today, the global pharmaceutical industry is worth roughly $1 trillion.”); see also Patricia Van Arnum, Global Pharma Market Expected to Reach $1 Trillion, PTSM: PHARMACEUTICAL TECH. SOURCING AND MANAGEMENT (June 2, 2011), available at http://www.pharmtech.com/global-pharma-market-expected-reach-1-trillion (same).

The author is using “innovators” to mean pharmaceutical drug companies that develop the initial drug and “generic drug companies” to mean companies that later develop knock-off versions of the original drug. See The Changing Business Models For Innovator-Drug and Generic-Drug Companies, PHARMATECH.COM (May 5, 2010), http://www.pharmtech.com/changing-business-models-innovator-drug-and-generic-drug-companies?rel=canonical; see also Generic Drugs, WORLD HEALTH ORGANIZATION http://www.who.int/ trade/glossary/story034/en/ (last visited Apr. 11, 2015).
U.S., prices typically fall between seventy and ninety percent. However, certain agreements called “reverse payment” or “pay-for-delay schemes” threaten to dissipate competition, ultimately causing harm to consumers. Under these agreements, innovator, patent-holding companies enter into agreements with generic companies through infringement or invalidation lawsuits. Innovator companies give financial incentives to generic companies to end their patent challenge and to delay coming onto the market. Such arrangements potentially restrain competition in the marketplace and inevitably lead to higher prices for patients, insurers, and public sector health programs.

The United States government is correct in trying to stop and discourage reverse payment settlements because these arrangements harm consumers more than they help. Governments in other nations are also aware of the harmful effects of these arrangements and the various agreements in place between drug companies to lessen competition in the marketplace. Part I addresses the history of drug regulations in the U.S. and how competition between innovator and generic companies occurs. Part II addresses government actions undertaken in an attempt to stop reverse payment settlements between innovator and generic companies. In this regard, the Federal Trade Commission (“FTC”) and the Department of Justice (“DOJ”) have become increasingly concerned with antitrust violations that potentially occur between generic and innovator companies. Thus, the Article will address: (1) how these government agencies have tried to end such collusive settlements; (2) government litigation against pharmaceutical companies to combat the use of reverse settlements; and, (3) the likely repercussions from FTC v. Actavis, in which the Supreme Court held that reverse settlements are subject to antitrust scrutiny while simultaneously holding that the payments are not presumptively illegal. Part III will entail a comparative analysis on how the European Union, the United Kingdom, and India’s regulatory regimes are combating the use of these arrangements.

---

2. Estimate based off several sources that estimated the relative cheapness of generic drugs over brand name equivalents. See David W Freeman, Prescription drug prices set to fall as patents expire, CBS News (July 25, 2011, 11:54 AM), http://www.cbsnews.com/news/prescription-drug-prices-set-to-fall-as-patents-expire/ (“Generic medicines - chemically equivalent to the original brand-name drugs - typically cost 20 percent to 80 percent less than the brand names.”).
II. PATENT AND DRUG REGULATORY REGIMES AND THE
PHARMACEUTICAL INDUSTRY

A. Regulation Through The Federal Food, Drug, and Cosmetic Act

The FDA has to approve all medicines for safety, efficacy, and quality before U.S. companies can produce and market them domestically. Chapter 9 of title 21 of the United States Code, also known as the Federal Food, Drug, and Cosmetic Act ("FFDCA"), was passed in 1938. Under the FFDCA, the FDA became the regulatory body that oversaw the safety of food, drugs, and cosmetics. Until 1962, drugs were approved for safety alone. The Thalidomide scare in 1962, which resulted in many babies born with birth deformities, led to amendments to the FFDCA that required proof of efficacy for new drugs by drug companies requesting FDA approval. In addition, companies have to show adherence to various quality standards, including, most significantly, Good Manufacturing Practices, which are standards the government deemed must be met to ensure adequate quality of products.

B. Patent Law

A U.S. patent grants an inventor the right to exclude others from making, selling or offering to sell, using, or importing into the U.S. the invention claimed in the patent. Patent holders have the right to pursue legal action against those who infringe the holder’s patents. Remedies available to patent holders include injunctions, damages, and attorneys’ fees (but only in “exceptional cases”). The U.S. has a limited research exception in which certain non-commercial uses of patented products or processes are

6. Id. (“Prior to 1962, drugs were approved for safety only…Thalidomide problem in infants - involving safety - resulted in the 1962 drug amendments to the Federal Food, Drug, and Cosmetic Act, which added a proof-of-efficacy requirement to new drug approval. Thus, new drugs must be proven safe and effective prior to the Food and Drug Administration’s (FDA’s) approval.”).
8. Id. § 271.
9. Id. § 283.
10. Id. § 284.
11. Id. § 285.
lawful. This research exception applies in only a small number of circumstances, for example, when the research does not intend to commercialize the drug product. Accordingly, the only use that would fall into this safe harbor is “an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity.” Another limited exception allows for the use of a patented pharmaceutical or biological product or process for the purpose of obtaining marketing approval; however, this exception only applies when specific procedure are followed after a required waiting period.

Innovator companies spend a lot of money on researching and developing new drugs. In addition, the process of obtaining patents and marketing approval on these drugs involves a lot of time and money. Innovator companies are leery of letting generic companies piggyback off the time and money the innovator company expended developing and registering their drugs. In fact, innovator companies spend a significant portion of their research efforts trying to extend or “evergreen” their exclusivity on blockbuster medicines by making slight changes to the chemical entity, the formulation, or the dosage, and by applying for patents on new uses or indications for existing medicines. Critics also charge that the industry engages in patenting around their successful product, creating patent thickets.

---

13. 2 Annotated Patent Digest § 10:6 (2015) (“Under some very narrow circumstances a use that can be characterized as experimental may not be an infringing use.”).
16. 35 U.S.C. § 271(e)(1) (“It shall not be an act of infringement to make, use or sell a patented invention (other than a new animal drug or veterinary biological product...) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs.”).
17. It is highly contested how much is actually spent on researching and developing new drugs. See Roger Collier, Drug development cost estimates hard to swallow, 180 CMAJ 3 (2009) available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2630351/ (“Some researchers fear that the growing expense of developing drugs will stifle innovation. But others claim it’s impossible to determine how far prices are truly rising because drug companies keep a tight grip on their financial data, releasing dribs and drabs on occasion, but only to economists with industry ties.”); see also Morgan S. et. al., The Cost of Drug Development: a Systematic Review, Health Policy. (2011); see also Matthew Herper, How Much Does Pharmaceutical Innovation Cost? A Look At 100 Companies, Forbes (Aug. 11, 2013, 11:10AM), http://www.forbes.com/sites/matthewherper/2013/08/11/the-cost-of-inventing-a-new-drug-98-companies-ranked/.
that forestall competition.  

**C. Hatch-Waxman Act**

*History and Purpose*

The FFDCA was amended by the Hatch-Waxman Act (“Act”). Congress passed the Act, also known as the Drug Price Competition and Patent Term Restoration Act, in 1984. The purpose of the Act was to increase competition in the pharmaceutical industry by incentivizing generic drug companies to enter the drug market. This would lead to a decrease in drug prices and increase innovation amongst the pharmaceutical companies who desire to outperform their competitors but can only do so with new products. Under the Act, generic companies are allowed easier entry to the market because generic companies no longer have to undertake the same clinical trials as innovator companies do before receiving FDA approval to market their generic drugs. The introduction of the Act made it financially feasible for generic companies to enter the market once a patent expired because they no longer had to go through the lengthy and expensive research and development process. Congress intended to balance the need for innovator companies to have strong patent protection in order to make reasonable profits from researching and developing new drugs while also ensuring that consumers would have readily available generic versions of these drugs once the patent term expired. As a consequence of this policy change, generic drugs now account for well over fifty percent of drugs on the market by volume, and over 10,000 generic drugs have entered the market since the Act was introduced.

19. Id.  
22. Id.  
23. Id.  
25. Id.  
27. Id.
All pharmaceutical companies have to follow specific procedures with the FDA prior to getting their products approved to sell on the market. The FDA’s drug approval process is outlined in 21 U.S.C. § 355. The process by which generic companies can seek FDA approval of their products is outlined in 21 U.S.C. § 505(j). The FDA allows generic drug companies to file an Abbreviated New Drug Application (“ANDA”) in order to gain approval to enter the market and sell their products. Unlike innovator companies that develop the original drug and who are required to submit a New Drug Application (“NDA”) with the FDA, generic companies no longer need to submit any NDAs. NDA applications are ordinarily quite extensive, containing information about chemical synthesis, stability, and solubility about pre-clinical and Phase I, II, and III clinical trials, and adherence to quality standards in manufacturing and record keeping. Information about patents relating to the drug must be included in the NDA. By contrast, the generic company’s ANDA would refer to or rely on the innovator company’s NDA application with regards to information about the drug’s safety and efficacy of the generic equivalent. Instead of resubmitting clinical trials, the generic company ordinarily submits evidence of bioequivalence that the generic product acts similarly to the product the innovator company developed. This minimal evidence is supplemented by its own quality-related evidence as well.

The FDA compiles information about patents mentioned in NDA’s in their “Orange Book.” The Orange Book can be obtained on the FDA’s website and contains all relevant information regarding the patented drugs. The only patents that may be submitted to the FDA are drug substance patents, drug product patents, and method of use patents (process pa-
Abbreviated New Drug Application Litigation

Producers of generic equivalents are permitted to file abbreviated new drug applications under specified circumstances. Essentially, companies are precluded from applying to register their generic equivalent unless they indicate that their product will not violate patents listed in the Orange Book. Generic companies have four ways of certifying this requirement.

One of the following four certificates must be listed in the ANDA: (1) that the required patent information relating to such patent has not been filed; (2) that such patent has expired; (3) that the patent will expire on a particular date; or, (4) that such patent is invalid or will not be infringed by the drug, for which approval is being sought.

Under 21 U.S.C. § 505(j)(2)(A)(vii)(IV), generic companies are given a 180-day market exclusivity period against other generic competitors when they file a subsection (IV) petition claiming that the Orange Book patents are invalid or will not otherwise be infringed. This 180-day exclusivity period incentivizes generic companies to challenge patents and seek early market entry. It commences when the generic company begins to offer its product on the market and is only available to the first ANDA filer of a drug and not to subsequent filers.

As stated above, a subsection (IV) certificate filing is commonly chosen by generic companies where a patent might actually be violated. This particular certificate filing, and not I-III, allows for a stay of registration procedures allowing the patent holder to defend the patent because the generic company is essentially stating that the patent listed in the Orange Book is invalid.

Innovator companies have forty-five days to file a patent infringement suit after receiving notice that a generic company has filed an ANDA and provided notice of this filing. Innovator companies that file a patent infringement lawsuit are given thirty months to defend their patents.
from the generic company. At the end of the thirty months, the FDA will grant drug approval to the generic company if the generic company successfully invalidates the innovator company’s patent or proves non-infringement. The FDA does not review patents submitted to the Orange Book for validity because the agency lacks authority to assess patent claims. About seventy-three percent of Orange Book patents are invalidated in subsection (IV)-related cases.

Data exclusivity is also important in the pharmaceutical industry. Patents and data exclusivity are different mechanisms innovators can use to protect new drug products. Patents can be granted at any time during the development of a drug and can encompass many claims whereas “data exclusivity” refers to the exclusive marketing rights a company has once approval from the FDA is garnered. Data exclusivity is therefore not part of the patent regime system. The exclusivity period for non-biologic (New Chemical Entity) drugs is five years; however, there can be a further three-year extension if certain new changes are made to the drugs. Innovators will often use both patents and exclusivity rights to protect their drugs because patents often expire before market approval is acquired. Exclusivity for non-biologic drugs can only be acquired on drugs that have an active moiety that has not already been approved by the FDA. During the five-year exclusivity period, the FDA will not accept an ANDA for a drug based

43. Id.
44. Id.
45. Drug Price Competition Hearing, supra note 27 statement of Daniel E. Troy, Chief Counsel of the U.S. Food and Drug Administration (“FDA does not undertake an independent review of the patents submitted by the NDA sponsor . . . . Issues of patent claim and infringement are matters of patent law, and FDA lacks the authority, the resources, and the capability to assess whether a submitted patent claims an approved drug and whether a claim of patent infringement could reasonably be made against an unauthorized use of the patented drug.”).
47. The patent term and the data exclusivity period do not have to run concurrently. Frequently Asked Questions On Patents And Exclusivity, FDA (July 8, 2014), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm
48. Id.
50. Id. (“An “active moiety” is defined as the molecule or ion responsible for the drug substance’s physiological or pharmacological action.”).
III. PAY-FOR-DELAY SCHEME IN THE PHARMACEUTICAL INDUSTRY

A. Antitrust Implications In The Pay-For Delay Scheme

Purpose of Antitrust Laws

Antitrust law is the study of anti-competitive market behavior and its effects. Antitrust laws were written to encourage market competition. Many antitrust violations depend on an analysis of “market power,” which is “the power to control prices or exclude competition.” One indication of whether a firm has market power is if it can raise prices above competitive levels with the benefits it receives from the price increase outweighing any losses it generates from the loss in sale volume. A firm can acquire and maintain market power so long as the acquisition does not lead to anticompetitive effects. Although certain antitrust violations involve abuses of market power, other violations are illegal because they are collusive or otherwise exclusionary and anti-competitive.

The Sherman Act is one of the most important antitrust statutes, stating, “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.” Anticompetitive effects are analyzed using either the rule of reason test or are judged illegal per se with no further market inquiry made. Under the rule of reason test, the court performs an extensive analysis on the competitive harms and beneficial effects of the practice. Certain practices so plainly lead to anticompetitive effects

51. Id. However, the FDA will accept an NDA for a drug with the same active moiety.
52. E. THOMAS SULLIVAN & JEFFREY L. HARRISON, UNDERSTANDING ANTITRUST AND ITS ECONOMIC IMPLICATIONS 1 (5th ed. 2009).
53. Id. at 2.
54. Id. at 3 (quoting United States v. E.I. Du Pont de Nemours & Co., 351 U.S. 377, 391–92 (1956)).
55. Id. at 23.
57. Id. § 1(a) (2012).
59. Id.
that judges can easily label them as illegal.\textsuperscript{60}

Since United States v. Joint-Traffic Assoc.,\textsuperscript{61} it has been established that practices that directly restrain the market are illegal per se.\textsuperscript{62} Under the per se rule, any agreements involving contract, conspiracy, or combination that falls into the per se category is illegal under Sherman Act.\textsuperscript{63} Activities that fall into the per se category include price-fixing and market division.\textsuperscript{64} Anticompetitive effects are presumed to occur from per se actions.\textsuperscript{65} The economic justification for making certain conduct per se illegal is that it would be a waste of the court’s time to consider defenses for actions that are very likely to be unreasonably anticompetitive.\textsuperscript{66}

The argument over whether pay-for-delay agreements violate antitrust laws stems from the fact that these are essentially agreements not to compete. The Supreme Court has already said that non-compete agreements in general are generally anticompetitive.\textsuperscript{67} Competition is reduced in non-compete agreements where potential competitors are monetarily incentivized by a dominant firm not to enter the market.\textsuperscript{68} However, patents owners have certain exclusive rights and thus protecting that exclusivity is not necessarily unlawful. For example, patentees can grant exclusive territorial licensees that lead to territorial market allocation that are not in violation of the Sherman Act.\textsuperscript{69} Accordingly, the patentee’s exclusionary right is often

\begin{thebibliography}{9}
\item \textsuperscript{60} Id.
\item \textsuperscript{61} 171 U.S. § 505 (1898).
\item \textsuperscript{62} Id. at 6 (“[T]he Court made clear that market practices that affect competition directly are illegal without inquiry into their reasonableness.”).
\item \textsuperscript{63} ANDREW I. GAVIL, ET AL., ANTITRUST LAW IN PERSPECTIVE: CASES, CONCEPTS AND PROBLEMS IN COMPETITION POLICY 105 (2d ed. 2008).
\item \textsuperscript{64} Id. However, some conduct that would normally be per se illegal may be legal in certain circumstances. HEALTH L. PRAC. GUIDE § 32:26 (2014) (“In sum, horizontal agreements to fix prices or allocate markets are per se unlawful unless they are ancillary to a larger transaction (such as a joint venture) likely to achieve significant efficiencies and the agreement is reasonably necessary to achieve those efficiencies. If the agreement is not one directly restricting competition on price or output, or it is ancillary, the rule of reason applies.”).
\item \textsuperscript{65} Id.
\item \textsuperscript{66} Id. at 104–05 (“From the point of view of administrative convenience and judicial efficacy, therefore, the search for the exceptional case—the truly ‘reasonable’ instance of such conduct—is not worth the cost of investigation.”) (quoting also Northern Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958) (“There are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtues are conclusively presumed to be unreasonable.”)).
\item \textsuperscript{67} Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1304 (11th Cir. 2003).
\item \textsuperscript{68} Id. (citing Palmer v. BRG of Georgia, Inc., 498 U.S. 46, 49–50 (1990) and United States v. Topco Assocs., 405 U.S. 596 (1972)).
\item \textsuperscript{69} Id. at 1305.
\end{thebibliography}
invoked as a defense against antitrust claims. On the other hand, there are limits to patent-based exclusionary rights, meaning that patent-holders can be found to have abused their patents when they collude for continuing monopoly control in circumstances that are not justified.

**Scope of Patent Test vs. Quick Look Test**

Courts have analyzed, and the circuits have split, on the proper test to determine whether reverse payment agreements violate antitrust laws: the scope of patent test or the quick look test. The D.C. Circuit, Sixth Circuit, and Third Circuit have favored the quick look test whereas the Eleventh Circuit, Second Circuit, and Federal Circuit have favored the scope of patent test.

The quick look test is a truncated rule of reason test; it is a less intensive analysis than the full rule of reason inquiry, but more rigid than the per se approach. Under the quick look test, the defendant has the burden of showing that their conduct is not anticompetitive. Reverse payment agreements would be subject to strict antitrust scrutiny under the quick look test.

In contrast, the scope of the patent test asks courts to inquire if the reverse payment agreements exceed the exclusionary scope of the patent. Agreements that do not exceed the patent scope are permissible. Under this test, there is a presumption that the patent is valid that can only be proven wrong by evidence of fraud to the Patent and Trademark Office or sham litigation. Most reverse payment agreements would not be found to violate antitrust laws under the scope of the patent test.

The DOJ and the FTC initiated numerous lawsuits challenging the legality of reverse payment agreements. As previously mentioned, there has been a circuit split surrounding this issue. The Supreme Court attempted to pro-
vide guidance on this issue in *F.T.C. v. Actavis, Inc.* However, as will be discussed later in this Article, the Actavis decision did little to resolve the issue of what type of scrutiny courts should use when deciding if these agreements violate antitrust law.

**B. Government Antitrust Lawsuits**

*Government Antitrust cases*

The FTC and the DOJ have been monitoring the development and progression of reverse payment agreements. In its summary report of settlement agreements between pharmaceutical companies for the fiscal year 2006, the FTC stated that in half of the twenty-eight final statements, there were provisions where the generic received compensation and agreed not to market its product for a set amount of time. The surge in these agreements occurred after the Eleventh Circuit reversed the FTC’s decision that reverse settlements violated the FTC Act. The FTC testified to Congress about the need for legislative action to stop these agreements.

The FTC maintained the position that these agreements force consumers to pay more for prescription drugs because of the loss of “cost savings resulting from generic entry after successful patent challenges.”

---

80. 133 S. Ct. 2223 (2013).


82. *Id.* (“The report notes that all of the agreements reported in FY 2006 occurred after the 11th Circuit Court’s decision in Schering-Plough v. Federal Trade Commission, reversing the FTC decision that two settlements involving a restriction on generic entry and compensation to the generic manufacturers violated the FTC Act.”).


84. *Id.*
The FTC’s annual report in 2012 further criticized reverse payment agreements in which it reported forty cases. The increasing occurrence of these agreements was of great concern to the FTC. In nineteen of the forty agreements noted in the 2012 annual report, as an incentive for the generic company to delay coming onto the market with a competing product against the brand name company, the brand name company agreed that for a specified amount of time it would not to develop or sell a drug that competed with the generic company’s drug. These agreements are lucrative for generic companies because the generics will face less competition when they enter the market, enjoy a greater market share, and will be able to charge consumers more for their product.

Consumers, businesses, insurers, and taxpayers will pay higher prices as a result of reverse payment agreements in contravention of the usual effect that “[g]eneric drugs are the key to making medicines affordable for millions of American consumers, and help hold down costs for taxpayer-funded health programs such as Medicare and Medicaid.” Generic drugs are ordinarily about eighty-five percent cheaper than brand name drugs. However, via reverse payment agreements, the delay of generic drugs costs Americans about $3.5 billion annually. If there was legislation that restricted these agreements, the federal deficit could be reduced by $5 billion in the next decade. The DOJ shares the FTC’s view that reverse payment agreements are unlawful.

86. Id.
87. Id.
88. Id.
89. Id.
91. Id.

The Supreme Court finally decided to weigh in on this matter when it granted certiorari in Actavis.\footnote{94. FTC v. Watson Pharmaceuticals, Inc., 677 F.3d 1298, 1312 (2012) and FTC v. Cephalon, 551 F.Supp.2d 21, 25 (D.D.C.2008) were both government initiated lawsuits against pharmaceutical companies that engaged in these agreements. The circuits were split on whether to side with the government. FTC v. Watson Pharmaceuticals, Inc., 677 F.3d 1298, 1312 (2012) and FTC v. Cephalon, 551 F.Supp.2d 21, 25 (D.D.C.2008) were both government initiated lawsuits against pharmaceutical companies that engaged in these agreements. The circuits were split on whether to side with the government.}

In \emph{FTC v. Watson Pharmaceuticals, Inc.},\footnote{95. 677 F.3d 1298, 1312 (2012).} the FTC brought antitrust claims in the Northern District of Georgia against a brand name pharmaceutical company and three generic companies.\footnote{96. FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).} Solvay Pharmaceuticals filed a NDA for a drug called AndroGel and also obtained a patent on the drug.\footnote{97. Id. at 2229.} Actavis, Inc., then known as Watson Pharmaceuticals, and Paddock Laboratories each separately filed an ANDA towards AndroGel.\footnote{98. Id.} Both generic companies certified under subsection IV.\footnote{99. Id.} Another generic drug manufacturer, Par Pharmaceutical, did not file an ANDA, but it had an agreement with Paddock in which both companies would share the patent litigation costs in return Par Pharmaceuticals sharing in Paddock’s profits if Paddock obtained approval for its generic drug.\footnote{100. Id.}

Solvay filed a patent infringement lawsuit against Actavis and Paddock.\footnote{101. Id.} Although the FDA approved Actavis’ first-to-file generic product within the thirty-month timeframe, all parties chose to enter into a settle-
ment agreement. Amongst other promises, Solvay agreed to pay each generic company millions of dollars in exchange for the generic companies’ agreement to delay their entry into the market. The FTC contended that the monetary payments compensated the generic companies to not compete until the time designated in the agreement; however, the companies claimed that the monetary payments was to compensate the generic companies for other services they promised to perform and was based on a weighing of the strengths and weaknesses of the parties’ case.

The District Court dismissed the case for failure to state a claim for which relief could be granted. The FTC appealed to the Eleventh Circuit Court of Appeals, which later affirmed the District Court’s ruling. The FTC then petitioned the Supreme Court for certiorari, which the Court accepted. The Supreme Court ruled that the Eleventh Circuit should have let the FTC’s claim proceed since reverse settlement agreements can sometimes restrain trade and consequently violate antitrust laws.

However, rather than adopting the quick-look test, the Supreme Court decided to use a revised rule of reason test when analyzing whether reverse payment agreements violate antitrust laws. The following five sets of considerations must be considered in the rule of reason analysis: (1) whether the agreements have a “genuine adverse effects on competition”; (2) whether “these anticompetitive consequences will at least sometimes prove unjustified”; (3) whether “a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice;” (4) whether it is necessary to litigate the validity of the patent; and, (5) whether there are other reasons why the parties may want to settle, even if settling includes monetary payments.

Private Antitrust Actions Post Actavis

The Actavis decision has had an impact in actions brought by private litigants, both competing generic companies, and direct purchasers who challenge the exclusionary, anti-competitive effects of reverse-payment/

---

102. *Actavis, Inc.*, 133 S. Ct. at 2229.
103. Id.
104. Id. at 2230.
105. Id.
106. Id.
107. Id.
108. Id. at 2227.
109. Id. at 2238 (“We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation. We reverse the judgment of the Eleventh Circuit. And we remand the case for further proceedings consistent with this opinion.”).
110. Id. at 2234–38.
delayed-entry agreements. One of the most recent private litigation lawsuits since Actavis is In re Lamictal Direct Purchaser Antitrust Litigation.111 This lawsuit is centered on a settlement between GlaxoSmithKline LLC ("GSK") — seller and manufacturer of Lamictal tablets and chewables, which treated epilepsy and bipolar disorder—and Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals ("Teva")—a company that wanted to sell generic versions of GSK’s drugs. The defendants sold generic versions of drugs GSK developed to treat epilepsy and bipolar disorder.112

The active ingredient in these drugs is lamotrigine.113 GSK had a patent on lamotrigine that was set to expire in July 2008.114 In 2002, Teva filed the first ANDA for lamotrigine and was thus entitled to the 180-day exclusivity period to be the sole generic company to manufacture the drug.115 GSK sued Teva for patent infringement and in 2005 both companies entered into a settlement agreement.116 Under the terms of this agreement, if Teva was permitted to market generic version of lamotrigine only shortly before GSK’s patent expired and only for a certain period of time after the expiration date, ensuring that Teva’s own generic tablets and chewables would not have to compete with GSK’s “authorized generic.”117

Plaintiffs in this lawsuit alleged that Teva and GSK’s reverse payment agreement violated antitrust laws.118 Plaintiffs questioned the legality of the settlement between GSK and Teva that both companies agreed upon after GSK sued Teva for patent infringement (Teva’s ANDA application included a subsection IV certification against all but one claim in the lamotrigine patent).119 Defendants filed a successful motion to dismiss, the plaintiffs appealed and subsequently the Court of Appeals for the Third Circuit remanded.120 The plaintiffs then moved for reconsideration of the motion to dismiss.121 The New Jersey District Court upheld the motion to dismiss.

According to the District Court’s interpretation of the Actavis ruling the
rule of reason test applies only to monetary patent settlements.\textsuperscript{122} Since there were no monetary exchanges in the agreement between GSK and Teva, the \textit{Actavis} scrutiny did not have to be applied.\textsuperscript{123} Nonetheless, in dicta, the New Jersey District Court applied the \textit{Actavis} scrutiny and still found that the GSK and Teva agreement did not violate antitrust laws.\textsuperscript{124}

Another recent private action is \textit{In re Lipitor Antitrust Litigation}.\textsuperscript{125} This case was brought on behalf of the class action plaintiffs who wanted to amend their complaint in response to defendant Pfizer Inc.’s motion to dismiss all the complaints.\textsuperscript{126} The plaintiffs purchased Pfizer’s drug, Lipitor.\textsuperscript{127} The plaintiffs alleged that Pfizer’s agreement with generic company Ranbaxy that resulted in Ranbaxy staying off the market for a certain time-period, violated antitrust laws.\textsuperscript{128}

In light of \textit{Actavis}, the plaintiffs sought to amend their complaint to clarify their reverse payment allegations.\textsuperscript{129} Pfizer argued that the amendments would be futile, the plaintiffs took too long to file their motion to amend, and Pfizer would be prejudiced if leave to amend were granted.\textsuperscript{130} The New Jersey District Court granted the plaintiffs’ motion to amend their complaint because “nothing in \textit{Actavis} strictly requires that the payment be in the form of money.”\textsuperscript{131} The New Jersey District Court also did not agree with Pfizer’s other arguments against granting the motion to amend the complaint.\textsuperscript{132}

\begin{itemize}
  \item[122.] \textit{Id.} at *5.
  \item[123.] \textit{Id.}
  \item[124.] \textit{Id.} at 10 (“...this Court has considered the settlement under the “five considerations” of \textit{Actavis}. It finds that the settlement would most likely survive.”).
  \item[125.] No. 3:12–cv–2389 (PGS), 2013 WL 4780496 (D.N.J. Sept. 5, 2013).
  \item[127.] \textit{Id.}
  \item[128.] \textit{Id.}
  \item[129.] \textit{Id.} at 13.
  \item[130.] \textit{Id.} at 26 (“Plaintiffs seek to demonstrate that the Pfizer/Ranbaxy settlement of their Accupril litigation, which was referenced in the Complaint, was, in reality, a payment by Pfizer to Ranbaxy to delay Ranbaxy’s launch of its generic version of Lipitor, regardless of the fact that Ranbaxy made a $1 million payment to Pfizer. Defendants argue that the proposed amendment would be futile because the amended allegations still fail to allege an actionable reverse payment under the Supreme Court’s standard in \textit{Actavis}, which Defendants say only applies to settlements involving large monetary payments from the brand name manufacturer to the generic.”).
  \item[131.] \textit{Id.}
  \item[132.] \textit{Id.} (“Nor does the Court agree that Plaintiffs have unduly delayed seeking leave to amend their complaints or that Defendants were prejudiced in any way. False In addition, Defendants bear the burden of demonstrating they would be prejudiced by the amendment, and they have not done so.”).
Another recent private action occurred in *In re Nexium (Esomeprazole)* Antitrust Litigation. This was a class action case brought by a group of wholesale drug distributors and health and welfare benefit funds against AstraZeneca and three generic drug manufacturer defendants who had entered into a reverse payment agreement. The Massachusetts District Court broadly applied *Actavis* despite the fact that the brand name pharmaceutical company made direct and indirect payments to the generic companies in the various reverse agreements; the court granted the defendants’ motion to dismiss in part and denied the motion in part.

**C. Future of Reverse Payment Agreements**

*Actavis* was not a success for the FTC and DOJ in the sense that the Supreme Court did not hold that reverse payment agreements should be scrutinized as per se illegal. Nonetheless, the government agencies should consider it a victory that it will be easier to bring antitrust lawsuits because all circuits must now apply the more stringent *Actavis* test.

In the future, it seems that the courts will be more likely to apply the enhanced rule of reason test from *Actavis* when money payments are part of the provision in the agreements. However, the government will still have to provide sufficient evidence that the transfer of money was intended to compensate the generic for staying out of the market for an agreed upon period of time, and not for other services rendered pursuant to provisions in the settlement agreement. It remains to be seen how the various lower federal courts will apply *Actavis* when there is no money payment associated with the agreements.

The *Actavis* ruling left many questions unanswered: “[H]ow the rule-of-reason will be applied in reverse payment cases, when and to what extent the validity of the patent will need to be tested as part of the rule-of-reason analysis, what types of direct economic evidence lower courts might consider when assessing the competitive effects of the reverse payment, what indirect evidence will serve as the most useful evidence of anticompetitive effects, whether market definition will play a meaningful role in the analysis, and how courts will analyze potential efficiencies that the Court acknowledged can arise from such agreements.”

135. *Id.* at 410–11.
It is very likely that there will have to be more intensive economic analyses on the effects of these agreements. The existence of a large payout by itself is not prima facie evidence of anticompetitive conduct because the Supreme Court explicitly rejected this as a general presumption. The Supreme Court did not state what constituted a “large and unjust” payment. In the midst of trying to strike a happy medium between per se illegality and the scope of patent test, the Supreme Court left many questions unanswered and there will likely be numerous future cases as the government, pharmaceutical companies, and consumers try to flesh out how to apply this new reverse payment test.

The FTC estimates that reverse payment agreements cost consumers $3.5 billion a year. This article submits that ultimately consumers will benefit from the Actavis ruling because there is at least a chance to strike down such agreements in districts where, previously, it was nearly impossible to bring antitrust suits against brand name and generic companies. The FTC and DOJ hope that there will be a significant decrease in the cost consumers have to pay for drugs.

Having completed a brief review of relevant U.S. jurisprudence on reverse-payments, the proceeding section will discuss how the European Union and United Kingdom are dealing with these types of settlement agreements.

IV. COMPARATIVE ANALYSIS OF DEALING WITH REVERSE PAYMENT AGREEMENTS

A. European Union

The U.S. is not the only country grappling with how to regulate the use of reverse payment agreements by pharmaceutical companies. The European Commission ("Commission") is the E.U.’s executive body. The
Commission’s roles include proposing legislation, implementing E.U. policies, and with the Court of Justice, enforcing E.U. law.\footnote{Id.}

Two rules in the Treaty on the Functioning of the European Union (“Treaty”) lay the foundation for European antitrust policy.\footnote{Competition, European Commission (last updated Aug. 16, 2012), http://ec.europa.eu/competition/antitrust/overview_en.html.} Article 101 of the Treaty prohibits “agreements between two or more independent market operators which restrict competition.”\footnote{Id.} Article 102 of the Treaty “prohibits firms holding a dominant position on a determined market to abuse that position, for example, by charging unfair prices, by limiting production, or by refusing to innovate to the prejudice of consumers.”\footnote{Id.} The Treaty grants the Commission with the power to fine parties that violate the E.U.’s antitrust rules.\footnote{Id.}

In 2009, the Commission issued a press release on its final report about the pharmaceutical sector.\footnote{Antitrust: shortcomings in pharmaceutical sector require further action, European Commission (July 8, 2009), http://europa.eu/rapid/press-release_IP-09-1098_en.htm?locale=en.} The Commission declared that there was a need for more competition in the pharmaceutical sector because the delay of generic drugs into the marketplace was increasing the cost of drugs for taxpayers and patients.\footnote{Id.} A final report found:

on the basis of a sample of medicines that faced loss of exclusivity in the period 2000 to 2007 in 17 Member States, [citizens] waited more than seven months after patent expiry for cheaper generic medicines, costing them 20% in extra spending. Generic delays matter as generic products are on average 40% cheaper two years after market entry compared to the originator drugs. Competition by generic products thus results in substantially lower prices for consumers.\footnote{Id.}

In response to its findings, the Commission increased its scrutiny on the pharmaceutical companies and conduct aimed at excluding competitors that were devoid of innovative efforts.\footnote{Id.}

The inquiry into the pharmaceutical sector began in January 2008 because the Commission noticed that fewer medicines were entering the market and wondered why there was increased delay in generic entry to the
Since the findings from the 2009 report were released, there have been three major cases where the Commission has objected to reverse payment agreements. In addition, since 2010, the Commission has been releasing yearly patent monitoring reports “to identify potentially problematic settlements from an antitrust perspective, in particular those that limit generic entry against a value transfer from an originator to a generic company.”

The E.U. regulators have begun fining drug companies that engage in reverse payment agreements. The sanctions against French drug maker Servier and Israel’s Teva are the third such sanctions by the E.U. These sanctions were very much needed since the agreements forced consumers to pay as much as twenty percent more for drugs than they otherwise would not have had to pay. Although Servier and Teva face fines of up to ten percent of their global turnover (Servier’s total sales in 2013 was 4.2 billion euros), the total fines will likely not exceed 300 million euros. The other two sanctions that the EU competition watchdog levied were total fines of 146 million euros (June 2013) and 16.3 million euros (December 2013).

Servier was found to violate Article 102 of the Treaty because “Servier misused such legitimate tools by shutting out a competing technology and buying out a number of competitors that had developed cheaper medicines, to avoid competing on their own merits. Such behavior violates EU antitrust rules that prohibit the abuse of a dominant market position.” Servier, and its competitors who it entered into agreements with were found to violate Article 101 of the Treaty.

Although one can argue that these fines pale in comparison to the total profits the companies make annually, it is a positive sign that E.U. antitrust regulators are trying to do something to show consumers that the government is taking actions to lower the cost of drugs. Hopefully, post-Actavis,
the FTC will be able to also fine U.S. drug-makers millions, if not billions, for reverse payment schemes.

B. United Kingdom

United Kingdom regulators are also cracking down on pharmaceutical companies utilizing reverse payment agreements. For example, the Office of Fair Trading (“OFT”) had been investigating the agreements GlaxoSmithKline (“GSK”) had made with generic companies between 2001 and 2004 in which the generic brands of GSK’s most popular antidepressants would not be on the market for a delayed period of time. Entry of the drugs into the market could have saved the NHS millions of pounds.

Until April 1, 2014, the OFT was responsible for consumer protection in the UK. As of April 2014, the Competition and Markets Authority (“CMA”) has taken over the duties of the OFT. The CMA investigates antitrust violations, which are governed by both the Competition Act of 1998 and the Treaty.

It will be interesting to see how aggressive the CMA decides to pursue pharmaceutical companies that enter into reverse payment agreements. After all, it is estimated that in the United Kingdom, generic drugs cost as much as eighty-five percent less than brand name counterparts. This big

162. Id.
difference in price between generic brand name drugs should serve as a big incentive for the CMA to look closely at these agreements.

C. India

India has relatively weak patent laws so as to ensure that drugs stay as affordable as possible since most of the population is unable to afford expensive drugs. 167 The patent laws also help local pharmaceutical companies compete with multinational companies selling to India. 168 Under India’s Patents Act of 1970, product patents could not be obtained for food or medicine. 169 However, the Trade-Related Agreement of Intellectual Property Rights (“TRIPS”) required India to modify the Patents Act of 1970 so as to comply with the minimum intellectual property standards laid out in TRIPS. 170 India and other developing countries that have weaker patent laws did not like the TRIPS requirements because they made it extremely difficult for local drug companies to compete with international companies selling in the local lands. 131 Importantly, product patents for medicines would be allowed and the patent term would have been extended to twenty years. 172

In response to the expiration of India’s transition period under TRIPS, India’s legislature added a provision that barred the patenting of new forms of known substances unless the new forms had a significant efficacy compared to the known substances. 173 Also, India has a high standard for the inventive step requirement, which makes it more difficult to obtain patents on medicines. 174 Yet another way India is ensuring that its local generic companies can compete while following TRIPS is by not having a patent linkage system. The U.S. is one of a few developed countries that have a patent linkage sys-

168. Id. This was significantly more than the patent term India previously had.
169. Id. at 5 (citing Patents Act, 1970, 27 INDIA A.I.R. MANUAL 450 (1979)). In particular consider § 5(a)-(b).
170. Id. at 28. TRIPS is the Agreement on Trade-Related Aspects of Intellectual Property Rights. It outlines the minimum requirements all World Trade Organization members have to enact in their intellectual property laws.
171. Id. at 29.
172. Id.
173. Molly F.M. Chen, Reconsidering the U.S. Patent System: Lessons From Generics, 45 VAND. J. TRANSNAT’L L. 1249 (2012); see id. at 1258 (“The Provision, § 3(d), bars companies from patenting new forms of known substances unless the new form demonstrates a significant enhancement in efficacy.”).
174. “Inventive step” refers to a patentability requirement where the invention that is to be patented should not already be obvious to one skilled in the ordinary art. Id.
Patent linkage is “the practice of linking the granting of . . . any regulatory approval for a generic medicinal product to the status of a patent for the originator reference product.” Patent linkage systems hinder generic competition. Bayer was unsuccessful in trying to persuade India’s High Court to read India’s Drugs and Cosmetic Act with its Patent Act because doing so would have created a de facto linkage regime.

India, therefore, has made numerous efforts to keep its drug market competitive in order for its generic companies to thrive. Instead of having a regulatory body that fines brand name pharmaceuticals (which almost exclusively are multinational companies), India has made it extremely hard for brand name companies to enter into its marketplace because the country has made it hard to obtain patents on medicines. However, the Indian government is still concerned about curtailting any potential pay-for-delay schemes that might occur and is starting to look into curtailting these schemes. The country’s competition regulator, the Competition Commission of India (“CCI”) may start examining reverse settlement agreements. The CCI might investigate two agreements, the agreements between: (1) F Hoffmann-La Roche Limited and Cipla Limited and (2) Merck Sharp and Dohme Corporation and India’s Glenmark Pharmaceuticals Ltd. The CCI will also start to investigate how the market is being impacted by the lack of entry of local drug makers. The CCI’s investigations are evidence that the government is concerned about these agreements even though the agreements may not be as prevalent as in other countries.

V. CONCLUSION

Competition in the marketplace is good because it ensures that consumers are getting the best products at the best prices. The U.S. patent laws incentivize innovation and reward those that come up with new products. Companies should not be allowed to distort market conditions by entering into anti-competitive reverse-payment or pay-for-delay agreements because ultimately it is the consumers that lose. Drug discovery is meant to better humankind, not make an already profitable industry even wealthier at the cost of patient access to life-saving drugs. Actavis should provide consum-

175. Id. at 1262.
176. Id. (“The court determined that patent linkage is only a TRIPS-Plus construction that is not applicable to India, which is only bound to the parameters of TRIPS itself.”).
177. Id. at 1265–66.
179. Id.
180. Id.
ers’ with confidence that regulatory bodies will be better able to protect them. There are different regulatory responses to reverse payment agreements. The EU and UK regulatory bodies are already fining drug companies who engage in such agreements, and the U.S. will finally be able to follow suit. In addition, the Indian government may start investigating these agreements. These different regulatory bodies are taking diverse actions to curtail the use of reverse payment agreements in the pharmaceutical industry. The governments are sending a message to the pharmaceutical industry that the industry is being carefully monitored.