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A Comparative Analysis of the Legal Framework and Case Law on Reverse Payment Settlement Agreements in the United States and South Korea

*Sung San Kim**

Abstract: In 2013, the U.S. Supreme Court issued a landmark decision, FTC v. Actavis, in which it ordered the lower courts to apply the rule of reason to “reverse payment settlement agreements.” As the leading jurisdiction for antitrust and intellectual property laws, the United States is once again poised to influence foreign jurisdictions on the issue of reverse payment settlement agreements. In this context, South Korea presents a ripe opportunity for a comparative study because it recently adopted a patent-approval linkage system under which reverse payment settlement agreements will likely become a contentious issue. In particular, the South Korean Supreme Court’s recent case, GlaxoSmithKline v. Korea Fair Trade Commission, offers valuable insight into how Korean courts will likely approach this issue. This Comment contends that the U.S. case law, including Actavis, offers important insights for the Korean legal community and that Korea’s experiment has potential to offering a fresh approach in tackling reverse payment settlement agreements.

* J.D., 2015, Northwestern University School of Law; B.A., 2006, University of California, Berkeley. I thank God for His amazing grace. I thank my wife and daughter, Jina and Elizabeth, for their unrelenting support and faith in me. Laura Kelly and the Northwestern Journal of International Law & Business’ editorial staff have provided invaluable support and feedback. Jin Woo Hwang was gracious to share his practical knowledge on the South Korean legal system. This Comment would not exist without them. Any error or shortcoming found in this Comment is mine.

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I. INTRODUCTION

On June 16, 2013, the U.S. Supreme Court issued a landmark antitrust decision in *Federal Trade Commission (FTC) v. Actavis, Inc.*, settling a circuit split on the issue of “reverse payment settlement agreements.”¹ The Court held that such agreements should be scrutinized under the “rule of reason” analysis instead of being analyzed under the “scope of the patent” test.² After settling the split, the Court remanded the case to be tried under the rule of reason analysis.³ Interestingly, the Court did not spell out the level of strictness that should be applied under the rule of reason analysis: “We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.”⁴

This Comment analyzes the Court’s holding, which shifts the balance from the scope of the patent test to the rule of reason analysis, and examines the potential impact that this shift will have in the development of antitrust law in South Korea. This study is important for two reasons. First, because U.S. antitrust law is highly developed and more advanced than that of many other nations, key decisions by U.S. antitrust agencies and courts can influence foreign jurisdictions.⁵ Second, the issue of reverse payment settlement agreements is gaining significant attention from

¹ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2223–47 (2013). Reverse payment settlement agreements arise under the context of the Federal Drug Administration’s Abbreviated New Drug Application (ANDA) regime of the Hatch-Waxman Act, 21 U.S.C. § 355. ANDA was originally intended to encourage the expedited entry of generic drugs into the brand-name drug company market by allowing generics to refer to the original drug company’s safety and efficacy data during the application process. *See infra* Part II(A). However, after the filing of an ANDA and the ensuing patent litigation, in practice the original drug company agrees to pay the generic drug company to stay out of the market. *Id.* These agreements are referred to as “reverse payment settlement agreements” and may also be referred to as “pay-for-delay” or “pay-to-delay” agreements. Shannon U. Han, *Pay-to-Delay Settlements: The Circuit-Splitting Headache Plaguing Big Pharma*, 15 VAND. J. ENT. & TECH. L. 913, 914 (2013); Marlee P. Kutcher, Comment, *Waiting is the Hardest Part: Why the Supreme Court Should Adopt the Third Circuit’s Analysis of Pay-for-Delay Settlement Agreements*, 44 LOY. U. CHI. L.J. 1093, 1095 (2013).

² *FTC v. Actavis, Inc.*, 133 S. Ct. at 2237. The scope of the patent test adopted by the Second Circuit presumes that the patent holder has the right to monopolize the market and to settle patent litigation unless the litigation is a sham or baseless. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 208–09 (2d Cir. 2006). Under the rule of reason analysis, the court balances the procompetitive efficiency generated by an agreement and weighs it against the anticompetitive effects. *See infra* Part III(A). Rule of reason analysis is an alternative to the “per se” rule, which holds price-fixing agreements as per se illegal. *Id.*

³ *FTC v. Actavis, Inc.*, 133 S. Ct. at 2238.

⁴ *Id.*

⁵ See David J. Gerber, *Competition Law*, 50 AM. J. COMP. L. 263, 270 (2002) (“U.S. antitrust has occupied the center of the competition law universe. It is the competition law to which others have looked and about which others have generally known more than they have known about other competition law systems. Although I have shown elsewhere that its influence has not always been as direct and straightforward as many have assumed, it has frequently played a ‘model’ role for decisionmakers in other systems.”).

scholars and practitioners in the fields of intellectual property and antitrust laws in South Korea. Such heightened interest most likely arose from the introduction of the patent-approval linkage system into Korea's pharmaceutical laws and a recent decision of the Supreme Court of the Republic of Korea that addressed a similar issue to the one in *Actavis*. Scholars have written articles in Korean law journals comparing *Actavis* to the recent Korean case, and leading law firms have published their forecasts of a patent-approval linkage system on Korea's pharmaceutical industry. This Comment surveys these legal developments in South Korea and attempts to answer the following questions that arise in this context.

First, why is Korea adopting a patent-approval linkage system that mimics the Hatch-Waxman Act and thereby creating an incentive structure that accommodates reverse payment settlement agreements similar to the United States? Second, what can we learn from the *GlaxoSmithKline v. Korea Fair Trade Commission* case⁶ regarding the Korean judiciary's stance on reverse payment settlement agreements? Third, what can Korea learn from the U.S. experience on reverse payment settlement agreements? Particularly, what can Korea learn from the U.S. Supreme Court's reasoning in *Actavis* and from the circuit splits that led to the Supreme Court's decision?

Regarding the first question, this Comment argues that there is a plausible explanation for Korea's adaptation of a regulatory structure similar to that of the Hatch-Waxman Act. Korea's regulatory agencies may be making a strategic choice to import a *working* pharmaceutical regulatory framework that balances the goals of patent laws and antitrust laws because a functioning regulatory framework is worth the risk of having to deal with reverse payment settlement issues. On the second question, this Comment explores the two decisions' similarities and differences. Specifically that, while on its face the *GlaxoSmithKline* court appears to confuse the rule of reason analysis and the scope of the patent test,⁷ the two courts' similar analyses are the result of independent legal reasoning under different legal systems. This Comment further asserts that the *Actavis* decision offers a preview of how Korean courts will likely decide reverse payment settlement agreements when they arise under the impending regulatory framework. Lastly, this Comment argues that the case law on reverse payment settlement agreements that has developed in the United States over the past twelve years, particularly the *Actavis* decision, offers a wealth of legal reasoning that could be useful for Korean regulatory agencies and courts. Building off of these resources will allow Korean agencies and courts to reach better decisions and allow Korean practitioners to put forth

⁶ Supreme Court [S. Ct.], 2012Du24498, Feb. 27, 2014 (S. Kor.).

⁷ As some Korean experts have argued, the issue in the GSK decision could have been easily decided by applying the scope of the patent test. *See infra* Part III(B)(5).

the most persuasive arguments in these matters.

In order to achieve these objectives, this Comment proceeds in the following order. First, Part II provides the statutory framework of the reverse payment settlement agreements and the conflicting circuit court splits leading up to *Actavis*. Part II also examines the Court's legal reasoning used in *Actavis*. Part III analyzes the decision's significance in U.S. domestic jurisdictions, especially regarding how lower courts will develop and refine the rule of reason analysis. This portion is important because *Actavis* is a U.S. case, and to understand it properly, one must understand the case's impact in the United States. Additionally, Part III examines the *GlaxoSmithKline* case and the recent proposal for a patent–approval linkage system in South Korea. It also addresses and answers the questions presented above. Finally, Part IV summarizes the findings and major propositions propounded in this comment.

II. BACKGROUND

In order to set up the context for the analysis that will appear in Part III, this Part introduces the following topics that will facilitate the reader's understanding of reverse payment settlement agreements. Subpart A provides the statutory framework of the Hatch–Waxman Act under which the issue of reverse payment settlement agreements arose. Subpart B highlights the importance of the 180-day exclusive marketing period, which was provided in the Hatch–Waxman Act as a key factor to incentivize parties to enter into reverse payment settlement agreements. Subpart C provides a brief survey of the conflicting circuit court decisions that led up to the *Actavis* decision. Finally, subpart D examines the Supreme Court's reasoning and holding in the *Actavis* decision.

A. Statutory Framework Under the Hatch–Waxman Act.

This subpart introduces the statutory framework under which reverse payment settlement agreements came into existence. Reverse payment settlement agreements arose under the drug regulatory framework created by the Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch–Waxman Act.⁸ Under the Hatch–Waxman Act, a pioneering drug company that develops an innovative drug must file for a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in order to receive marketing approval.⁹ Obtaining a NDA approval is a burdensome and costly process, and pioneering drug

⁸ Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch–Waxman Act), 21 U.S.C. § 355(b)(1) (2006).

⁹ *Id.* § 355(b).

companies invest significant resources to gain such approvals for their innovative drugs.¹⁰

In order to foster competition and drive drug prices closer to the market price, Congress included the Abbreviated New Drug Application (ANDA) process in the Hatch–Waxman Act that encourages the market entry of generic-drug companies.¹¹ Under the ANDA process, once the pioneering drug company has obtained marketing approval through a NDA, a generic-drug company may apply for an ANDA with the FDA to obtain marketing approval for its generic version of a brand-name drug.¹² An important aspect of the ANDA is that, if the ANDA is approved, the first-to-file applicant of an ANDA is given a 180-day exclusive marketing period for its generic version of the drug before other generic-drug companies may enter the market.¹³

In order to file an ANDA, the generic-drug company must certify that its drug has the same active ingredients and is biologically equivalent to the original brand-name drug.¹⁴ Because such certification induces patent infringement, the Hatch–Waxman Act specifies how the parties will identify and resolve potential patent conflict. First, the pioneering drug manufacturer must list the “number and the expiration date of any [relevant] patent” in the NDA.¹⁵ Second, the ANDA applicant must assure the FDA that its generic version of the drug will not infringe on the brand-name manufacturer’s patent using one of the following four methods: (i) certifying that the brand-name manufacturer has not listed any relevant patents; (ii) certifying that any relevant patents have expired; (iii) requesting approval of marketing when relevant patents expire; or (iv) certifying that any listed, relevant patent “is invalid or will not be infringed

¹⁰ See *FDA Drug Approval Process Infographic*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm295473.htm> (last updated Apr. 25, 2014) (indicating that drug companies must complete preclinical animal testing and three phases of clinical tests involving humans before filing a NDA); see also Matthew Herper, *The Cost of Creating a New Drug Now \$5 Billion, Pushing Big Pharma to Change*, FORBES (Aug. 11, 2013, 11:10 AM), <http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/> (“A company hoping to get a single drug to market can expect to have spent \$350 million before the medicine is available for sale. In part because so many drugs fail, large pharmaceutical companies that are working on dozens of drug projects at once spend \$5 billion per new medicine.”).

¹¹ See H.R. REP. NO. 98–857, pt. 1, at 14 (1984) (“The purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962.”); see also Alicia I. Hogges-Thomas, *Winning the War on Drug Prices: Analyzing Reverse Payment Settlements Through the Lens of Trinko*, 64 HASTINGS L.J. 1421, 1425 (2013).

¹² 21 U.S.C. § 355(j).

¹³ *Id.* § 355(j)(5).

¹⁴ *Id.* § 355(j)(2)(A)(ii), (iv).

¹⁵ *Id.* § 355(b)(1).

by the manufacture, use, or sale” of the drug described in the ANDA.¹⁶ The fourth option, known as the “Paragraph IV” or “ANDA IV” certification, amounts to a generic-drug company’s challenge to the pioneering drug company’s patents and is treated as an automatic infringement of the latter’s patent rights.¹⁷

After a generic-drug company files a Paragraph IV certification, if the brand-name patentee brings a patent infringement lawsuit within forty-five days, the FDA must withhold approving the generic drug for a thirty-month period while the disputing parties resolve the patent lawsuit.¹⁸ If the patent litigation is decided during this period, the FDA follows the decision of the court.¹⁹ If, however, the patent litigation is not concluded by the end of the thirty-month period, the generic-drug company’s marketing is approved.²⁰

Reverse payment settlement agreements arise out of this situation. Instead of pursuing the litigation to the fullest extent, the parties settle with the understanding that the original-drug company will pay the generic-drug company a large sum of money in return for the generic’s assurance that it will not enter the market until a designated time.²¹ It is called reverse payment because normally, in patent litigation, one would expect the infringing party to pay a settlement amount to the patentee. The Supreme Court cited a noted antitrust scholar on this point: “Where only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle the lawsuit.”²² However, in this case the patentee pays the alleged infringer in exchange for a promise to stay out of the market.

B. Importance of the 180-Day Exclusive Marketing Rights.

As noted above, the Hatch–Waxman Act includes an important exclusive marketing provision that sets up the incentives for parties to settle the patent lawsuit. Under the Act, the generic-drug company that was first to file an ANDA is entitled to a 180-day exclusive marketing period after the FDA’s marketing approval.²³ Subsequent ANDA filers cannot market their drug until the 180-day exclusive marketing period has been exhausted.²⁴ This 180-day period is an important incentive for generic-drug companies to enter the existing market because they can reap enormous

¹⁶ *Id.* § 355(j)(2)(A)(vii)(I)–(IV).

¹⁷ 35 U.S.C. § 271(e)(2)(A) (2006).

¹⁸ 21 U.S.C. § 355(j)(5)(B).

¹⁹ *Id.*

²⁰ *Id.*

²¹ *See* Kutcher, *supra* note 1, at 1102.

²² *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2235 (2013).

²³ 21 U.S.C. § 355(j)(5).

²⁴ *Id.*

profit during the exclusive marketing period.²⁵ However, the 180-day exclusivity “only goes to the first ANDA-IV filer,” and subsequent filers cannot get this privilege “even if the first ANDA-IV filer settles and the subsequent ANDA-IV filer succeeds in proving lack of infringement or patent invalidity.”²⁶ Since the major incentive for challenging a patented drug under ANDA is the 180-day exclusivity period from which generics gain significant profit, if the possibility for getting the exclusivity reward is removed, generics are less incentivized to challenge the patent. Under this framework, “the agreement creates a bottleneck, in which no other generic can enter until the first ANDA filer’s exclusivity is used.”²⁷ Therefore, when a brand-name-drug company pays the first ANDA filer to stay out of the market, it “prevents all other generic companies from entering the market for the duration of the settlement.”²⁸

This regulatory framework creates the following incentives for the original- and generic-drug companies. For the original-drug company, paying the first-to-file generic-drug company is a near guarantee to a monopoly during the settlement period.²⁹ Losing the patent litigation, on the other hand, means a great loss in potential profit from the brand-name drug.³⁰ Thus, the incentive to pay to delay the generic’s entry is immense for original-drug companies. For the first-to-file generic, losing the litigation maintains its status quo while winning the litigation presents the opportunity to reap substantial profits during the 180-day exclusive marketing period and beyond. As long as the original-drug manufacturer offers a reverse payment settlement amount similar to or greater than the generic-drug company’s expected profit for marketing the drug, they are incentivized to accept that offer. As a result, the 180-day exclusive marketing period granted only to the first-to-file generic gives incentives both to the brand-name-drug company and the generic-drug company to enter into a settlement. The unique regulatory framework that incentivizes reverse payment settlement agreements has spawned numerous litigations by the Federal Trade Commission (FTC), which resulted in a circuit split leading up to the Supreme Court’s *Actavis* decision.

²⁵ C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1578–79 (2006).

²⁶ Alicia I. Hogges–Thomas, *An American Drug Problem: Reclaiming Consumers’ Rights under the Hatch–Waxman Act*, 37 VT. L. REV. 737, 741 (2013). “The 180-day reward is . . . not transferred to the next ANDA-IV filer.” *Id.* at 742.

²⁷ Melanie J. Brown, *Reverse Payment Settlements in the European Commission’s Pharmaceutical Sector Inquiry Report: A Missed Opportunity to Benefit from U.S. Experience*, 33 COLUM. J.L. & ARTS 377, 382 (2010).

²⁸ Hogges–Thomas, *supra* note 26, at 742.

²⁹ *Id.*

³⁰ *Id.*

C. Circuit Split Leading Up to *FTC v. Actavis*.

The FTC has long disfavored reverse payment settlement agreements for their potential anticompetitive effects and has launched numerous lawsuits in several U.S. jurisdictions that resulted in a marked split among the circuit courts.³¹ Prior to the Supreme Court’s grant of certiorari on this issue, there were three competing legal approaches to reverse payment settlement agreements: (1) the per se illegal rule, (2) the scope of the patent test, and (3) the rule of reason analysis.³² A recent comment offers a comprehensive summary of the cases that led to the circuit split on this issue.³³ Since that work need not be repeated, only relevant highlights of these cases will be provided here.

The D.C. Circuit decided the first case—applying the per se illegal test—in *Andrx Pharmaceuticals, Inc. v. Biovail Corp. Int’l*.³⁴ There, the plaintiff, Andrx Pharmaceuticals, Inc. (Andrx), argued that its reverse payment settlement agreement with a generic was lawful because “its conduct was not only permitted under but clearly contemplated by the Hatch–Waxman’ Amendments.”³⁵ The court disagreed, stating that the agreement was a “manipulation of the exclusivity period trigger date [that] extended the legal bar.”³⁶ Invoking the per se illegal rule, the court stated that “[t]o be ancillary, and hence exempt from the per se rule, an agreement eliminating competition must be subordinate and collateral to a separate, legitimate transaction”³⁷ The court concluded that the agreements in question “were not necessarily ancillary restraints but rather could reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions.”³⁸ Therefore, Biovail’s injury, according to the court, was the “type the antitrust laws were designed to prevent.”³⁹

Another example of applying the per se illegal rule can be found in the Sixth Circuit case, *In re Cardizem CD*.⁴⁰ In that case, the court analyzed the same agreement that at issue in *Andrx Pharmaceuticals*.⁴¹ The Sixth Circuit concurred with the D.C. Circuit and held that the agreement was “at its core, a horizontal agreement to eliminate competition . . . , a classic example of a per se illegal restraint of trade.”⁴² The court cited as the key

³¹ Kutcher, *supra* note 1, at 1108–27.

³² *Id.*

³³ *Id.*

³⁴ See generally *Andrx Pharm., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799 (D.C. Cir. 2001).

³⁵ *Id.* at 809.

³⁶ *Id.* at 810.

³⁷ *Id.* at 814–15.

³⁸ *Id.* at 811.

³⁹ *Id.* at 813.

⁴⁰ See generally *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

⁴¹ *Id.*

⁴² *Id.* at 908.

factor for its decision, the 180-day period of marketing exclusivity, which delayed the entry of all other competitors as well as the disproportionately large payment \$89.83 million settlement that Hoescht Marion Roussel, Inc. paid Andrx to keep its generic product off the market.⁴³ Thus, the earliest cases that addressed reverse payment settlement agreements condemned them as per se illegal.

A separate line of cases decided by the Eleventh Circuit and the Second Circuit introduced the scope of the patent test.⁴⁴ This test was considerably more lenient toward reverse payment settlement agreements because it shielded the agreements from antitrust scrutiny as long as they fell within the exclusionary potential of the patent.⁴⁵ In *Valley Drug Co.*, the Eleventh Circuit reversed the district court's per se treatment of the reverse payment settlement agreement in question because it "failed to consider the exclusionary power of Abbott's patent in its antitrust analysis"⁴⁶ Because the terms of the agreement terminated when the patent in question expired, the court viewed that the effect of the agreement "appears to be no broader than the potential exclusionary effect of the [patent]."⁴⁷ In light of this, the court expressed its concern that the antitrust scrutiny "would undermine the patent incentives" and "impair the incentives for disclosure and innovation."⁴⁸ In addition, because of the factual uncertainty of what was actually considered in the payment amount, "it [was] difficult to infer from the size of the payment alone that the [patent] infringement suits lacked merit."⁴⁹ Thus, the court held that "[w]hen the exclusionary power of a patent is implicated . . . , the antitrust analysis cannot ignore the scope of the patent exclusion."⁵⁰

In *Schering-Plough*, the Eleventh Circuit expressed its view that "neither the rule of reason nor the per se analysis is appropriate in this context."⁵¹ Both approaches were inappropriate "because they seek to determine whether the challenged conduct had an anticompetitive effect on the market" when by their nature "anticompetitive effect is already present" in a patent.⁵² The court clarified its rule stating, "the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."⁵³ Thus, the

⁴³ *Id.* at 907.

⁴⁴ Kutcher, *supra* note 1, at 1111–12.

⁴⁵ *Id.* at 1114.

⁴⁶ *Valley Drug Co. v. Geneva Pharm. Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003).

⁴⁷ *Id.* at 1305.

⁴⁸ *Id.* at 1308.

⁴⁹ *Id.* at 1310.

⁵⁰ *Id.*

⁵¹ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005).

⁵² *Id.* at 106566.

⁵³ *Id.* at 1066.

Eleventh Circuit's treatment of reverse payment settlement agreements was primarily geared towards protecting the patent holder's rights as long as the agreement in question was within the scope of the patent.

The Second Circuit in *In re Tamoxifen* embraced the scope of the patent test and made it more deferential.⁵⁴ The court declined to adopt the per se rule for reverse payment settlement agreements because it “[did] not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation.”⁵⁵ Instead, the court expressed that “[s]o long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.”⁵⁶ Thus, unless the plaintiff can establish that the underlying patent litigation was baseless, “even ‘excessive’ payments, to settle the dispute were therefore not necessarily unlawful.”⁵⁷ Thus, this line of cases moved away from per se illegality of reverse payment settlement agreements and set a trend towards the more deferential scope of the patent test.⁵⁸ This trend appeared to solidify when the Federal Circuit adopted the scope of the patent test in *In re Ciprofloxacin Hydrochloride*,⁵⁹ “stressing the general public policy favoring patent litigation settlements”⁶⁰

In 2012, however, the Third Circuit split from this trend in *In re K-Dur* and introduced the rule of reason to decide the issue of reverse payment settlement agreements.⁶¹ First, the court attacked the “scope of the patent test’s almost un rebuttable presumption of patent validity” because such presumption “is intended merely as a procedural device and is not a substantive right of the patent holder.”⁶² In the context of ANDA IV litigation, “the underlying suit concerned patent infringement rather than patent validity.”⁶³ Because the patent holder, rather than the challenger has the burden of showing the infringement in a patent infringement case, it would not make sense to apply the presumption of validity rule in an ANDA IV litigation.⁶⁴

The court further noted that, “in passing the Hatch–Waxman Act, Congress [wanted to draw] a careful line between patent protection and the need to provide incentives for competition in the pharmaceutical

⁵⁴ Kutcher, *supra* note 1, at 1120.

⁵⁵ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2006).

⁵⁶ *Id.* at 208–09.

⁵⁷ *Id.* at 213.

⁵⁸ See Kutcher, *supra* note 1, at 1121.

⁵⁹ See generally *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).

⁶⁰ Kutcher, *supra* note 1, at 1122.

⁶¹ See generally *In re K–Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

⁶² *Id.* at 214.

⁶³ *Id.*

⁶⁴ *Id.*

industry.”⁶⁵ This, according to the court, “strongly supports the application of rule of reason scrutiny of reverse payment settlements in the pharmaceutical industry.”⁶⁶ The court ultimately remanded the case to the district court to apply “a quick look rule of reason analysis based on the economic realities of the reverse payment settlement”⁶⁷ Under the “quick look” rule, the existence of a reverse payment settlement established “prima facie evidence of an unreasonable restraint of trade”⁶⁸ The defendants could rebut this “by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.”⁶⁹ The Third Circuit’s decision adopting the quick look test, therefore, was the most lenient treatment of reverse payment settlement agreements, which collided with the approaches adopted by other circuit courts.

Thus, the Third Circuit’s split generated competing theories on how to deal with reverse payment settlement agreements. Because of these divergent opinions among the circuits, the Supreme Court granted certiorari to review the issue in *FTC v. Actavis*.

D. A Review of *FTC v. Actavis*.

The Supreme Court granted certiorari in *FTC v. Actavis*—an Eleventh Circuit decision—to examine reverse payment settlement agreements for the first time. In *Actavis*, respondents, Solvay Pharmaceuticals, had filed a NDA for a brand-name drug called Androgel in 1999.⁷⁰ In 2000, the application was approved by the FDA, and in 2003, Solvay secured the relevant patent and published the information with the FDA.⁷¹ After the patent information became public, Actavis filed an ANDA in the same year with the FDA to get marketing approval of its generic version of Androgel.⁷² Another generic-drug company, Paddock Laboratories, also filed a separate ANDA for its generic version of the drug.⁷³ Par Pharmaceutical joined Actavis in the lawsuit, and both Actavis and Paddock certified under Paragraph IV that Solvay’s patent was “invalid or will not be infringed by the manufacture, use, or sale” of their generic version of Androgel.⁷⁴ Solvay filed a patent infringement action against

⁶⁵ *Id.* at 217.

⁶⁶ *Id.*

⁶⁷ *Id.* at 218.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *FTC v. Actavis, Inc.*, 133 S.Ct. 2223, 2229 (2013).

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.* at 2228–29.

Actavis and Paddock, and thirty months later, the FDA approved Actavis's first-to-file application.⁷⁵

In 2006, however, all the parties involved in the patent litigation agreed to a settlement.⁷⁶ Under the terms of the settlement, Actavis agreed not to enter the market with its generic product until August 31, 2015 and also agreed to promote Androgel to urologists.⁷⁷ Paddock and Par Pharmaceutical also made similar promises.⁷⁸ In return, Solvay agreed to pay \$19–\$30 million annually to Actavis for nine years, and \$12 million and \$60 million total to Paddock and Par respectively.⁷⁹ Although the companies stated that the payment was made in consideration of the generic companies' efforts to market Androgel, the FTC argued that the payment far exceeded the value of such services and was instead made as a condition for not entering the market monopolized by Androgel.⁸⁰ The FTC filed suit against all four parties in 2009, alleging violation of § 5 of the Federal Trade Commission Act.⁸¹ The district court held "that these allegations did not set forth an antitrust law violation," and accordingly dismissed the FTC's complaint.⁸² The Eleventh Circuit affirmed the district court holding, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."⁸³ The FTC sought certiorari because the court of appeals had reached different outcomes on the "application of the antitrust laws to Hatch–Waxman–related patent settlements"⁸⁴

The Supreme Court held that the Eleventh Circuit incorrectly dismissed the complaint under the scope of the patent test without considering the applicability of antitrust laws to the case.⁸⁵ In its opinion, the Court stated that while it concedes that the case may fall within the scope of the exclusionary potential of the patent, this characterization does not "immunize the agreement from antitrust attack."⁸⁶ "For one thing," the Court said, "[t]he patent here may or may not be valid, and may or may not be infringed."⁸⁷ An invalidated patent does not carry the right to exclude

⁷⁵ *Id.* at 2229.

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.* at 2229–30.

⁸² *Id.* at 2230.

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.* at 2230–31.

“all except its owner from the use of the protected process or product.”⁸⁸ According to the Court, “paragraph IV litigation in this case put the patent’s validity at issue, as well as its actual preclusive scope.”⁸⁹ That litigation, as the Court emphasized, was inappropriately settled by the reverse payment settlement agreement.⁹⁰ The Court noted the settlement was “unusual” and expressed its concern that “settlements taking this form tend to have significant adverse effects on competition.”⁹¹ Because of these reasons, “it would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well.”⁹²

Then the Court reviewed its own precedents, which “ma[de] clear that patent-related settlement agreements can sometimes violate the antitrust laws.”⁹³ In concluding the first part of the opinion, the Court evoked the statutory policy of the Hatch–Waxman Act by stating that “the general procompetitive thrust of the statute, its specific provisions facilitating challenges to a patent’s validity, . . . and its later-added provisions requiring parties to a patent dispute triggered by a paragraph IV filing to report settlement terms to the FTC and the [Department of Justice]” suggest a view contrary to the Eleventh Circuit’s.⁹⁴ The Court even cited Senator Hatch’s legislative testimony that “[i]t was and is very clear that the [Hatch–Waxman Act] was not designed to allow deals between brand and generic companies to delay competition.”⁹⁵

In the second part of the opinion, the Court addressed the Eleventh Circuit’s concern that “antitrust scrutiny of a reverse payment agreement would require the parties to [litigate the validity of the patent, which will prove] time-consuming, complex, and expensive.”⁹⁶ The issue here was whether the “value of settlements and the patent litigation problem” outweighed the value of antitrust policy.⁹⁷ Nevertheless, the Court concluded that “this patent-related factor should not determine the result here . . . [,]” but instead gave five reasons why “the FTC should have been given the opportunity to prove its antitrust claim.”⁹⁸

The first reason was that “the specific restraint at issue has the

⁸⁸ *Id.* at 2231.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.* at 2232.

⁹⁴ *Id.* at 2234.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

‘potential for genuine adverse effects on competition.’⁹⁹ The Court observed that the settlement at issue here “simply keeps prices at patentee-set levels[,] . . . [while dividing] the benefit between the [challenged] patentee and the [patent] challenger,” resulting in the consumer’s loss.¹⁰⁰ The disproportionate settlement amount may “provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.”¹⁰¹

In addition, responding to the question of whether the high payment of a large reverse settlement amount invites other generics to challenge a patent, the Court pointed to the 180-day marketing exclusivity period.¹⁰² Subsequent challengers do not get the benefit of the 180-day marketing exclusivity.¹⁰³ Thus even if a subsequent challenger successfully challenges the original-drug company and invalidates the patent in question, this decision would not give the subsequent challenger the coveted exclusive marketing period and instead would allow all other generics to jump into the market.¹⁰⁴ Thus, reverse payment settlement agreements with a first patent challenger can be an effective deterrent to all other challengers because it “removes from consideration the most motivated challenger, and the one closest to introducing competition.”¹⁰⁵ The Court thus noted that due to “Hatch–Waxman’s unique regulatory framework, including the special advantage that the 180-day exclusivity period gives to first filers, . . . the patentee’s ordinary incentives to resist paying off challengers . . . appear to be more frequently overcome.”¹⁰⁶

The second reason that the Court provided for why the FTC should be given an opportunity to prove its antitrust claim was that the “anticompetitive consequences [of reverse payment settlement agreements] will at least sometimes prove unjustified.”¹⁰⁷ Although there were “offsetting or redeeming virtues” of reverse payment settlement agreements, the Court noted that such considerations do not justify dismissing the FTC’s complaint.¹⁰⁸ Instead, the antitrust defendant can show “that legitimate justifications are present” and convince the court of the lawfulness of the agreement’s terms under the rule of reason.¹⁰⁹

The third reason provided by the Court was that, “where a reverse

⁹⁹ *Id.*

¹⁰⁰ *Id.* at 2234–35.

¹⁰¹ *Id.* at 2235.

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 2235–36.

¹⁰⁸ *Id.* at 2236.

¹⁰⁹ *Id.*

payment threatens to work unjustified anticompetitive harm, the patentee likely has the power to bring that harm about in practice.”¹¹⁰ Again, the Court here noted that “[t]he size of the payment from a branded drug manufacturer to a generic challenger is itself a strong indicator of such power.”¹¹¹

The Court’s fourth reason was that “an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed.”¹¹² Here, the Court addressed the Eleventh Circuit’s concern that it is “normally not necessary to litigate patent validity to answer the antitrust question.”¹¹³ The Court first noted that “[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival . . . [.]”¹¹⁴ which “suggests that the payment’s objective is to maintain supracompetitive prices . . . ” and to “prevent the risk of competition.”¹¹⁵ The Court proposed a solution that “the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing the court to conduct a detailed exploration of the validity of the patent itself.”¹¹⁶

Lastly, in providing its fifth reason for why the FTC should be given an opportunity to prove its antitrust claim, the Court stated, “the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit.”¹¹⁷ In other words, the Court observed that there are many other forms of settlements that a patent holder and challenger can work out such as “allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point.”¹¹⁸ For the Court, the relevant antitrust question was involved the parties’ reasons for entering into reverse settlement payment agreements.¹¹⁹ If the reason was “a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.”¹²⁰ Therefore, with the foregoing five reasons, the Court addressed the Eleventh Circuit’s concern regarding the cost of litigation and provided justification for why the FTC should at least be given a chance to prove its antitrust claim under the rule of reason.

In the final section of the opinion, the Court rejected the FTC’s

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 2236–37.

¹¹⁷ *Id.* at 2237.

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

invitation to adopt the presumptive rule, or a quick look approach, because reverse payment settlement cases are too complex to be handled under this approach.¹²¹ Thus, the Court concluded, “the FTC must prove its case as in other rule-of-reason cases.”¹²² The Court mentioned that there is “a sliding scale in appraising reasonableness,” and thus, “the quality of proof required should vary with the circumstances.”¹²³ However, instead of offering a guideline for this inquiry, the Court said it would “leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.”¹²⁴

III. ARGUMENT

In Part III, this Comment dives into a comparative analysis between the U.S. Supreme Court’s *Actavis* case and a prominent South Korean case, *GlaxoSmithKline v. Korea Fair Trade Commission*, which dealt with reverse payment settlement agreements in a similar context. In order to achieve this, this part proceeds in the following order. First, subpart A discusses how the *Actavis* case will impact the courts in the United States. Subpart B provides the context for why *Actavis* is interesting and relevant to the current development of antitrust laws related to reverse payment settlement agreements in South Korea. In particular, subpart B(1) introduces South Korea’s proposed patent-approval linkage system, which will in effect introduce a regulatory framework similar to the Hatch–Waxman Act in South Korea. Subpart B(2) analyzes the impact that the patent-approval linkage system will have on South Korea’s legal landscape. Subpart B(3) introduces and analyzes *GlaxoSmithKline*. Subpart B(4) provides a comparative analysis between *Actavis* and *GlaxoSmithKline*. Subpart B(5) delves into a deeper analysis of the *GlaxoSmithKline* case and its relevance to the laws and regulations pertinent to reverse payment settlement agreements in South Korea. Finally, subpart C will identify some of the lessons from a South Korean lawyer’s perspective that can be learned from the U.S. experience.

A. Domestic Impact of the Rule of Reason Analysis.

Because *FTC v. Actavis* is a recent decision, the Supreme Court’s holding that the rule of reason analysis applies has only been addressed in a limited number of lower court cases.¹²⁵ Accordingly, an assessment of the

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.* at 2237–38.

¹²⁴ *Id.* at 2238.

¹²⁵ Circuit courts have not yet directly addressed the issue of reverse payment settlement agreement. Only indirect references to the *Actavis* case are found among a few circuit court cases. For example, in a

U.S. domestic impact would be at best premature and speculative. However, a general discussion of the significance of the Court's decision and its reasoning is necessary to set up the context for a comparative analysis with South Korean antitrust laws.

Actavis settles what kind of legal scrutiny should be applied by the courts when analyzing the legality of reverse payment settlement agreements. Lower courts were previously split between the scope of the patent test and the rule of reason analysis. The Supreme Court now requires all courts to employ the traditional rule of reason analysis in these cases. Thus, reverse payment settlement agreements are no longer subject only to patent laws but to antitrust laws as well.

Lower courts must now look to the traditional rule of reason analysis when addressing cases regarding reverse payment settlement agreements.¹²⁶ Under the traditional rule of reason analysis, “the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.”¹²⁷ According to rule of reason case law, “[t]he plaintiff bears an initial burden of demonstrating that the alleged agreement produced adverse, anticompetitive effects within the relevant markets”¹²⁸ Once the plaintiff meets this burden, the defendant must prove that there are sufficient procompetitive justifications for the agreement.¹²⁹ The agreement must be necessary or well-tailored to achieve the claimed efficiency justifications.¹³⁰ Then, the burden again shifts to the plaintiff to demonstrate that the anticompetitive effects outweigh the procompetitive

First Circuit class-action lawsuit, the court mentioned the *Actavis* holding but did not engage in the rule of reason analysis because the “merits of [the] plaintiffs’ antitrust challenge [were] not before [the court].” *In re Nexium Antitrust Litig.*, 777 F.3d 9, 16 (1st Cir. 2015). A few federal district courts have applied the rule of reason analysis in their decisions on reverse payment settlement agreements. While these cases arose in the context of motion to dismiss or summary judgment litigations, they provide a glimpse of how courts may examine reverse payment settlement agreements in the future. For a brief discussion of these district court cases, see *infra* notes 126 and 136.

¹²⁶ In a recent Pennsylvania federal district court case, the court held that “evidence of a large payment is required for a plaintiff to satisfy its initial burden of demonstrating anticompetitive effects under the *Actavis* rule of reason analysis.” *King Drug Co. of Florence v. Cephalon, Inc.*, Nos. 2:06-cv-1797, 2:06-cv-1833, 2:06-cv-2768, 2:08-cv-2141, 2015 WL 356913, at *10 (E.D. Pa. Jan. 28, 2015) (citing *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 75 (3d Cir. 2010)). After the initial burden has been established, “whether or not the reverse payment is unjustified or unexplained is examined under the standard rule of reason burden-shifting framework, with the defendant bearing the burden of providing evidence that the reverse payment is justified by procompetitive considerations.” *Id.* at *11. Thereafter, “the plaintiff must . . . rebut those justifications and establish that the ‘restraint is not reasonably necessary to achieve the stated objective.’” *Id.*

¹²⁷ *Cont’l T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977).

¹²⁸ *Schering–Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005).

¹²⁹ *Id.*

¹³⁰ *Nat’l Collegiate Athletic Ass’n v. Bd. of Regents Okla. Univ.*, 468 U.S. 85, 116, 116–20 (1984).

justification.¹³¹

The effect of adopting the rule of reason for deciding reverse-payment-settlement-agreement cases is that these agreements will be more difficult to sustain than under the scope of the patent test. The courts that had previously adopted the scope of the patent test can no longer dismiss the case and uphold the legality of suspicious agreements merely because there is no indication of a sham agreement and because the agreement appears to fall within the exclusionary potential of the patent.¹³² In the United States, then, the balance has shifted toward applying antitrust scrutiny in reverse-payment-settlement-agreement cases.

Even though the Supreme Court said that the lower courts are to adopt their own level of scrutiny for the rule of reason analysis, it is unlikely that each circuit court's version will vary significantly. This is because the Supreme Court throughout its opinion implicated what factors it considered significant in applying antitrust scrutiny. Toward the end of its opinion, the Court said that “the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the pay[er's] anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”¹³³ In determining whether the paying party will have market power to cause anticompetitive harm, the Court said that “the ‘size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of [market] power.’”¹³⁴ Regarding whether a result of patent litigation is needed to decide the antitrust issue, the Court pointed to “the size of the unexplained reverse payment” as a “workable surrogate.”¹³⁵

Given this context, the initial burden of proof borne by the competition agencies under the rule of reason analysis is unlikely to be taxing.¹³⁶ Courts will likely accept an unreasonably large settlement

¹³¹ U.S. v. Microsoft Corp., 253 F.3d 34, 59 (D.C. Cir. 2001).

¹³² *The Supreme Court 2012 Term, Leading Cases, Federal Statutes and Regulations: Hatch-Waxman Act — Reverse Payment Settlements — FTC v. Actavis, Inc.*, 127 HARV. L. REV. 358, 367 (2013) (“Under a broad reading of *Actavis*, however, almost all settlement agreements between generics and developers could be subject to antitrust challenge . . .”).

¹³³ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013).

¹³⁴ *Id.* at 2236.

¹³⁵ *Id.*

¹³⁶ A federal district court in California held that, in determining large, unjustified settlement amounts, “courts must be able to calculate [the] value [of unjustified payment]” and that nonmonetary payments, which can be calculated by “many plausible methods,” can be included in that amount. *United Food & Com. Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, No. 14-md-02521-WHO 2014 WL 6465235, at *11 (N.D. Cal. Nov. 17, 2014) (citing *In re Effexor XR.*, 2014 WL 4988410, at *23 and *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013)). The court then examined the meaning of “large” and “unjustified” payment. *Id.* at *6–8. Large payments can be either “a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market” at the one extreme and “anything more than the

amount as strong evidence of antitrust violation, and defendants will have to prove facts that justify the large sum payment or offer evidence of the procompetitive effects of the agreement. However, what level of excessive payment is unreasonable or what sort of procompetitive justifications the courts will accept will likely vary among the circuits. As was the case in the *Actavis* decision, the courts will carefully scrutinize the incentive structure of the participants, and this analysis will likely be fact intensive.

For the competition agencies and defendants in an antitrust claim, proving the unreasonableness of the size of the settlement or disproving the justification for a settlement will be a paramount issue. For brand-name-drug companies and generic-drug companies considering entering into reverse payment settlement agreements, how the courts will view their settlement amount and the potential justification they can provide for the terms of the settlement will influence their decision to include certain terms and monetary value in the settlement.

Given the analysis above, it is reasonable to conclude that the Supreme Court has given a rather precise instruction when it ordered the circuit courts to apply the rule of reason analysis. Due to their rich case law on the rule of reason analysis, the courts in the United States will have a good framework under which they can apply the Supreme Court's instructions in future reverse-payment-settlement cases. Would this be the same for Korean courts? With this understanding in mind, this Comment will now turn to how the *Actavis* decision may impact South Korea's unique legal landscape in regard to reverse payment settlement agreements.

B. *Actavis* and Reverse Payment Settlement Agreements in South Korea.

The following subparts examine South Korea, a jurisdiction outside the United States where reverse payment settlement agreements could potentially arise as a controversial issue. As mentioned in the introduction, the issue of reverse payment settlement agreements is garnering significant attention among legal scholars and practitioners in South Korea because of two recent events: the adoption of the patent-approval linkage system and the recent decision of the South Korean Supreme Court on the *GlaxoSmithKline* case. The following subparts explore these two events in detail.

value of the avoided litigation costs plus any other services provided from the generic to the brand manufacturer" at the other extreme. *Id.* at *13. Justified payments are "traditional settlement considerations, such as avoided litigation costs or fair value for services." *Id.* The court acknowledged that the plaintiff there would be unable to establish whether the payment was justified because the case was only at the motion to dismiss stage. Instead, plaintiff's allegation of large and unjustified payment was deemed plausible because of "the status of the underlying patent litigation—the first case was tried and submitted for a bench decision and the second case had proceeded past the pleading stage." *Id.*

1. Introduction of the Patent-Approval Linkage System into Korean Pharmaceutical Laws

On March 15, 2012, the United States and South Korea entered into a free trade agreement (FTA),¹³⁷ in which the two countries agreed that South Korea would adopt a patent-approval linkage system.¹³⁸ As one of the more important changes proposed under the FTA relevant to the pharmaceutical industry, the patent-approval linkage system would combine the patent system with the pharmaceutical approval process.¹³⁹ Prior to the introduction of the linkage system, the Ministry of Food and Drug Safety (MFDS), when reviewing a drug application, would not consider whether there was an existing patent that the drug in the application might infringe.¹⁴⁰ The result was that patent litigation often arose after the new drug had already been approved by the MFDS.¹⁴¹

According to the changes proposed under the FTA, the MFDS drug application process will be linked to the patent process in a way similar to the ANDA process under the Hatch–Waxman Act.¹⁴² Article 18.9(5) of the FTA provides for the implementation of the patent-approval linkage system of both signatories of the FTA.¹⁴³ According to the relevant provisions,

¹³⁷ *The U.S.–Korea Free Trade Agreement (KORUS)*, EXPORT.GOV, <http://export.gov/FTA/korea/index.asp> (last updated Mar. 15, 2012, 2:46 PM).

¹³⁸ Jeong Hwan, *FTAwa uilyo jeyagsaneobui gyeongjaengbeob isyu* [*FTA and Competition Law Issues in the Healthcare Industry*], 156 GYEONGJAENGJEONEOL [J. COMPETITION] 54, 55 (2011) (S. Kor.).

¹³⁹ Jin Woo Hwang, *Heogateugheo yeongyedoui doibgwa gongjeonggeolaebobui jeogyong* [*The Introduction of Approval–Patent Linkage System and the Application of Korea’s Monopoly Regulation and Fair Trade Act*], 7 J. LAW & TECH. 5, 67–84 (2011) (S. Kor.).

¹⁴⁰ *Id.* at 77.

¹⁴¹ *Id.*

¹⁴² Cho Young Sun & Jin Hyunsuk, *Overview and Implication of the Drug Patent–Approval Linkage System in South Korean Regulation*, PRACTICAL LAW, <http://global.practicallaw.com/3-557-9230#> (last accessed Mar. 23, 2015, 9:30 PM).

¹⁴³ U.S.–Korea Free Trade Agreement, U.S.–S. Kor., art. 18.9(5), Mar. 15, 2012, available at http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file273_12717.pdf. The Agreement provides the following:

Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, that Party shall: (a) provide that the patent owner shall be notified of the identity of any such other person that requests marketing approval to enter the market during the term of a patent notified to the approving authority as covering that product or its approved method of use; and (b) implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of a patent notified to the approving authority as covering that product or its

where a party—meaning the signatories of the FTA—permits the person applying for approval of the marketing of a pharmaceutical product to “rely on that information or on evidence of safety or efficacy information of a product that was previously approved,” it must do so under two conditions.¹⁴⁴ First, the party must notify the patent owner “of the identity of any such other person that requests marketing approval to enter the market during the term of a patent” (the notification system).¹⁴⁵ Second, the party must “implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of [the] patent . . .” (the marketing prevention system).¹⁴⁶ Thus, the FTA essentially provides a mechanism that allows the generic-drug company to use the safety and efficacy information of an original-drug company to apply for its own approval, similar to the ANDA application in the United States. By requiring the original patent holder to be notified and by requiring the implementation of a marketing prevention system, the FTA requires Korea to link its patent system with its pharmaceutical drug approval system.

The notification requirement went into effect immediately after the FTA went into force.¹⁴⁷ Under the new notification system, the patent holder who received marketing approval “must file an application for registration in the Green List to the MFDS within 30 days from the date of the marketing approval.”¹⁴⁸ If a generic-drug company files an application for a drug approval using the safety and efficacy information of a drug listed on the Green List, the applicant “must submit a document showing the relationship between the patent of the listed drug and the drug applied for approval.”¹⁴⁹ The applicant then has to notify, within seven days from the date of application, “the person who obtained the original [drug] approval of the listed drug, and the patent holder.”¹⁵⁰

One difference between the notice systems of the United States and Korea is that in Korea the applicant is exempt from the notification requirement if the applicant has obtained a decision from the court or the Korean Intellectual Property Tribunal (KIPT) “that the patent of the listed drug is invalid, or the drug applied for approval is not within the scope of the patent rights of the listed drug.”¹⁵¹ This provision takes account of the

approved method of use.

Id.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ Cho & Jin, *supra* note 142.

¹⁴⁸ *Id.* The Green List is a list of existing patents linked to the drug approval system to alert the generics of an existing patent. *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

fact that in South Korea a generic company can file a suit to determine the validity and scope of the patent “at any time with the KIPT . . . [even] before the patent holder initiates patent infringement litigation.”¹⁵² While in the United States the patent litigation suit is triggered with an ANDA IV certification, which brings the cost of patent litigation into the antitrust lawsuit, in Korea the patent litigation can be resolved prior to the generic’s application to enter the market. This means that the policy argument favoring settlement over the cost of litigation—which the Third Circuit accepted as a major factor for adopting the scope of the patent test—may not be an issue in cases where the patent infringement issue is resolved prior to the generic’s drug approval under the proposed rules in South Korea.

Unlike the notification system that simultaneously went into effect with the FTA, the marketing prevention system is still in the making in South Korea. Pursuant to the FTA’s call to implement measures for the marketing prevention system, the MFDS announced on November 23, 2013, “that it would prepare a unique patent-approval linkage system that takes into account the South Korean legal system and the characteristics of its pharmaceutical industry.”¹⁵³ On March 21, 2014, the MFDS published a draft proposal for the amendment to the Pharmaceutical Affairs Act, which included the proposed rules that set up the marketing prevention system.¹⁵⁴ The MFDS subsequently published an updated version of the draft proposal on July 25, 2014.¹⁵⁵

However, the updated proposal, expected to take effect on March 15, 2015, after a period of public comments,¹⁵⁶ bears a striking resemblance to the Hatch–Waxman Act. According to the proposed rules, a patent holder can apply for marketing prevention to the MFDS within forty-five days of receiving a notice from the generic-drug company of its application for marketing approval.¹⁵⁷ The patent holder must, however, have filed a claim for “positive scope confirmation of patent rights with KIPT” or “prohibition of infringement with a court” prior to filing the application.¹⁵⁸ Two critical provisions in the draft proposal suggest the South Korean patent-approval linkage system generate a near-identical regulatory framework to that of the Hatch–Waxman Act.

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ Yaksabeob Ilbugaejungbeobyul(an) Ibbeobyego [Legislative Notice: Proposed Partial Amendment to the Pharmaceutical Law], Announcement of the Ministry of Food & Drug Safety No. 2014–63, Mar. 21, 2014 (S. Kor.).

¹⁵⁵ Yaksabeob Ilbugaejungbeobyul(an) Jaebbeobyego [Legislative Re-Notice: Proposed Partial Amendment to the Pharmaceutical Law], Announcement of the Ministry of Food & Drug Safety No. 2014–201, Jul. 25, 2014 (S. Kor.) [hereinafter Yaksabeob No. 2014–201].

¹⁵⁶ Cho & Jin, *supra* note 142.

¹⁵⁷ Yaksabeob No. 2014–201, *supra* note 155, art. 50, § 8(1).

¹⁵⁸ *Id.*

First, once the MFDS approves the application for marketing prevention, the generic-drug company is stayed from marketing its drug for up to twelve months from the date of application.¹⁵⁹ While the Hatch–Waxman Act provides an automatic stay period of thirty months, Korean experts in the field think that the decision to set the stay period at twelve months is “because it generally takes less than 12 months for the KIPT or a court to reach a conclusion on a patent dispute.”¹⁶⁰

Second, the proposal gives a one-year exclusive marketing right to applicants who: (1) first filed an application for marketing approval based on the safety and efficacy information of the patent holder and (2) prevailed in a patent litigation or administrative adjudication that was filed prior to the filing of the application for marketing approval.¹⁶¹ The marketing exclusivity period is longer than the 180-day period under the Hatch–Waxman Act. Korean experts attribute this to “the specific national circumstances, where hospitals typically decide to purchase drugs through yearly bidding; a shorter exclusive marketing period would render the exclusive marketing rights to become practically useless.”¹⁶²

Still, the proposal seems to take the concerns of reverse payment settlements into account. The proposed regulations provide that the marketing exclusivity terminates when the drug marketing is delayed for two months without reasonable justification.¹⁶³ Termination of the exclusivity can also occur if the person who obtained the rights receives a judicial or an administrative decision to have violated any one of the three enumerated articles of the Monopoly Regulation and Fair Trade Act (Fair Trade Act), namely: “Prohibition of [the] Abuse of Market-Dominating Position,” (Article 3-2, § 1)¹⁶⁴ “Prohibition of Unfair Collaborative Acts,” (Article 19, § 1)¹⁶⁵ or “Prohibition of Unfair Trade Practices” (Article 23, § 1).¹⁶⁶ These conditions, under which the marketing exclusivity period terminates, appear to have been put in place to reduce the incentives of the patent holder to enter into a reverse payment settlement agreement because the patent holder can no longer exclude all generics from the market by paying off the first challenger.

¹⁵⁹ *Id.* art. 50, § 9(3)(1).

¹⁶⁰ Cho & Jin, *supra* note 142.

¹⁶¹ Yaksabeob No. 2014–201, *supra* note 154, art. 50, § 10(1).

¹⁶² Cho & Jin, *supra* note 142.

¹⁶³ *Id.*; Yaksabeob No. 2014–201, *supra* note 154, art. 50, § 11(3).

¹⁶⁴ Dokjeom gyuje mit gongjeong georaeae gwanhan beobyul [Monopoly Regulation and Fair Trade Act], Act. No. 8666, Oct. 17 2007, art. 3, § 2 (S. Kor.), translated in Korea Legislation Research Institute online database, http://elaw.klri.re.kr/eng_service/main.do (login and search required).

¹⁶⁵ *Id.*, art. 19, § 1.

¹⁶⁶ *Id.*, art. 23, § 1; Yaksabeob No. 2014–201, *supra* note 154, art. 50, § 11(1)(4).

2. Analysis of the Patent-Approval Linkage System's Impact and Lessons Learned

One of the questions raised in Part I was: Why is Korea adopting a patent–approval linkage system that mimics the Hatch–Waxman Act and thereby creating a similar incentive structure that accommodated reverse payment settlement agreements in the United States? Although there are many possible explanations,¹⁶⁷ this may be a strategic choice by South Korean rule makers. The Hatch–Waxman Act and the amendment to the South Korean Pharmaceutical Law attempt to carefully balance the competing goals of patent laws and antitrust laws.¹⁶⁸ While the policy makers want to encourage innovation of pioneering drug companies that develop new drugs, they also want to encourage generic-drug companies to enter the market and bring prices to competitive levels, especially when the patent is weak.¹⁶⁹

Because of the inherent conflict, it can be argued that the antitrust problems, including reverse payment settlement agreements, will appear in different forms no matter what the regulatory framework looks like.¹⁷⁰ Policy makers may attempt to draft detailed statutes and regulations that address all scenarios of antitrust harm, but there will always be the unknown or unintended consequence of the rules when the statutes and regulations are applied. As such, it may have made sense for Korean policy makers to borrow a working patent-approval linkage system from a country that has the longest and most extensive legislative and judicial experience and, from there, to make specific adjustments to those provisions that appear to encourage reverse payment settlement agreements. Also, because the patent–approval linkage system was birthed out of the U.S.–Korea FTA, it may have made sense to adopt a system that is the most compatible between the two countries.

This in fact may explain what had happened with the most recent draft proposal amendments to the Korean Pharmaceutical Law. The proposal includes all the nuts and bolts that make the patent-approval linkage system work as well as incentives for generics to enter the market, including the

¹⁶⁷ Other possible explanations include that the adoption was a result of U.S. diplomatic pressure or internal pressure by lobbyists that represent the interest of multinational pharmaceutical corporations.

¹⁶⁸ *The Supreme Court 2012 Term Leading Cases: Hatch–Waxman Act—Reverse Payment Settlement Agreements—FTC v. Actavis, Inc.*, *supra* note 132, at 365 (“[T]he Hatch–Waxman Act, after all, was an act of compromise intended to strike an appropriate balance by providing stronger protections for the developers of legitimately novel drugs while incentivizing generic manufacturers to challenge weak patent claims. It does not clearly resolve the issues raised by the intersection of patent and antitrust.”).

¹⁶⁹ *Id.*

¹⁷⁰ See generally Thomas A. Faunce & Joel Lexchin, ‘Linkage’ Pharmaceutical Evergreening in Canada and Australia, 4 AUSTL. & N.Z. HEALTH POL. 8 (2007), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1894804/>.

notice system, the marketing prevention system, and the exclusive marketing period. At the same time, those provisions that incentivize reverse payment settlement agreements—like the 180-day exclusive marketing period of the Hatch–Waxman Act—have been imported, albeit modified, so that incentives for entering into reverse payment settlement agreements are mitigated.

Second, although it remains to be seen how the new regulations will work out in South Korea, if they are successful at preventing or reducing the occurrence of anticompetitive reverse payment settlement agreements, then the rules may provide a viable model for the United States. This is especially true because the American rules were very closely adopted by South Korea.¹⁷¹ While the United States has attempted to address reverse payment settlements through the judiciary system, the successful outcome of Korea's rules may persuade the United States to amend its own statutes and regulations as an alternative method for tackling the issue of reverse payment agreements. Still, as was the case in the United States, the South Korean statutory framework that attempted to bridge the conflicting goals of patent law and antitrust law resulted in the judiciary trying to resolve the intricate issues raised in reverse payment settlement agreements.

3. *GSK v. KFTC Pharmaceutical: A Mixed Decision*

The second event that triggered considerable interest among antitrust scholars in South Korea was the case involving a patent settlement agreement between GlaxoSmithKline (GSK) and Dong-A Pharmaceuticals (Dong-A), which climbed all the way to the Supreme Court of the Republic of Korea and was ultimately decided on February 27, 2014.¹⁷² The Supreme Court's opinion was relatively short, affirming most of the issues that were appealed from the Seoul High Court, which had issued its decision on October 11, 2012.¹⁷³ The Seoul High Court's opinion included an extensive analysis on the issue of the applicability of antitrust laws to the agreement that settled the patent dispute between GSK and Dong-A. The facts of the case are provided here in detail to help understand the issue at hand.

In 1985, GSK developed Ondansetron, an innovative antiemetic agent for which it submitted a patent application in South Korea in 1985 and received approval in 1992.¹⁷⁴ Following a new drug approval by the MFDS in 1996, GSK marketed Ondansetron under the brand name Zofran.¹⁷⁵ In

¹⁷¹ Cho & Jin, *supra* note 142.

¹⁷² Supreme Court [S. Ct.], 2012Du24498, Feb. 27, 2014 (S. Kor.).

¹⁷³ Seoul High Court [Seoul High Ct.], 2012Nu3028, Oct. 11, 2012 (S. Kor.).

¹⁷⁴ Chul Ho Kim & Jin Woo Hwang, *Yeogigeub habuie daehan migug EU mich hangugui choegeun gyeoljeong* [Recent Decisions in the United States, Europe and Korea Regarding Reverse Payment Agreement], 9–5 J. L. & TECH. 44, 53 (2013).

¹⁷⁵ *Id.*

2000, GSK's market share of antiemetic drugs was 47%.¹⁷⁶ In 1999, Dong-A obtained a patent of its own version of Ondansetron, which it was able to produce using two different production methods.¹⁷⁷ Following a new drug approval by the MFDS, Dong-A marketed Ondaron, the generic version of Zofran, in South Korea starting in September 1998.¹⁷⁸ GSK filed a patent infringement suit in the Seoul District Court in October 1999, but on April 17, 2000, the two companies entered into three agreements: (1) a marketing and supply contract for Ondansetron; (2) an exclusive marketing and supply contract for Valtrex; and (3) a compromise contract.¹⁷⁹

According to the Compromise Contract, Dong-A agreed to cease the production and sales of Ondaron for five years and GSK agreed to withdraw the patent infringement litigation.¹⁸⁰ The five years included a short period at the end when GSK's patent was set to expire.¹⁸¹ This contract was subsequently extended for another five years at which point GSK's patent had already expired.¹⁸² Under the marketing and supply contracts, GSK granted Dong-A the marketing rights to Zofran in national and public hospitals in South Korea and the exclusive marketing rights to Valtrex, which was a new drug that had not yet entered the market.¹⁸³ In return, Dong-A promised not to develop, produce, or market drugs that were identical or similar to Zofran or Valtrex.¹⁸⁴

As a result of these agreements, the Korea Fair Trade Commission (KFTC) determined that the two companies were in violation of Article 19 of the Fair Trade Act, which prohibits unfair collaborative acts, including “[l]imiting the area in which a transaction arises or the transaction counterpart” and “[p]ractically restricting competition in a particular business area by means of interfering or restricting the activities or contents of business by other enterprisers (including the enterpriser who has conducted the activity).”¹⁸⁵ The KFTC ordered the parties to take corrective measures and imposed a total fine of 5.17 billion Korean Won (approximately \$4.59 million USD).¹⁸⁶

GSK and Dong-A each appealed KFTC's decision to the Seoul High

¹⁷⁶ *Id.*

¹⁷⁷ *Id.* at 53–54.

¹⁷⁸ *Id.* at 54.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ Dokjeom gyuje mit gongjeong georaeae gwanhan beobyul [Monopoly Regulation and Fair Trade Act], Act. No. 8666, Oct. 17 2007, art. 19, § 1(4), (9) (S. Kor.), translated in Korea Legislation Research Institute online database, http://elaw.klri.re.kr/eng_service/main.do (login and search required).

¹⁸⁶ Kim & Hwang, *supra* note 174, at 54.

Court.¹⁸⁷ The court rendered a separate decision for each appellant. In the GSK appeal, the court first determined that Korea's Fair Trade Act applies to restrictive conduct that falls outside the legitimate scope of the patent.¹⁸⁸ Applied to the case at hand, the court looked at the following facts about the compromise contract to determine whether the restrictive conduct fell outside the scope of the patent: (1) whether the agreement restricted the production and marketing of Ondaron to the period after the expiration of the patent; (2) whether the agreement restricted production of Ondansetron even when produced with methods not covered by the patent; and (3) whether the agreement restricted production and sales of Valtrex which had nothing to do with the patent at issue.¹⁸⁹ Because GSK gave economic benefits to Dong-A that were beyond the normal level, KFTC inferred intent of collusion between GSK and Dong-A and determined that the agreement was outside the scope of the patent and, therefore, within the purview of the Fair Trade Act.¹⁹⁰

The court further found the agreement's restriction of sales and marketing beyond the patent validity period to be in violation of Article 19, §§ (1) and (4) of the Fair Trade Act.¹⁹¹ In addition, the provision in the compromise contract that restricted the development and production of other drugs in potential competition with Zofran or Valtrex was ruled unreasonably restrictive.¹⁹² For these reasons, GSK's appeal was dismissed.¹⁹³

Regarding Dong-A's appeal, the Seoul High Court ruled similarly to that of the GSK decision. One notable difference was that the agreement regarding Valtrex was deemed a separate issue under unjust concerted practices because the use, effect, and market for Valtrex were different from those of Zofran.¹⁹⁴ Since the KFTC did not raise a claim regarding this separate coordinated action, the court reversed the corrective order and fines related to Valtrex.¹⁹⁵ The remaining points of the appeal were dismissed.¹⁹⁶

Both GSK and Dong-A appealed the decisions of the Seoul High Court to the Supreme Court of Korea.¹⁹⁷ As of today, the Supreme Court has decided on GSK's appeal, affirming the applicability of antitrust laws

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.* at 55.

¹⁹¹ *Id.*

¹⁹² *Id.*

¹⁹³ *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at 57.

to the settlement agreement at issue.¹⁹⁸ Interestingly, the court also suggested its stance on reverse payment settlement agreements.¹⁹⁹

The court then expressed the following opinion on this situation. First, whether the agreement is ‘not a legitimate exercise of rights under the patent act’ must be determined on a case-by-case basis according to whether the patent holder affected fair and free competition through an agreement where it maintains its monopoly status by providing a portion of its monopoly profit to its counterpart of the agreement.”²⁰⁰

Second, in order to determine the foregoing, “the court must comprehensively consider how the agreement was reached, the content of the agreement, the period of the agreement, size of the economic benefit given for the agreement, cost of patent litigation and projected recuperation, and the existence of other reasons that legitimize the price of the agreement.”²⁰¹ This portion of the Korean Supreme Court’s opinion is arguably the first impression of the Court’s experience with reverse payment settlement agreements and thus deserves attention. Further analysis on this opinion will be provided in this comment after a comparative analysis between this case and *Actavis*.

4. Case Comparison: *GSK v. Dong-A and Actavis*

Comparing *GSK* to *Actavis* is tricky because, while there are significant similarities between *Actavis* and the *GSK* decision, but there is also a key difference that suggests that *GSK* did not address the issue of reverse payment settlement agreements at all. On the similarities first, both cases involved an agreement between an original-drug company and a generic-drug company in which the original-drug company offered substantial economic benefits to the generic-drug company in return for the generic-drug company’s promise to stay out of the original-drug company’s patented drug market. *GSK*’s offer of economic benefits to Dong-A was counterintuitive because normally one would expect the party that infringes the patent to pay the penalty to the patent holder. Here, the direction of the payment was reversed, so the agreements in both cases bear a key characteristic of a reverse payment settlement agreement.

¹⁹⁸ Supreme Court [S. Ct.], 2012Du24498, Feb. 27, 2014 (S. Kor.).

¹⁹⁹ *Id.* (The court described the situation upon which its opinion applied as follows: “This is a situation where a patent holder of a pharmaceutical drug, in the course of attempting to manufacture and sell its drug that can potentially to be infringed upon by a third party, agrees to provide certain economic benefits to a third party who contends the efficacy or the scope of the rights of the patent, and in return, receives consent to resolve or delay the patent dispute.” Korean court opinions are notorious for their long, compounded sentences. For the sake of preserving the integrity of the original text, the text within the above quotation is an almost literal translation of the court’s opinion.)

²⁰⁰ *Id.*

²⁰¹ *Id.*

Second, the out-of-the-ordinary level of economic benefit that the original-drug company paid to the generic-drug company was an important factor to both the U.S. Supreme Court and the Korean courts. In *FTC v. Actavis*, the Court said that “the ‘size of the payment from a branded drug manufacturer to a generic challenger is a strong indicator of such power.’”²⁰² Because such a sizeable payment indicated market power, the Court deemed this as one of the reasons that the costly antitrust scrutiny associated with a rule of reason analysis was worth the price.²⁰³ Similarly, in both the Seoul High Court’s and Korean Supreme Court’s decisions, the court inferred intent of collusion from the fact that the economic benefit conferred by GSK to Dong-A was larger than what one would expect in a normal transaction. It was for this reason that the Fair Trade Act was implicated.

Third, in both cases, the tension between the scope of the patent and the applicability of antitrust laws was an important step in determining the final outcome of the case. In *GSK*, the court first determined whether the GSK–Dong-A agreement was a legitimate exercise of power conferred to GSK within the scope of the relevant patent.²⁰⁴ Because the court determined that the agreement fell outside the scope of GSK’s patent, the court proceeded to further analyze whether the agreement violated the Fair Trade Act.²⁰⁵ In *Actavis*, the Supreme Court established as the first step of its analysis that the agreement between Actavis and Solvay was within “the exclusionary potential of the patent.”²⁰⁶ The Court then determined that regardless of that fact the agreement must undergo antitrust scrutiny.²⁰⁷

According to some Korean practitioners, however, *GSK* does not precisely deal with the same legal issue as *Actavis* because of one factual difference. In *GSK*, the settlement’s restriction on Dong-A’s marketing of its generic drug included the time beyond the patent’s expiration date.²⁰⁸ Thus, judging whether the value of antitrust policy outweighs the value of the patent or the settlement does not arise because the agreement between GSK and Dong-A fell outside the scope of the legitimate exclusionary power of its patent. Because the restriction applied beyond the patent’s validity period, it was *obvious* that antitrust laws were implicated in that case. On the other hand, the *Actavis* court rigorously analyzed *whether* the antitrust laws should be applied. Unlike the *GSK* case, the agreement between Actavis and Solvay addressed a timeframe within the period when

²⁰² *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013).

²⁰³ *Id.*

²⁰⁴ Kim & Hwang, *supra* note 174, at 56.

²⁰⁵ *Id.*

²⁰⁶ *FTC v. Actavis, Inc.*, 133 S. Ct. at 2230.

²⁰⁷ *Id.*

²⁰⁸ Kim & Hwang, *supra* note 174, at 56.

Actavis's patent was still valid.²⁰⁹ Thus, the determination whether to apply antitrust law in that case was subject to the tension between the exclusionary potential of a patent and precompetitive goals of antitrust laws. With these similarities and differences in mind, we now return to a fuller analysis of the *GSK* case and its significance in analyzing the Korean court's disposition of reverse payment settlement agreements in Korea.

5. Further Analysis of the *GSK* Case and Its Relevance to Reverse Payment Settlement Agreements

Based on the text of the opinion of the Supreme Court of Korea, one may get the impression that the court is confounding the scope of the patent test with an analysis that is similar to the rule of reason analysis. Based on the reasoning used by the Seoul High Court, the *GSK* case should have been fairly easy to decide.²¹⁰ The mere fact that the agreement extended beyond the patent validity period indicated that the agreement was outside the scope of the patent. Thus, at that point the court could have just dismissed the patent issue and applied the antitrust laws. Applying the antitrust laws, the court decision should have been a simple application of Article 19's prohibition of unjust concerted practices, which restricts agreements that "[p]ractically restrict[] competition."²¹¹

However, the *GSK* case appears to engage in policy analysis that resembles the reasoning used by the U.S. Supreme Court in *Actavis*. For example, the Supreme Court of Korea listed factors such as "the size of the economic benefit given for the agreement, cost of patent litigation and projected recuperation, and the existence of other reasons that legitimize the price of the agreement" that must be "comprehensively considered."²¹² These were almost identical to the factors considered by the U.S. Supreme Court's *Actavis* decision in adopting the rule of reason. The Supreme Court of Korea also opined that whether the agreement in question affects competition must be determined on a case-by-case basis.²¹³ Along with the court's order to "comprehensively consider" the above-mentioned factors, this case-by-case examination also resembles the methodology used in the rule of reason of U.S. courts.

The fact that the Korean Supreme Court appeared to import this line of legal reasoning seems odd because in its opinion it clearly mentioned that the reverse payment settlement extended beyond the validity period of

²⁰⁹ *Id.*

²¹⁰ *Id.*

²¹¹ Dokjeom gyuje mit gongjeong georaeae gwanhan beobyul [Monopoly Regulation and Fair Trade Act], Act. No. 8666, Oct. 17 2007, art. 19 (S. Kor.), translated in Korea Legislation Research Institute online database, http://elaw.klri.re.kr/eng_service/main.do (login and search required).

²¹² Supreme Court [S. Ct.], 2012Du24498, Feb. 27, 2014 (S. Kor.).

²¹³ *Id.*

the underlying patent. Why would the court use the reasoning fit for resolving reverse payment settlement agreements under the rule of reason when it pointed out facts that clearly indicated that the agreement extended beyond the exclusionary power of the patent?

One explanation may be found in the characteristic of Korean judicial opinions. According to one Korean legal scholar, while Korean legal opinions show strength in the choice of applicable laws, identifying relevant facts, and applying the laws to the facts, they are generally weak in developing legal standards for application in future cases.²¹⁴ The reason for this is that Korea is a civil law country with a legal system modeled after continental law.²¹⁵ Thus, unlike in a Common Law system, judges' decisions are not binding in South Korea.²¹⁶ Under the civil law regime, South Korean judges apply the facts to the statutes and regulations promulgated by the legislature.²¹⁷ Thus, the various factors considered in the court's decision—like the unreasonably excessive settlement amount—may simply be one of the facts, rather than an element of the law, that the Korean Supreme Court recited when applying the relevant facts to the provisions in the Fair Trade Act. Thus, a plausible explanation is that the Korean Supreme Court arrived at its decision independently of U.S. case law.

However, if the court in this case had access to the U.S. opinions on reverse payment settlement agreements, it may have incorporated parts of the U.S. court's analysis into its decision in the absence of the binding precedents which were present in the *Actavis* case. Unlike the United States, South Korea does not have the extensive case law under which the rule of reason analysis was developed. Without such background, the Korean court may have incorporated some of the reasoning of U.S. decisions without having the obligation to consider the fine distinction between the scope of the patent test and the rule of reason analysis.

Therefore, while the Korean Supreme Court used the language to comprehensively consider various factors similar to those appearing in the *Actavis* rule of reason analysis, such similarity may well be a coincidence derived from independent legal analysis by the two courts. Because both cases present similar sets of facts under a similar regulatory structure, it may not be too surprising that judges from different legal systems arrive at similar outcomes.

²¹⁴ Jin-suk Byun, *Sabeobminjujuuiwa beobwonui pangyeolmun* [Judicial Democracy and Case Opinions of Courts], 12-0 ILGAMBEOBHAG [ILKAM L. REV.] 241, 251-52 (2013) (S. Kor.).

²¹⁵ Eun Young Lee, *Hangug minbeobui byeoncheon* [Five Decades of Korean Civil Code: Its Formation and Transition], 9-0 HANGUGMUNHWAYEONGU [KOR. CULTURE RESEARCH] 175, 177 (2005).

²¹⁶ Byun, *supra* note 214, at 244-45 (stating that although Korea does not have *stare decisis*, Korean courts nonetheless take similar previous cases "into consideration").

²¹⁷ *Id.* at 251.

Whatever the reason for the similarity of the two opinions, the *GSK* decision is an example of how the Korean courts may decide a future case that will accurately represent the issue of reverse payment settlement agreements. For example, the *GSK* case indicates that Korean courts may be open to studying and borrowing the reasoning of U.S. case law. If this is the case, it will not be surprising for the Korean Supreme Court to implement a similar line of reasoning when an actual reverse payment settlement agreement comes before the court. Similarly, while the Korean cases may not specifically distinguish the scope of the patent test from the rule of reason analysis, because Korean judges operate under a civil law system, practitioners can expect Korean courts will take a comprehensive approach and weigh the various competing factors when deliberating reverse payment settlement agreements.

C. What Korea Can Learn from the U.S. Experience.

The reasoning adopted by *Actavis* as well as the rich case law spanning over twelve years provide a valuable jurisprudential tool in dealing with questionable settlements between brand-name- and generic-drug companies in Korea. Because *GSK* did not directly address a reverse payment settlement issue, one may be tempted to conclude that *Actavis* and the relevant U.S. case law will have little influence on Korean anti-competition laws. However, if the recently proposed amendments to Korea's Pharmaceutical Laws come into effect, similar incentive structures that fostered reverse payment settlements in the United States may be created in Korea. If so, the question of the applicability of antitrust laws in cases where the reverse payment settlement agreements are within the exclusionary scope of the patent could become relevant. Under this scenario, the reasoning in *FTC v. Actavis*, which advocated the rule of reason test, may be useful for antitrust authorities and courts in South Korea.

One could argue that the *Actavis* decision is only relevant to the United States because the issue arises in the context of the Hatch–Waxman Act's unique ANDA procedure and because the reasoning and holding are a culmination of decades of U.S. antitrust case law. However, the *Actavis* decision has potential to have influence beyond the United States courts. This is because the *Actavis* decision contains the U.S. Supreme Court's sophisticated reasoning on whether antitrust analysis is relevant when an agreement that potentially restricts competition falls within the scope of a patent of one of the parties. It also showcases the U.S. Supreme Court's attempt at balancing the policy interests of the patent laws and antitrust laws. These issues will recur regardless of the specific legal structure or statutory framework adopted by different jurisdictions. And for these issues, U.S. case law and the *Actavis* opinion present a powerful analytic

arsenal for other jurisdictions to use, including South Korea. Several important lessons come to mind.

For one, the U.S. experience with the *per se* rule, scope of the patent test, and rule of reason analysis applied by the different circuit courts provides the reasoning used for adopting the respective rules as well as their advantages and disadvantages. The U.S. courts also engaged in economic analyses to determine the reasonableness of a payment amount measured against the parties' incentives and the cost of litigation, which may provide empirical data to Korean courts.²¹⁸ In addition, the U.S. courts have experimented with different procedural rules and allocations of the burden of proof under the scope of the patent test and the rule of reason analysis; such exercise has exposed the relative efficiencies and problems of each procedural approach.²¹⁹ These are just a few of the judicial experiences that the U.S. case law presents to the rest of the world.

For this reason, *Actavis* is an important decision for the lawyers, regulators, private companies in Korea, and other jurisdictions around the world. For countries like South Korea where there is a realistic prospect of the introduction of a statutory framework that creates similar incentive structures to the United States, *Actavis* and the preceding cases among circuit courts are a valuable analytic inventory.

IV. CONCLUSION

This Comment has sought to analyze the recent Supreme Court decision *FTC v. Actavis* and offer a comparative perspective on the legal issue of reverse payment settlement agreements as they arise in the United States and South Korea. For the courts in the United States, the assessment of this case's impact is still premature. Perhaps in a few years when a number of district courts and circuit courts have addressed the issue, another commentator may assess the impact.

In Korea, reverse payment settlement agreements will likely become a central legal issue in the pharmaceutical industry and in the intersection between antitrust and patent laws.²²⁰ The introduction of the patent-approval linkage system may create a regulatory framework similar to the Hatch–Waxman Act in Korea and thereby replicate an incentive structure that fosters reverse payment settlement agreements. I argued that Korean policy makers strategically imported the Hatch–Waxman's regulatory framework almost intact because they took into account the advanced

²¹⁸ See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 209 (2d Cir. 2006).

²¹⁹ See *supra* Part III(A).

²²⁰ Keum Nang Park, Hui Jin Yang & Eunkyong Lyu, *Ip in the Life Science Industries 2014: South Korea's Patent-Approval Linkage System*, INTELL. ASSET MGMT. (IAM) MAG. July–Aug. 2014, at 121, 124, available at <http://www.iam-magazine.com/Magazine/Issue/66/Management-report/South-Koreas-Patent-Approval-Linkage-System>.

standing of U.S. laws and the inherent conflicting goals present in the regulatory framework. Although Korea has modified some provisions to prevent or reduce the incentives for reverse payment settlements, their efficacy remains to be seen.

The *GSK* decision was puzzling because it appeared to confound the scope of the patent test with the rule of reason analysis. Such a result, however, most likely extends from independent decisions by two courts that operate under two distinct legal systems. The *GSK* case is important because it provides a glimpse of how future cases on reverse payment settlements in Korea may look. Lastly, the *Actavis* case and other relevant U.S. case law provide rich analytic tools for Korean courts to look into when they decide cases on this issue. For these reasons, courts, regulatory agencies, lawyers, businesses, and scholars in South Korea will find it beneficial to pay close attention to *Actavis* and the subsequent development of case law in the United States.