I Want a New (Generic) Drug: A Comparative Case for Shifting U.S. Generic Drug Policies to Increase Availability and Lower Healthcare Costs

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Cover Page Footnote
* J.D. 2024, Northwestern Pritzker School of Law. My gratitude to Professor Laura Pedraza-Fariña for her guidance throughout the process of writing this note and to the entire staff of the Northwestern Journal of International Law and Business for their diligent work throughout the publication process.
I Want a New (Generic) Drug: A Comparative Case for Shifting U.S. Generic Drug Policies to Increase Availability and Lower Healthcare Costs

Immer S. Chriswell*

Abstract:
Enacted in 1984, Hatch-Waxman was intended to increase generic drug availability and make critical healthcare more affordable for Americans. In the nearly forty years following, while it has increased availability of drugs, it has also allowed drug originators to create avenues to profit in ways not intended when the original compromise was struck, undermining its success. Moreover, given a weak antitrust standard against reverse settlement payments proscribed in Actavis, the U.S. faces a dilemma to further improve access to generic medications in the future. The E.U.’s approach to generic drugs, while presently geographically fragmented, is simpler and has a clear antitrust standard against reverse settlement payments which can provide a touchstone for the U.S. to reform its policy to better achieve the goals originally sought in Hatch-Waxman.

* J.D. 2024, Northwestern Pritzker School of Law. My gratitude to Professor Laura Pedraza-Fariña for her guidance throughout the process of writing this note and to the entire staff of the Northwestern Journal of International Law and Business for their diligent work throughout the publication process.
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1. INTRODUCTION

Globally, the cost of prescription drugs remains a critically pressing issue, and generic drugs play a key role in efforts to drive costs down.¹ Key to the availability of generic drugs are patent law, generic drug approval processes, and antitrust policies. In the pursuit of bringing low-cost generic drugs to market, the United States’ and European Union’s regulatory approaches present a stark contrast, which exemplifies the importance of selecting the appropriate incentives to further this goal while maintaining drug innovation.

This comment will compare the European and American standards governing generic drug production, its interaction with drug patent laws, and antitrust policy surrounding reverse settlement payments. I will argue that the United States’ attempt to strike a compromise in its policy between drug originators² and generic drug producers has provided significant incentives to originators which has slowed the effectiveness of generic drugs on pricing in the U.S. market despite wide availability. Moreover, the antitrust standards intended to prevent such behavior have not done so and have instead left significant room for originators to slow generic drug entry. Further, it will argue that the E.U. system, despite its current system’s geographically fractured nature of patent rights and drug approvals, is preferable to the U.S. because it lacks the incentives given to drug originators that exist in the U.S. Moreover, as the E.U. is moving to solve these problems through centralizing drug approvals and patent rights, when this is successfully implemented, the system will be more effective in enabling generic drug entry across all member states.

In the United States, between 2015 and 2018, roughly 48.6 percent of Americans used one prescription drug in the last 30 days.³ Nearly a quarter of the population was using three or more prescriptions.⁴ Prescription drugs such as PrEP can cost as much as $2,000 per month for the brand-name drug, pushing some to forgo a critical step in medical treatment, here in preventing the transmission of HIV.⁵ In a country with such pervasive use

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¹ See S. Vincent Rajkumar, The high cost of prescription drugs: causes and solutions, 10(6) BLOOD CANCER J. 71; see also Aaron S. Kesselheim et al., The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform, 316 JAMA 858 (2016); see also Jonathan H. Watanabe et al., Cost of Prescription Drug-Related Morbidity and Mortality, 52 ANNALS OF PHARMACOTHERAPY 829 (2018).

² Drug originators are parties who create new, brand-name medicines to market, whereas generic companies create medicines that “work in the same way and provide the same clinical benefit and risks as their brand-name counterpart[].” U.S. Food & Drug Administration, Generic Drug Facts, https://www.fda.gov/drugs/generic-drugs/generic-drug-facts.


⁴ Id.

⁵ Sarah Varney, Many Americans still paying high costs months after insurers were ordered to cover HIV preventive care, CNN, (Feb. 28, 2022, 6:19 AM),
of prescription drugs, the need for affordable medications is essential to the welfare of Americans.

This is the role generic drugs play in the market. A 2019 U.S. Food and Drug Administration Report found that depending on the number of generic companies selling a particular drug, prices of that drug fall by 39 to 95 percent.\(^6\) As of 2021, 90 percent of all prescriptions dispensed in the United States are for generic drugs.\(^7\)

This was not the case leading up to 1984 when the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act,” or “Hatch-Waxman”) was passed. In 1984, only 18 percent of drugs prescribed in the United States were generic medicines.\(^8\) That was due to patent policy as well as the policies at the time of the Food and Drug Administration (“FDA”), the agency that certifies the safety and efficacy of a given drug.\(^9\) Gaining FDA approval prior to 1984 for generic drug manufacturers required lengthy and costly clinical trials, which the brand name they intended to create a generic of had already gone through.\(^10\) Generic manufacturers were disadvantaged by this process because they lacked a patent grant to recoup the cost of the trials, as well as the fact that they were not permitted to begin testing the generic drug until after the originator’s patent expired because it constituted infringement, effectively extending the monopoly duration of the patent holders by forcing them to start the approval process once the patent was no longer in force.\(^11\) The restrictions and barriers on generic manufacturers all represented significant windfalls for drug originators, who could continue to price higher until a generic entered the market. Realizing the critical importance of increasing the market penetration of generic drugs, U.S. Senators Orrin Hatch and Henry Waxman sought to solve this problem through a bipartisan compromise that attempted to reconcile entirely opposing forces: those in favor of increasing generic availability and those seeking to strengthen originators’ patent rights.\(^12\)

The enactment of the Hatch-Waxman signaled Congress’s goal of

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\(^7\) U.S. FOOD AND DRUG ADMIN., OFFICE OF GENERIC DRUGS 2021 ANNUAL REPORT.


\(^10\) Id.

\(^11\) Id at 300.

\(^12\) 114 Cong. Rec. 11-82 (1984).
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bringing more generic drugs to market while balancing incentives to drug innovators. It did so by expediting generics’ ability to enter the market, creating incentives for being the first generic in the market, and providing a way to challenge weak patents blocking markets. In return, drug originators received protections for their patent rights and their investment in going through FDA approvals. While there have been corresponding increases in generic drug availability by volume in the U.S., the share by value of drugs is nowhere near consummate. Moreover, given the compromise struck, originators have created strategies to leverage the Act in their favor to slow generic entry.

On top of these strategies designed to disincentivize and slow generic entry, originators separately sought to buy out generic competitors through reverse settlements. In a reverse settlement, when a drug originator is suing a generic for patent infringement, the originator pays the generic company in order to settle the claims in exchange for the generic’s agreement to stay off the market for a period of time, solidifying the patent’s security. Until 2013, these agreements were not the subject of any antitrust scrutiny, which seeks to promote competition, prevent monopolization by any market actor and acts to halt agreements in commerce that restrain competition impermissibly.

Because a patent is a temporary grant of a monopoly to a person or company in exchange for their innovation, patents generally sit outside the authority of antitrust law. However, in 2013, the Supreme Court held in *FTC v. Actavis* that reverse settlement payment agreements may still be subject to antitrust scrutiny if the payment generates a question of the patent’s validity; it should then be analyzed under the “rule of reason” standard. However, the high court did not provide extensive details in this decision, and thus it left the courts to struggle for consensus, and enabled these settlements to continue since their fate is not certainly doomed when challenged.

In comparison, the E.U. struggles with its current system, which is member state-driven, but successful member states see generic drug penetration at similar market share by volume and greater share by value to the United States, and none see as stark volume-to-value market share ratios as the U.S. This is because they do not have a corollary framework to Hatch-Waxman, which gives incentives to originators in exchange for generic ease of entry. By not enacting such a framework, geographic fracturing becomes the main issue to strategize around. There are fewer levers to enable reverse settlements, and a stronger antitrust standard against reverse settlements makes the failure of almost all agreements that could pass scrutiny in the U.S. certain to fail in the E.U. Thus, while flaws exist within the E.U. system, it can serve as a valuable guidepost for the U.S. to adjust its policies to better effectuate the goals Hatch-Waxman

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purported to have.

Section II of this comment will lay out how Hatch-Waxman, the U.S. approach to generic drug admission, came to be along with the critiques that come associated with it. It will further explain the U.S. approach to the outgrowth of Hatch-Waxman, reverse settlements, and how Actavis has fallen short of looking out for consumer welfare through its vagueness.

Section III will explore the European Union’s generic drug approval system and the challenges that it faces due to a geographically fractured approach. It will also review the landmark cases Lundbeck and Servier and the strict standard which they set, before comparing the U.S. and E.U. system alongside what others have said.

Finally, Section IV will propose several adjustments to the U.S. system based on what is successful about the E.U. approach to generic drug approval and associated antitrust principles. This includes a stricter antitrust standard and removing or modifying several of the key leverage points which Hatch-Waxman provided to drug originators in order to enable lower healthcare costs to Americans.

2. THE UNITED STATES’ SYSTEM OF DRUG PATENT RIGHTS ENABLED THROUGH ANTITRUST POLICY

The United States’ nationwide spending on prescription drugs saw a tenfold increase from 1980 to 2018, going from $30 to $335 billion.\(^\text{14}\) Per capita spending on prescription drugs has gone from $140 to $1,073 over the same period, and as a result the U.S. has seen the share of total healthcare spending on prescriptions go from less than 5% to around 11% today.\(^\text{15}\) While those numbers have somewhat plateaued and even seen slight decreases as a percent of total spending, they have not seen any significant downward trend since the mid-2000s.\(^\text{16}\) While there are justifiable rationales for this, such as increase in overall availability of drugs, increase in per capita prescription rates, and innovation,\(^\text{17}\) the monopoly grant of their patent combined with antitrust doctrine which has further protected these interests certainly plays a role in protecting drug originators’ profits.\(^\text{18}\)

This is driven by the compromise position that Hatch-Waxman made when it was enacted and has only been furthered by the Actavis decision at the Supreme Court and the subsequent lack of clarity in the lower courts. While Hatch-Waxman created important pathways to increasing generics market share, it also created several avenues by which drug originators


\(^{15}\) Id.

\(^{16}\) Id.

\(^{17}\) Id.

\(^{18}\) Kesselheim, *supra* note 1, at 861.
could seek to maximize the value of their patent. When combined with an Actavis regime that is not sufficiently skeptical of reverse settlement deals between generic manufacturers and drug originators, the overall framework has served to enable the efforts of drug originators to stymie further progress of generic drug availability in the United States.

a. Hatch-Waxman’s Unstable Compromise Between Innovation and Access

Hatch-Waxman was significant because it signaled a shift in U.S. policy toward the emphasis on generic drugs as a key part of the U.S. healthcare system.\(^\text{19}\) However, a bill of this magnitude could not be passed without tradeoffs to drug originators because of their important role in innovating new drugs, as well as the lobbying power that they held.\(^\text{20}\) When Hatch-Waxman was finally signed into law, generic manufacturers were provided with an avenue to gain market share through a faster and more straightforward go-to-market process with incentives to do so. However, these gains were limited by additional protections for drug originators, which have and still now represent a barrier to further progress in advancing the goals of Hatch-Waxman to promote generic drug availability.\(^\text{21}\) This section will explore this unstable compromise, identifying the key points of leverage in the U.S. prescription drug market.

i. Solving generic manufacturer’s go-to-market disincentives

Hatch-Waxman’s primary purpose was to create incentives that would increase interest in generic drug production and marketing in the United States, which prior to enactment faced significant headwinds given the regulatory framework.

Prior to Hatch-Waxman’s enactment in 1984, the 1962 Kefauver-Harris Amendments to the Food, Drug, and Cosmetic Act controlled the process of marketing approval for all drug manufacturers.\(^\text{22}\) Under this regime, all pharmaceutical companies seeking to sell a drug in the United States went through the lengthy process of clinical trials to be submitted for review.\(^\text{23}\) This meant that both brand-name drug originators and generic drug manufacturers would go through this lengthy and expensive process of producing clinical trial data for the same drug as many times as it was duplicated in the market.\(^\text{24}\)

On top of the requirement that generics essentially reproduce data that

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\(^{19}\) Kesselheim & Darrow, supra note 9, at 297.

\(^{20}\) Id at 306.


\(^{22}\) Kesselheim & Darrow, supra note 9, at 297.

\(^{23}\) Id.

\(^{24}\) Id. at 345–346.
had already been reviewed, in 1984 the U.S. Court of Appeals Federal Circuit decided Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc. which added a further delay.\textsuperscript{25} Bolar held that generic manufacturers could not begin the process of testing their generic of an approved drug to produce the requisite clinical trial data for the FDA until after the patent of the originator expired.\textsuperscript{26} The court reasoned that allowing the manufacturer to even test the generic drug in preparation for obtaining approval would be a violation of the patent holder’s monopoly rights,\textsuperscript{27} despite the fact that this holding itself was a de facto extension of the patent holder’s monopoly.

For generics without patent protection, these were two significant disincentives to go to market, as recouping the costs associated with the full FDA approval process without a patent-conferring monopoly is not a wise business strategy.\textsuperscript{28} This, in combination with the litigation risk a generic may face for patent infringement, meant that the returns offered to these businesses may not have been commensurate with the risks.\textsuperscript{29} Moreover, the overall social efficiency of this process contained obvious waste, with drugs that are already proven safe and effective being required to duplicate the entire FDA approval process, all at the cost of consumers. Hatch-Waxman solved these problems by changing the path to market approval and offering incentives and solutions to generics to offset the litigation risk they faced.

Abandoning the duplicative and prohibitively expensive FDA trials as the means to generic entry, Hatch-Waxman created the Abbreviated New Drug Application (ANDA) process, where applicants are instead required to demonstrate that their product “performs in the same manner as the innovator drug.”\textsuperscript{30} This can be accomplished in a variety of ways, such as proving “bioequivalence,” which compares the rate of absorption of the generic drug to the innovator’s. A successful application would show the same amount of active ingredient reaches the patient’s bloodstream in the same amount of time, which does not require full clinical trials to prove.\textsuperscript{31}

Hatch-Waxman not only created the ANDA process, but it also moved up the time at which generic manufacturers can begin this process, as section 271(e) supersedes the Bolar ruling, allowing generics to experiment

\textsuperscript{26} Id at 863.
\textsuperscript{27} Id.
\textsuperscript{28} See Kesselheim & Darrow, supra note 9, at 298.
\textsuperscript{29} See Erika Lietzan, The History and Political Economy of the Hatch-Waxman Amendments, 49 SETON HALL L. REV. 53, 84 (2018) (citing to research which indicated that at the time of Hatch-Waxman’s passage through Congress, more than 100 drugs had expired patents without a generic competitor because of the investment required).
\textsuperscript{31} Id.
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and test for bioequivalence before the drug originator’s patent expires.\textsuperscript{32}
Overall, Hatch-Waxman represented a replacement of the significant barriers built into the previous regulatory process with a more streamlined and generic-friendly process.

With regards to the risk of infringement litigation that generic companies can face when entering the market, Hatch-Waxman sought to incentivize generics to take the risk in launching and also provide them with a means to litigate offensively rather than defensively against drug originators. Recognizing that generic manufacturers may prefer to wait until another generic has successfully entered a certain drug market without an infringement challenge, Hatch-Waxman incentivizes the party who is the “first filer” for generic approval for a drug by granting a period of exclusivity.\textsuperscript{33} During this period, the first company to file for generic approval (or multiple if done on the same day) is given the right to compete exclusively against the drug originator for 180 days, beginning on the date of their launch.\textsuperscript{34} This 180-day grant of exclusivity represents an opportunity for millions in incremental revenues earned during the period.\textsuperscript{35} Once this period ends, other generic manufacturers may enter the market.\textsuperscript{36}

The other way in which Hatch-Waxman allows generic companies to manage the litigation risk of entering the market is through “Paragraph IV” challenges. When an ANDA application is submitted, the generic company must state either that (1) a patent does not exist for the drug they are seeking to market, (2) that it is expired or will expire before entering the market, or (3) that “such patent is invalid or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted.”\textsuperscript{37} This final option is what is known as a “Paragraph IV certification.”\textsuperscript{38} If a generic company is successful in asserting its paragraph IV certification, the originator’s patent is invalidated or the generic is

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\textsuperscript{32} Kesselheim & Darrow, supra note 9, at 305.
\textsuperscript{34} Id.
\textsuperscript{37} ANDA Guidance, supra note 33, at 2 (emphasis added).
\textsuperscript{38} Id.
declared non-infringing, and the generic can enter the market immediately and retains the 180-day exclusivity period.\footnote{Id.}

This provision allows generics to directly challenge what they believe are weak or invalid patents, which should not stop their entry to the market as a part of applying to enter the market, rather than wait for the originator to file suit.\footnote{Kesselheim & Darrow, supra note 9, at 325.} Paragraph IV challenges most often occur when a generic manufacturer is trying to challenge a secondary patent on a drug that does not seek to protect the original innovating molecule’s patent, but instead other features of the drug such as its coating.\footnote{Id. at 320–321.} These patents are often intended to serve as a blocker to extend the original molecule’s monopoly period.\footnote{Id.}

ii. “Balancing” the Act for brand-name drug originators

These significant gains for generic manufacturers came directly at the cost of drug originators, who remained important for their role in the market as innovators of new prescription drugs.\footnote{Id. at 301.} In order to “balance” the bill to encourage drug originators to still innovate, Congress enacted provisions intended to give enhanced protections to drug originators.\footnote{Lietzan, supra note 29, at 56.} The protections made adjustments to the patent term of drugs in reference to the FDA marketing process and provided a procedural remedy for originators to combat Paragraph IV certifications.\footnote{Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).}

Prior to Hatch-Waxman, the requirement that generics go through the same preclinical and clinical testing process combined with Bolar’s ruling meant that this process could not begin until the patent expired, serving to\footnote{Conrad & Lutter, supra note 6, at 2–3.} \textit{de facto} extend the patent monopoly beyond the official expiry date. With these requirements now gone, drug originators faced a shortening of the window to recoup investment and maximize profits, given the effect generics have on drug pricing.\footnote{See generally Duxin Sun et al., Why 90% of Clinical Drug Development Fails and How to Improve it? 12 ACTA PHARMACEUTICA SINICA B 3049 (2022).} This combines with the fact that roughly ninety percent of drugs fail in clinical trials,\footnote{See generally Duxin Sun et al., Why 90% of Clinical Drug Development Fails and How to Improve it? 12 ACTA PHARMACEUTICA SINICA B 3049 (2022).} representing costs that cannot be recouped in the market through launch, which increases the burden on successful products to produce returns. Moreover, even successful preclinical and clinical trials take at least three to four years and commonly longer, and while a patent is valid for twenty years, the FDA marketing
process takes place as this period runs.\textsuperscript{48} In response to the provisions which significantly altered the status quo of generic entry to market, Hatch-Waxman provides for "patent term restoration." This provides that half of the time spent in the preclinical and clinical testing period, up to a maximum of five years, shall be added to the exclusivity period for the patent when a drug receives marketing approval.\textsuperscript{49} Thus, drug originators gained a significant extension to their monopoly for engaging in the FDA process, which not only gave them approval for market entry but also significant data on the drug's performance useful to future development.

With regards to the newly created Paragraph IV certification generics could pursue, Hatch-Waxman recognized that the potential loss of a patent for an originator represented significant risk. Seeking to "balance" this provision, Hatch-Waxman requires that the generic manufacturer provide notice to the manufacturer of the certification and a forty-five day window for originators to subsequently file an infringement lawsuit against the generic.\textsuperscript{50} Hatch-Waxman further provides that the filing of an infringement suit by the originator against a Paragraph IV challenger triggers an automatic thirty-month stay during which the FDA cannot approve the generic drug applicant.\textsuperscript{51} This is intended to allow litigation to play out.\textsuperscript{52} However, if the lawsuit is not resolved during the stay, the generic can launch in the market "at risk" while still in litigation. This counterweight in the Paragraph IV process thus has a two-fold effect in tilting the playing field in their favor: it acts as a no-questions-asked extension of exclusivity for originators,\textsuperscript{53} and it imposes costs on generic manufacturers by delaying entry.

\subsection*{iii. Academic Commentary on Hatch-Waxman}

The legacy that Hatch-Waxman has left 40 years after its passing is, at best, described as a mixed bag. The rate of total prescriptions in the U.S. has risen from 19\% of total prescriptions dispensed\textsuperscript{54} to 84\% as of 2012.\textsuperscript{55} However, despite this increase, generic drugs make up only 18\% of U.S. prescription drug spending when measured by dollars spent.\textsuperscript{56} Moreover,
spending on prescription drugs as a percentage of total U.S. healthcare spend remains at around 11% (more than double its share in the 1990s) and has remained at roughly this share since the mid-2000s. While Hatch-Waxman has achieved increases, it has failed to mitigate the price of prescription drugs for Americans.

As many have noted, this is driven by the fact that the attempted balance involved satisfying entirely opposing interests, which may not have been necessary to begin with, and that the compromise position has enabled behaviors by drug originators who have acted to undercut the legislation.

At the time of the passage of Hatch-Waxman, the data and studies that were used to support drug originators’ claims that regulation had already resulted in reduced innovation and further restrictions would follow without patent term restoration were hotly contested. The efficacy of granting patent term restoration to increase innovation was far from certain and a significant concession granted to drug originators in Hatch-Waxman. The problem with the compromise which was struck was that, while it gave generics a gain by accelerating their pathway to the market, the patent restoration given to drug originators was the exact opposite regulation to this faster path. Moreover, given that drug originators have been accused of applying for patents too early and delaying preclinical and clinical testing, patent term restoration arguably rewards drug originators with extended patent exclusivity when the originators are wasting significant time themselves. Similarly, the thirty-month stay for infringement cases initiated during Paragraph IV certification was originally set to be 18 months and was only included in the legislation the hour before the final language of Hatch-Waxman was introduced on the floor. This decision was derided by many, despite claims made that this made the bill “opposed by no one and backed by all of the groups concerned.”

Data since the enactment of Hatch-Waxman has done little to prove that these negotiations have done much for the innovation which was claimed to be of great importance, but has shown a longer effective patent term for originators. As Kesselheim and Darrow note, while data has not shown any relationship between innovative R&D and Hatch-Waxman,
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there does appear to be a strong correlation between generic competition
and innovation (a study from 1985-2001 found that the “most important
predictor” of a new product for an originator was the impending loss of a
patent and presumed generic entry). Given the lack of evidence showing
that these compromises to the benefit of drug originators have
accomplished little and the contestation they faced during the writing of the
bill, it is fair to think about a future with an adapted version of Hatch-
Waxman.

Regardless of this debate over the compromises made, what has been
very clear in the 40 years since Hatch-Waxman was passed is the
aggressive manner by which drug originators have sought to undermine it
and maximize their leverage against generics, to the detriment of
consumers. Two notable examples of these strategies are patent thickets and
captive generics.

Patent thickets are the outgrowth of the thirty-month stay that Hatch-
Waxman provided to originators for infringement litigation initiated in
response to a Paragraph IV challenge. Because the stay is issued without
any assessment of the challenged patent’s strength, drug originators have
been incentivized to accumulate “thickets” of secondary patents, which
serve to cover other features of the medication such as coating rather than
the innovative drug itself, in order to retain patent rights to initiate an
infringement suit. Thus, originators gain an extension and incremental
monopoly revenues while generics face litigation costs, other costs
associated with delays to market, and a loss of leverage against originators.
These benefits are conferred on the back of patents which, as Scott
Hemphill and Bhaven Sempat have found, cause 89% of settlements in
litigation, and in which drug originators are victorious only 32% of the time
those cases are litigated to conclusion. Given the lack of innovative
quality of secondary patents, this runs directly counter to the intention of
Hatch-Waxman to reward drug originators for innovating new molecules.

Alongside the legal hurdles that originators have created with patent
thickets are the competitive hurdles that generics may face in the market in
the form of captive generic drugs. A captive generic drug is a generic
created by the drug originator that can be launched at any time without
additional paperwork, including during the first filer’s 180-day exclusivity
period. This is not expressly forbidden by Hatch-Waxman, and generic

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65 Id. at 308–309.
66 Kesselheim & Darrow, supra note 9, at 304.
67 See C. Scott Hemphill & Bhaven Sempat, Drug Patents at the Supreme Court, 339
SCIENCE 1386, 1386–1387 (2013) (finding that secondary patents are 89 percent of
settlements in litigation, and drug originators only win 32 percent of cases litigated to
conclusion).
69 Robin Feldman, Captive Generics: The Wolf in Sheep’s Clothing, 59 HARV. J. ON
companies unsuccessfully argued to convince the Supreme Court of its inconsistency with Hatch-Waxman.\textsuperscript{70} Despite the Court’s ruling on this matter, the namesake of the bill themselves\textsuperscript{71} and a 2011 Federal Trade Commission (FTC) report indicate otherwise. The FTC report shows that captive generics negatively impact drug prices and generic entry and were a cause of the pay-for-delay schemes which emerged after Hatch-Waxman.\textsuperscript{72}

From the time Hatch-Waxman was written into law until today, it has been debatable how much additional protection, if any, drug originators needed. Since its passage, little evidence has come to light to bolster originators’ positions, while at the same time, they have acted aggressively to create legal and competitive hurdles for generics to effectively flip the playing field back in their favor. It is unsurprising that, in the face of this aggressive posturing, generic manufacturers sought to settle rather than fight in many circumstances. Through insufficient scrutiny of such settlements between should-be market competitors, reverse settlements further enable originators to act to the detriment of consumers.

\textit{b. Reverse Settlement Payments and Antitrust Implications}

Reverse settlements are agreements between generic manufacturers and drug originators that became popular after Hatch-Waxman as a means to reconcile the roadblocks that originators erected to Paragraph IV litigation. In the settlement, the generic manufacturer(s) agree to delay their entry to the market in exchange for cash and other incentives that represent incremental revenue opportunities. These deals operated in a legal grey area due to lingering questions about whether the patent the originator held exempted the settlements from antitrust scrutiny, which the Supreme Court finally addressed a circuit split on the issue in \textit{Actavis}. While the Court held that the settlements could be subject to scrutiny, it did not bar such settlements and left the details of the framework that should be used to assess them to the lower courts.

While Hatch-Waxman was written as a framework by which generic drugs are supposed to be increasingly available to Americans, it simultaneously and unintentionally also created the framework by which generic companies and drug originators have negotiated to keep those same generics off the market. Because the Paragraph IV certification process and any subsequent infringement litigation initiated by the originator puts the future of the originator’s patent in danger, they are incentivized to find an out-of-court solution to avoid risk if the patent is weak. Given the potential revenues that the 180-day exclusivity period, captive generic drugs, and the automatic 30-month stay for infringement litigation represent for both

\textsuperscript{70} \textit{Id.} at 391.


\textsuperscript{72} Feldman, \textit{supra} note 69, at 393.
parties, these naturally became the central levers of negotiating what are known as reverse settlement agreements.

In a reverse settlement agreement, rather than the allegedly infringing generic making a payment to avoid litigation, the drug originator compensates the generic company. This can be in a variety of forms, including cash, business arrangements, or both. In exchange, the generic manufacturer agrees to delay their entry into the drug’s market for a set period of time, which typically falls closer to the end of the patent term. This not only ends the challenge to the patent’s validity, but it also forecloses other generic manufacturers from entering the market or challenging the patent because the 180-day exclusivity conferred by Hatch-Waxman to the first filing generic is not forfeited as a result of a reverse settlement.

These settlements began occurring more frequently in the 1990s as drug originators saw an opportunity to erase uncertainty in Paragraph IV and began to see criticism from the FTC as early as 1999. In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) required the disclosure of Paragraph IV settlements to the FTC for review but said nothing as to their validity. However, it was only in 2013 when the Supreme Court addressed the issue of reverse settlements in *Actavis*. 

i. *Actavis* leaves it to the lower courts

The Supreme Court addressed the validity of reverse settlement payments for the first time in 2013, holding that some, but not all, may run afoul of antitrust laws in *FTC v. Actavis*. In this case, the FTC challenged a 2006 agreement between drug originator Solvay Pharmaceuticals and generic manufacturer Actavis, Inc. Solvay created the brand name drug AndroGel, filing a New Drug Application in 1999, receiving FDA approval in 2000, and a patent in 2003. However, in that same year of patent receipt, generic manufacturers Actavis and Paddock Laboratories filed an ANDA and certified under paragraph IV that the patent was invalid and

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75 Id.
76 Id.
77 Kesselheim & Darrow, *supra* note 9, at 331.
78 Id.
80 Id. at 144.
81 Id. There were two other generic manufacturers who were parties to this litigation.
82 Id.
their drugs were non-infringing.\textsuperscript{83} Solvay responded by initiating patent infringement litigation against the generic manufacturers and obtaining the thirty-month stay.\textsuperscript{84} At the conclusion of the stay, the FDA approved the generic ANDAs; however, in 2006, with this approval already processed, the parties settled the litigation.\textsuperscript{85} Under the terms of the settlement, Actavis\textsuperscript{86} agreed to not bring its generic product to the market until 2015, that it would instead promote AndroGel to urologists, and in exchange would receive an annual payment of nineteen to thirty million dollars annually.\textsuperscript{87} The parties claimed that the amount agreed to was for the services provided by Actavis and was unrelated to their abstention from the market.\textsuperscript{88}

The FTC challenged the agreement under Section 5 of the Federal Trade Commission Act (FTCA); however, the claims were dismissed in district court for failure to state a claim due to the monopoly that a patent grants, and the Eleventh Circuit affirmed.\textsuperscript{89}

On review in the Supreme Court, writing for the majority, Justice Breyer reversed and remanded the case, holding that while Solvay’s patent may allow anticompetitive effects of a settlement regarding it to be excused by the exclusionary provisions of a patent, that does not make it entirely immune from antitrust laws.\textsuperscript{90} The court explained that because a successful Paragraph IV challenge invalidates the patent and its monopoly, the reverse settlement may not actually fall within a patent’s grant of monopoly rights.\textsuperscript{91} This requires that the assessment of antitrust liability not simply be weighed against patent policy, but must also be viewed under the lens of procompetitive antitrust policies which seek to avoid price-fixing schemes by competitors.\textsuperscript{92} In order to make the determination whether a reverse settlement at issue requires antitrust scrutiny, the Court further explained that the underlying patent infringement and validity determination need not be resolved.\textsuperscript{93}

Instead, the Court explained that because “an unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival,” this “suggests that the payment’s objective is to maintain supra-competitive prices to be shared,” which would

\textsuperscript{83} Id.
\textsuperscript{84} Id. at 145.
\textsuperscript{85} Id.
\textsuperscript{86} All generic parties to the litigation made similar promises in exchange for annual payouts from Solvay.
\textsuperscript{87} Id.
\textsuperscript{88} Id.
\textsuperscript{89} Id. at 145–46
\textsuperscript{90} Id. at 147.
\textsuperscript{91} Id.
\textsuperscript{92} Id. at 147–48.
\textsuperscript{93} Id. at 157.
be in violation of U.S. antitrust laws.\textsuperscript{94} This explanation by the Court has come to be known colloquially as the “Actavis Inference,” which serves to allow lower courts to excise the litigation of the patent from the initial assessment because of its limited value for the purpose of an antitrust evaluation.\textsuperscript{95} Upon establishing this unexplained large reverse payment, the Court stated that courts should proceed with a “rule of reason” analysis, which is a multi-step burden-shifting test that weighs the anti and pro-competitive effects of the settlement at issue.\textsuperscript{96}

The Court’s decision was notable for two reasons beyond answering the existing circuit split. First, it did not choose to apply a stricter standard to reverse settlements, such as a \textit{per se} ban or a presumption of illegality.\textsuperscript{97} The Court explained this was because the settlement’s illegality depended on the payment amount relative to acceptable rationales such as anticipated future litigation costs, other services provided, or the lack of an acceptable explanation.\textsuperscript{98} Second, the Court provided only a vague description of when the rule-of-reason analysis would proceed, and “[left] to the lower courts the structuring” of the actual analysis.\textsuperscript{99}

ii. The lower courts’ prolonged struggle for consensus and clarity

While the \textit{Actavis} decision clarified the circuit split that reverse settlements were not beyond antitrust scrutiny, it did not do much in the way of directing lower courts on pursuing such scrutiny. As a result, lower courts have inefficiently struggled since to effectuate this decision, with two questions central to it. First, the definition of what constitutes a “payment” which is “large and unjustified” has required extensive litigation to produce moderate consensus, and there remain disagreements among the lower courts.\textsuperscript{100} Second, once the inference has been reached, without guidance on the rule-of-reason analysis from the Supreme Court, lower courts have been forced into extensive and varying analyses to ascertain the value exchanged in these deals and whether the rationales are justified.\textsuperscript{101}

Although district courts initially disagreed over whether a “payment” was either cash only or both cash and non-cash considerations, subsequent reviews by appellate courts have led to a consensus that both qualify in

\textsuperscript{94} Id.


\textsuperscript{96} \textit{Actavis}, 570 U.S. at 159.

\textsuperscript{97} Id. at 158–59.

\textsuperscript{98} Id.

\textsuperscript{99} Id. at 160.

\textsuperscript{100} See generally Lisa Jose Fales, Paul Feinstein et al., \textit{Welcome to the Wild, Wild West: Actavis Five Years Later}, Antitrust, Summer 2018.

\textsuperscript{101} Id. at 20.
making the *Actavis* inference.\textsuperscript{102} This was an important consensus to be reached because without it, alternative settlement structures such as “No-Authorized Generic” agreements (where drug originators agree to not launch or license their own generic during first filer exclusivity), co-promotion of the brand name drug, or product development agreements would have been able to effectively disable the core of *Actavis*.\textsuperscript{103}

On the question of the meaning of “unjustified,” the *Actavis* decision did provide examples of what is justified, such as payments that are roughly avoided litigation costs, those relevant to an agreed upon service, or those that reflect “traditional considerations.”\textsuperscript{104} This has provided courts a touchstone as they evaluate deals which often seem commercially unreasonable, as there is little evidence the deals exist outside of these settlements.\textsuperscript{105}

However, the payment has to be “large and unjustified,” and with regard to “large,” the Court provided little guidance and lower courts have struggled to agree on what is relevant to this part of the inquiry.\textsuperscript{106} Some courts have structured this by largely leaning on the language of *Actavis*, and finding payments larger than avoided litigation costs to satisfy this prong.\textsuperscript{107} Others have required comparison of the amount greater than litigation costs to be assessed relative to any additional services being provided,\textsuperscript{108} or to be viewed by a reasonable jury as “significant enough to induce a generic challenger to abandon its patent claim.”\textsuperscript{109} While anticipated litigation costs are a reasonable point to evaluate settlements from for the Actavis inference, including costs beyond litigation costs is problematic because it presumes that they have value and are not disguised, anticompetitive terms which a rule-of-reason analysis would not credit. Moreover, allowing a judge to proceed without a firm standard from the Supreme Court in evaluating the excess would enable judges who feel less favorable to the design of the *Actavis* to require an even higher threshold of payment to satisfy what is a “large” payment.\textsuperscript{110}

In addition to the problem of defining what would constitute a large payment, the next issue that the courts are now saddled with is that of measurement. Given the complicated structure described above, this places an excess burden on the courts of assessing the potential value of certain

\begin{thebibliography}{110}
\bibitem{102} Fales, Feinstein et al., *supra* note 100, at 19.
\bibitem{103} Id.
\bibitem{104} *Actavis*, 570 U.S. at 156.
\bibitem{105} Fales, Feinstein et al., *supra* note 100, at 20.
\bibitem{106} Id. at 18–19.
\bibitem{107} Id. at 19.
\bibitem{109} *King Drug Co. of Florence, Inc v. Cephalon, Inc.*, 88 F.Supp. 3d 402, 417 (E.D. Penn. 2015); See also Fales, Feinstein et al., *supra* note 100, at 18.
\end{thebibliography}
unconventional business arrangements while simultaneously speculating as to the potential cost of litigation the trial at hand could produce.

All of the above uncertainty and debate over what would constitute a reverse settlement agreement in violation of U.S. antitrust laws is ultimately at the cost of consumers. Because there is less certainty as to what types of deals will be rejected, and the subsequent antitrust analysis which proceeds from it is complicated and lengthy, generics and drug originators are enabled to continue the practice, depriving the public of generic drug availability during the period which courts are forced to grapple with these issues in efforts to undue problematic reverse settlements.

3. EUROPEAN SYSTEM OF PATENT RIGHTS & ANTITRUST

In contrast to the United States’ system, the European Union differs in both its generic drug approval procedure and in how its courts have treated reverse settlement payments in their seminal cases, *Lundbeck*\(^\text{111}\) and *Servier*.\(^\text{112}\) The E.U. lacks a corollary to Hatch-Waxman and as a result, there are less areas of value within the approval process which can be exploited to extract a reverse settlement process. While the geographically patchwork nature of drug approval and patents plagues generics presently and gives leverage to originators, the strong court standard which has been taken on reverse settlements by the European Commission serves to largely neutralize this threat. Despite Europe’s own challenges with drug pricing and generic availability, its design in this regard is superior to the United States, and through the implementation of the Unified Patent Court (UPC), they are proactively solving their problems.

a. European Union generic drug approval and patent challenges

The European Union’s approach to generic drug approval, in contrast to the U.S., lacks a corollary to Hatch-Waxman, and as a result is a more straightforward approval process on paper. The one lingering complexity which frustrates the E.U. is the geographically patchwork nature of its patent and drug approval system. The granting of individual national intellectual property rights within the European Union makes it difficult for generics to challenge those patents due to cost, and the lack of access to the centralized drug approval process harms smaller countries in the E.U. However, the E.U. is acting to make changes to address these challenges, which would reduce the most prominent challenge which the E.U. faces in improving its generic drug access problem.

The E.U. marketing authorization of generics has the same options as originators do but can only pursue authorization after the eight-year “data exclusivity” period that the patent holder has, which is shorter than the

\(^{111}\) Case AT.39226 - Lundbeck (2013).

\(^{112}\) Case AT.39612 – Perindopril (Servier).
market exclusivity a drug typically has. Outside of gaining approval in just one member state of the E.U., there are three other options for marketing approval which give multiple country or E.U.-wide approval: the centralized procedure, the decentralized system, and mutual recognition. The centralized process is generally the path which originators take, and few generics use. It requires submission to the Committee for Medicinal Products for Human Use (CHMP), takes an average of 14.8 months, and on approval gives E.U.-wide authorization. In mutual recognition, a generic will apply to a “reference Member state” and then seek approval in “concerned Member states,” who make their decision based on the reference state’s approval. Disputes, if raised by the member states, may delay the process up to 120 days. In the decentralized process, the applicant chooses a country as the reference member state, which prepares an assessment draft for the other member states to consider and approve. The advantage of this over mutual recognition is that manufacturers receive their approvals simultaneously. Generics use these pathways because access to the centralized procedure is not guaranteed for them. Thus, generics are incentivized to apply in markets where they can obtain fast approvals and where the best business opportunity lies, which is to the detriment of smaller E.U. markets. As the European Medicines Agency (EMA) continues to grow further, and with efforts on patents to increase centralization, there may be opportunities for generics to change this practice and seek E.U.-wide approval more frequently. This system is

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113 Generic and Hybrid Medicines, European Medicines Agency, https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/generic-hybrid-medicines. Data exclusivity refers to a period of time when drug originators can maintain their research data private from other companies, whereas marketing exclusivity refers to the period of time when drug originators can sell the patented medicine without competition.

114 Inga Abed, The approval process of medicines in Europe, 23 MEDICAL WRITING 117, 117 (2014). Approval for only one country is based on the laws of the member state.

115 Id. at 119–120.


117 Abed, supra note 114, at 119.

118 Id.

119 Id. at 120.

120 Id.


obviously geographically fractured, which is a problem the United States does not have, however there are still less value streams which are created within the approval processes available without any corollary to Hatch-Waxman. Instead, the main obstacle which Europe has had is this historically national system of generic approval and patent challenge.

The E.U.’s patent system has similar, largely national processes and rights which have become key to drug originators’ strategies. Both the individual national patent systems of each member state and the European Patent Office’s (EPO) grants create nation-based intellectual property rights, which require generic companies to challenge them in each state rather than through a single system. In an attempt to solve this problem, the E.U. launched the UPC and the unitary patent in 2023, which aims to create a single body that would give an E.U.-wide intellectual property right which would be enforced by an E.U. adjudicatory system. While it would be a boost for drug originators who no longer have to file in individual countries, it is arguably a bigger opportunity for generic companies because they can challenge and invalidate only a single patent to gain access to the entire E.U. This risk is clear because, at present, pharmaceutical companies are opting out of the new system, which has a transition period of at least seven years, weakening the effect of what should be a powerful aid to generic drugs. While the E.U. should take further action to accelerate member states joining, it is actively in pursuit of solving the main problem which gives drug originators leverage against generic companies. While this geographic patchwork certainly creates an advantage for originators to strategically slow generic growth in the E.U. and gives them leverage in negotiating agreements, the E.U.’s antitrust backstop has largely stopped significant reverse settlement activity since its seminal decisions, made in the mid-2010s, take hard stances against them.

b. The Lundbeck and Servier decisions make E.U. antitrust policy clear

The E.U. began to scrutinize reverse settlements in January 2008, culminating with a pharmaceutical industry report. The report noted the importance of speed to the market for generic drugs, because prices drop on average 40 percent two years after generic market entry. At the time, generic companies in the E.U. were averaging seven months to market after

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124 Helen Collis and Edith Hancock, After a 70-year wait, will Europe’s new patent system be a total flop?, POLITICO, https://www.politico.eu/article/70-year-wait-europe-unitary-patent-system/.  
125 Id.  
126 Id. As of this comment, seventeen countries have joined, where a European patent gives a grant in as many as 39 countries.  
127 Schumaker, Paun, & Leonard, supra note 123.  
128 Id.  
the expiration of originators’ exclusivity, with high-volume medicines averaging four months.\textsuperscript{130} Had market entry taken place directly after the loss of exclusivity, it was shown that savings on these drugs would have increased twenty percent from 2000-2007.\textsuperscript{131}

The report identified multiple roadblocks that likely contributed to this delay, including reverse settlement payments. It identified 200 settlements, covering 49 medicines (31 best-selling medicines), half of which impacted the generic company’s ability to market the medicine.\textsuperscript{132} Of those, a “significant proportion” transferred value from the originator to the generic company.\textsuperscript{133} In its final report, the European Commission created categories for these settlements: Category A (no restriction on generic entry), Category B.I (restriction on generic entry but no value transferred between parties) and Category B.II (restriction on generic entry and value transferred between parties).\textsuperscript{134} At the time of the report, the Commission did not opine on the potential anticompetitive nature of Category B.II agreements, suggesting it would require further scrutiny.\textsuperscript{135}

In 2013, the Commission finally acted on these concerns, fining drug originator Lundbeck and four generic manufacturers for six reverse settlement agreements across various member states which restricted market entry for generics of citalopram, an antidepressant with a patent expiry in 2002.\textsuperscript{136} These deals were brokered after Lundbeck initiated an infringement action, with Lundbeck buying the generic manufacturers’ already existing supply of the drug and agreeing to a profit-sharing model so long as the generics stayed out of the market.\textsuperscript{137}

In its decision, the Commission stated that in settlements where infringement is established, settlements based on each party’s assessment of strength do not exceed the grant of a patent and are not invalid.\textsuperscript{138} However, settlement agreements where a generic company stayed out of a market in exchange for value of any kind were subject to scrutiny.\textsuperscript{139} Turning to the agreements at hand, the Commission, in scrutinizing them, held that they violated section 101(1) of the Treaty on the Functioning of the European Union (TFEU) because (1) there was potential competition between the parties when the agreement occurred; (2) the generics agreed to limit their efforts through the agreement; and (3) they provided a transfer of value for these efforts, which reduced the incentive of generic companies to

\textsuperscript{130} Id. at 9.
\textsuperscript{131} Id. at 10.
\textsuperscript{132} Id. at 14.
\textsuperscript{133} Id.
\textsuperscript{134} European Commission, Pharmaceutical Sector Inquiry, 270 Figure 106 (2009).
\textsuperscript{135} Id. ¶ 763.
\textsuperscript{136} Case AT.39226 – Lundbeck (2013).
\textsuperscript{137} Case T-472/13, Lundbeck v. Comm’n, ¶ 39 (Sept. 8, 2016).
\textsuperscript{138} Case AT.39226 – Lundbeck ¶ 604 (2013).
\textsuperscript{139} Id.
Potential competition, according to *Lundbeck*, measures “real concrete possibilities” which means analyzing the possibilities at the time of patent expiry, when generics test viable production and when they prepare for market entry. The court affirmed that launching when “at risk” on the belief the originator’s patent is valid suffices as potential competition given evidence of the significance of the efforts by the generic to prove this out.

In regard to (2) and (3), the court affirmed that not all reverse payments are subject to TFEU 101(1) as a payout can be based on concerns over the strength of the patent, but when payment is combined with generic delay from market, this combination replaces any argument by the parties about patent strength and places it within TFEU 101(1)’s scrutiny.

Lundbeck appealed and the decision was upheld in 2016. Because of the high general likelihood of an anticompetitive effect of the agreement, the General Court held it did not have to investigate the deal’s actual anticompetitive impact, but simply prove the elements of the deal which created that likelihood.

In the other seminal case for the E.U. on reverse settlements, the Commission fined Servier and five generic manufacturers in 2014 for reverse settlement payments. Affirming the logic employed in *Lundbeck*, it held that the agreements were restraints “by object,” which meant that no further inquiry was necessary to support this. Despite this assertion, the Commission provided additional analysis of each agreement to show the effects of the agreement despite this lack of necessity, likely because of *Cartes Bancaires*, a case which had narrowed the scope of what constituted restriction of competition “by object.” This analysis added to the 101(1) framework by further analyzing the effect on potential competition that the

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140 Id. ¶ 604–609.
142 Id. ¶ 157. In *Lundbeck*, Merck entered the market while it was challenging the patent and other generics applied for authorization.
143 Id. ¶ 360.
144 Case T-472/13, Lundbeck v. Comm’n, ¶ 341 (September 8, 2016).
145 Case AT.39612 – Perindopril ¶1407, ¶1481, ¶1668, ¶1857, ¶2000 (Servier).
146 Id. ¶1110–1112, ¶1144.
147 Id. ¶1112.
148 Id. at ¶1272, ¶1412, ¶1518, ¶1671, ¶1862.
149 Damien Geradin, et al., *Reverse Payment Patent Settlement in the European Union and the United States*, George Mason University Legal Research Paper 1, 25 (2015). In *Cartes Bancaires*, the European Commission held that a French payment card association’s fees were anticompetitive and restrictions by object. Because it would otherwise exempt the Commission from having to make the case that the deals were anticompetitive, raising concerns about enforcement, the Commission stated that restriction of competition by object should be found in “undertakings which reveal a significant degree of harm to competition that it may be found that there is no need to examine their efforts.” Case C-67/13, Groupement des cartes bancaires (“CB”) v. European Comm’n, (Sept. 11, 2014).
deal had. Factors which were referenced in regard to one of the deals included the potential litigation threat a generic posed to Servier, the generic as a commercial threat, and also its role in providing assistance to generics in other countries, all of which the reverse settlement removed, harming the market.

The Commission further determined that Servier had violated TFEU 102 through the abuse of its dominant position, as “Servier used its market power in order to induce a number of closed generic threats to withdraw from competition.” Because Servier was able to induce almost all of its generic competitors as a part of a strategy to delay generic entry, the Commission found that the cumulative effect of this strategy, along with an acquisition done, was in violation of section 102.

These two cases lay out the EU’s approach to reverse settlement payments. Lundbeck lays out the framework by which reverse settlement payments should be analyzed to find an anticompetitive agreement, and Servier bolsters this by providing the effects analysis that affirms when Lundbeck is proven, the anticompetitive effect is certain. Neither decision discussed any potential procompetitive effects of these side deals as justifications in affirming the presumed anticompetitive effects.

c. Comparing the generic drug process in the American and European markets

When considering the ultimate goal of Hatch-Waxman, which was to increase the availability of generic drugs to Americans and therefore making critical healthcare more affordable, it is clear that while Europe’s geographic patchwork is a limiting factor, the remainder of its approach to generic drug entry and reverse settlements is preferable and the U.S. could benefit from adopting its clearer approach. Some may argue that Europe has an alarming number of member states where they have a worse generic market share by volume, while the United States excels at this. However, volume rates are influenced by additional factors in Europe regarding prescription and national insurance purchasing practices, and despite the low market shares by volume, many of these countries have near consummate generic market shares by value to the United States despite their low volume. Several member states such as Germany and the UK (a former member state during the study) are on par with the U.S. by volume.

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150 Case AT.39612 – Perindopril ¶1484 (Servier).
151 Id. ¶ 1493–1496.
152 Id. ¶ 2931.
153 Id. ¶ 2960–2961.
155 Id.
while having nearly double the market share by value, in fact.\textsuperscript{156} Hatch-Waxman and the Actavis decision are a part of the cause for this gap, and when examining how the European approach would change U.S. outcomes, it is clear it would represent a gain toward the stated goals of Hatch-Waxman.

For example, during\textit{In re Bystolic Antitrust Litigation}, the drug originators and several generic competitors entered into an agreement to end a patent challenge on Bystolic.\textsuperscript{157} In upholding the agreement, the court held that the “side deals” struck between parties who would otherwise be competitors were not “unjustified” despite being a supply agreement for the generics to the originator worth $5-6 million.\textsuperscript{158} The court rationalized the agreement served an economic purpose that was not disproven.\textsuperscript{159} Under the Lundbeck and Servier approach this supply agreement would be rejected on its face for transferring value in exchange for not competing in the market.\textsuperscript{160} This is the clearly the correct outcome because under principles of increasing generic competition to increase availability and lower prices, an agreement to remove a generic competitor from the market to instead become a supplier for the brand name which they sought to compete with clearly allows these two competitors to share in the retained monopoly profits to the detriment of consumer welfare. Moreover, further clarity on what “large and unjustified” means will not serve to entirely fix the problem because, as Hovenkamp points out, the parties will simply act to restrain competition up until that limit.\textsuperscript{161}

The problem with the Actavis decision relative to Lundbeck and Servier beyond the lack of clarity is that even if Actavis’ standard were clearer on what is “large and unjustified,” the analysis continues into the rule of reason framework and allows further justification of these agreements to be argued. By adopting a rule of reason analysis after the Actavis inference is established, the Supreme Court gave too much latitude to drug originators in both standards and has enabled reverse settlements over litigating patents to conclusion to continue to occur counter to Hatch-Waxman’s intent and sound antitrust policy. This becomes even clearer when considered alongside a 2002 FTC report that showed generic companies won 73 percent of cases that they litigated to a close.\textsuperscript{162} To encourage these challenges to patent validity to persist, the European standards of Lundbeck and Servier would act as an incentive to pursue invalidating patents while effectuating more sound antitrust policy

\textsuperscript{156} Id.
\textsuperscript{157} \textit{In re Bystolic Antitrust Litig.}, 583 F. Supp. 3d 455, 464 (S.D.N.Y 2022).
\textsuperscript{158} Id.
\textsuperscript{159} Case T-472/13, Lundbeck v. Comm’n at ¶ 484.
\textsuperscript{160} Id.
\textsuperscript{161} Hovenkamp, supra note 110, at 457.
\textsuperscript{162} Id. at 457; Feldman, supra note 35, at 9.
in this area. By embracing a strong presumption against these deals, firms have little incentive to engage in value transfers given a clear bright line rule against such agreements, along with extensive reporting requirements for their deals. Additionally, monitoring the market would be possible to observe any agreements being struck outside the scope of a settlement. This would take the burdens of the unlitigated patent challenge from the wallets of consumers and instead encourage generic companies to compete against, rather than cooperate with originators. This is crucial to consumer welfare because even a few months of monopoly power can equate to hundreds of millions of dollars without sales, at direct cost to consumers.\textsuperscript{163} At present, there are fewer than ten cases on record which have been pursued against pay-for-delay settlements in the EU, whereas in the United States there are far more, and as of the FTC’s latest reports, consummation of these agreements is still ongoing.\textsuperscript{164}

Applying the EU’s strong presumption against reverse settlement payments would be consistent with the Hatch-Waxman Act’s intent. In \textit{Actavis}, the court even quoted Senators Hatch and Waxman to prove this point: Senator Hatch, in 2002 before the MMA was passed, said it “was and is very clear that the [Hatch-Waxman Act] was not designed to allow deals between brand and generic companies to delay competition.”\textsuperscript{165} Senator Waxman similarly introduced a separate bill intended to stop “collusive agreements . . . by the brand company for delays in the introduction of lower cost, generic alternatives.”\textsuperscript{166}

What would further discourage the above litigation from occurring would be embracing a regulatory environment similar to the E.U. because it lacks the value streams which have become the basis of the reverse settlements at issue. While the E.U.’s geographic patchwork does provide some strategic cover and potential rationale for a reverse settlement, it has acknowledged this problem and is seeking to reduce this incentive through the implementation of the UPC, which will effectively make patents a bundle of rights rather than individual, national grants.\textsuperscript{167}

While at the time the passage of Hatch-Waxman represented a shift in American policy towards improving generic availability in the interest of lower costs, generic manufacturers and originators have instead come to use it as a framework for sharing monopoly profits because a bargained settlement creates an outcome preferable to litigation for both parties absent

\textsuperscript{163} Feldman, \textit{supra} note 35, at 9–10.
\textsuperscript{165} 148 Cong. Rec. 14,437 (2002).
\textsuperscript{166} 146 Cong. Rec. 18,774 (2000).
\textsuperscript{167} Collis & Hancock, \textit{supra} note 124.
Comparative Study of US and EU Generic Drug Regimes
44:285 (2024)

an antitrust penalty. These settlements disrupt the architecture of Hatch-Waxman, intended to encourage competition and trade its intended public social benefits for private benefits to each manufacturer. This framework does not exist in Europe, and deals cannot be struck on these terms because neither party has the rights necessary to negotiate using them. There is no 180-day exclusivity or 30-month stay for a patent infringement litigation. The last major negotiating point for Europe is the largely national system of rights which it is seeking to solve.

This is not to suggest that absent Hatch-Waxman’s provisions, reverse settlements would not be favorable to both parties in some circumstances still. Despite Europe’s lack of strong incentives compared to the U.S., reverse settlements have still occurred. As Professor Herbert Hovenkamp has shown, restraint in favor of sharing the patent’s monopoly profits can still produce an optimal outcome for both parties. However, the absence of provisions which aid originators would serve to complicate the negotiations as generics would have less reason to strike a deal. This would also serve to reduce any incentive to file an infringement suit unless it was truly meritorious, expediting time to market. While the initial intent of Hatch-Waxman was to provide and balance incentives between pharmaceutical actors, the current results with reverse payment settlements are simply the included parties enriching themselves at the expense of the public.

4. RECOMMENDATIONS

While the U.S. to this point has had success in increasing market penetration of generic drugs from dismal levels, in order to further this goal today, there are lessons to be learned from the E.U. system. First, the U.S. should adopt a per se rule against reverse settlement payments except where a cash payment is made to avoid future litigation costs to erase the flexibility which Actavis provides. Second, the U.S. should remove the exclusivity protection of any generic company that settles its Paragraph IV litigation, allowing the exclusivity to pass to a subsequent generic manufacturer. Finally, the 30-month automatic stay for infringement proceedings under Paragraph IV should be modified such that it only serves to benefit drug patents which are truly innovative and provide social good, and not follow-ons where the innovation is not the core drug, but ancillary elements.

168 Hovenkamp, supra note 110, at 454.
169 Laurenz Bové, A bitter pill to swallow: The legality of reverse payment patent settlements, 53 JURA FALCONIS 682, 702 n. 4 (2016).
170 Hovenkamp, supra note 110, at 456.
a. **Adopting a per se rule against reverse settlement payments similar to Lundbeck**

As discussed above, the United States’ standard for reverse settlement payments has led to wasteful litigation and deals that restrain competition for the benefit of the pharmaceutical industry at the expense of consumers.

Applying a *per se* rule against agreements as described in *Lundbeck*\(^{171}\) (i.e., those that are Category B.II) would better effectuate sound antitrust policy by focusing on the nature of the agreement’s effects on competition rather than its value as a settlement of litigation. In doing so, deals such as those from *In re Bystolic*\(^ {172}\) would be rightfully rejected as a transfer of value in exchange for market delay without any further analysis. Modifying this rule to only allow cash payments, which represent the future litigation costs avoided, will make any court scrutiny of the deal more straightforward. Additionally, it will discourage settlements by generic companies, who are unlikely to settle for a one-time payout representing litigation costs that would be far less than their potential profits, while also allowing them to settle in matters where they find in discovery they are less likely to succeed than anticipated.

Given the rate at which cases that are litigated to the end are successful,\(^ {173}\) eliminating the ability to negotiate an agreement restricting market entry in exchange for value would increase the likelihood of cases being fully litigated and weak patents being invalidated. Moreover, combined with the suggestion below to scrutinize the 30-month stay period, it would lower the incentive for drug originators to initiate infringement actions under Paragraph IV to begin with, which creates the necessary environment for these deals.

b. **Remove the 180-day exclusivity period for any settlement agreement that restricts entry of first filer**

One of the most important features of the reverse settlement payment in the United States is that the 180-day exclusivity granted to the first filer enables the forestalling of any other generic company. If Hatch-Waxman were amended to remove that period of exclusivity from the first filer, and instead bestow it on the company which was next to file for marketing approval along with allowing that company to then file a Paragraph IV challenge, it would again further restrict the ability to use reverse settlements to forestall generic drugs.

Because settling with a first filer (or multiple first filers) would not necessarily be the end of litigation on a specific medicine, the drug originator would have less reason to pursue a settlement with any party.

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\(^{171}\) Case AT.39226 – Lundbeck (2013).
\(^{172}\) 583 F. Supp. 3d 455.
\(^{173}\) See Feldman, *supra* note 35, at 27 (“generic applicants have prevailed in 73 percent of the cases in which a court has resolved the patent dispute.”).
Moreover, because the first filer no longer offers the drug originator a way to forestall the remainder of the market from entering, the value of the settlement to the drug originator would be lower, which would make it less likely a settlement could be reached on worse terms.

The lower settlement offer would be less attractive to the generic company on an absolute basis and also on the basis that the loss of the 180-day exclusivity would actually be a large increase in cost on their end as a result of settling. Thus, by removing the 180-day exclusivity period, it is possible to remove a significant incentive which aligns the interests of these parties during Paragraph IV litigation.

c. Fine-tune the 30-month stay which is granted to drug originators under Hatch-Waxman

The 30-month stay is a good incentive placed to allow drug originators to pursue the litigation of patents which they truly believe are valid and enforceable against the challenging generic. However, the automatic nature of it assumes that the medicine in question is actually a new innovation, which frequently is no longer the case, with originators extending their drug monopoly through follow-on patents, which do not involve the introduction of a new, innovative drug to the market.174 By patenting these weaker traits of the innovative drug, such as a new coating or other adjustments, weaker patents serve as a barrier to generic drugs, as they have to pursue Paragraph IV litigation just to get to market given the incentive for drug originators to file for infringement.175

This provision of Hatch-Waxman should be refined to reward only original drug innovations by requiring the FDA to scrutinize the patents which they are receiving for marketing authorization and only grant the 30-month stay to new molecules. Absent a finding of a new molecule, the drug originator could also be granted a stay if it shows it covers other products which are included in other types of exclusivities, such as in pediatrics.

An alternative solution to this, rather than relying solely on the FDA to perform such scrutiny, would be for the PTO and FDA to collaborate and create a process by which they categorize patents which are being put in for marketing authorization with the FDA into those which merit exclusivity and those which are follow-on patents which should not receive the 30-month stay. Given the recent announcement of a joint USPTO-FDA listening session to advance President Biden’s “Promoting Competition in the American Economy” executive order, there is an increasing realization of the opportunity that administrative collaboration represents.176

174 See Kesselheim & Darrow, supra note 9, at 304.

175 Id.

Removing this 30-month stay would significantly improve the ability of generic drugs to get to market once the initial patent expires by eliminating what was a heavy incentive for a drug originator to file an infringement lawsuit, regardless of the strength of its follow-on patent.

It is understandable that suggesting adjustments to Hatch-Waxman and antitrust policy when generic drug penetration by volume has reached all-time highs in the United States seems dubious. However, as laid out above, the harms which consumers are bearing as the result of existing policies which uphold weak patents, the anticompetitive deals that entrench them, and advantage drug originators by allowing them to erect new barriers to entry are not cognizable anymore and run counter to the goals of Hatch-Waxman to increase generic availability in the interest of driving down the cost of crucial healthcare.

It can be argued that Hatch-Waxman is not meant to solely benefit generic drug manufacturers, but to balance the incentives between the parties in the market and protect the innovators. Drug originators bear a large risk, and often see high rates of failure at various stages of development. Thus, the drugs which they can successfully patent need to bear not only the costs of the individual process, but the cost of the portfolio which they are developing. If additional profits were removed from this, it is argued that there would be less investment in risky innovations. However, the concerns about this compromise that have existed since the beginning have come to fruition, and it is clear that the protections given are not entirely necessary. A 2020 study by the NIH found that the pharmaceutical industry far outperforms the nonpharmaceutical industry, with net income margins as a percentage of revenue of 13.8 percent to 7.7 percent. It is unlikely the elimination of reverse settlement payments will decrease the profitability of pharmaceutical companies such that the returns do not match their risk profile.

5. CONCLUSION

When the Hatch-Waxman Act was passed, it was intended to bring more generic drugs to the market for the American people, thus bringing down the cost of healthcare. While it has succeeded on an absolute basis, there are significant drawbacks that still exist. Modifying the Hatch-Waxman Act, as well as the Actavis antitrust doctrine would go to removing side-deals which have restrained further progress at the expense of consumers.

177 See Kesselheim & Darrow, supra note 9, at 305.