

WHERE DO WE GO NOW? THE HATCH–WAXMAN ACT TWENTY-FIVE YEARS LATER: SUCCESSES, FAILURES, AND PRESCRIPTIONS FOR THE FUTURE

Linda P. Nussbaum & John D. Radice***

In this Article we place the Hatch–Waxman Act in its historical context and discuss the new legal paradigm that the Act created. Such an expansive piece of legislation was certain to, and did, have unintended consequences. We examine those consequences and attempts to recalibrate the Act to account for them. After cataloguing certain problems that still plague the Hatch–Waxman framework, we offer a cautious assessment of the Act and a prescription for consideration of ideas both realistic and precatory that policymakers should consider when assessing further amendments to the Act. Finally, we consider the impact of these suggestions on competition within the developing area of biologic products.

I. IN THE BEGINNING

The United States Food and Drug Administration (“FDA”) was created through the Federal Food and Drugs Act in 1906 as part of the response to

* Linda P. Nussbaum is a Director at Grant & Eisenhofer, P.A. and focuses her practice on complex antitrust class and individual actions. Ms. Nussbaum has extensive experience as lead or co-lead plaintiffs’ counsel in numerous direct purchaser pharmaceutical antitrust class actions, including in many of the cases discussed in this Article. Ms. Nussbaum has lectured extensively at American Bar Association meetings and elsewhere on various aspects of antitrust law.

** John D. Radice is a Senior Counsel at Grant & Eisenhofer, P.A., and focuses his practice on complex antitrust class actions, especially direct purchaser pharmaceutical antitrust class actions, and False Claims Act cases. Mr. Radice, too, has represented plaintiffs in many of the cases discussed in this Article.

Upton Sinclair's exposé of the meat industry in *The Jungle* and the outcry that followed that book's publication.¹ The law primarily focused on the marketing and labeling of drugs, but lacked provisions enabling the FDA to conduct pre-marketing review of drugs.² Though the 1906 law was an admirable step forward, its limitations were brought into sharp relief in 1937 when more than one hundred people suddenly died after taking Elixir Sulfanilamide, a medication whose active ingredient, when used in powder or tablet form, is an effective treatment for streptococcal infections, but which is deadly when diluted with diethylene glycol to form a liquid administration.³

The Elixir Sulfanilamide disaster galvanized public opinion regarding strengthening the regulatory framework covering medicines and other products and paved the way for the passage of the Federal Food, Drug, and Cosmetics Act of 1938 ("the FDCA").⁴ This law strengthened the FDA's powers by empowering the Agency to conduct limited pre-market reviews for safety and to keep unsafe new drugs off of the market.⁵

Over time, the 1938 Act was also found wanting, and in response to another crisis—this time involving the drug Thalidomide—it was amended in 1962.⁶ Thalidomide was used in Europe as a sedative and to treat nausea in pregnant women. While the drug was undergoing clinical trials in the United States researchers discovered its association with a dramatic birth defect known as phocomelia, which afflicted newborns with missing or truncated, flipper-like arms or legs.⁷ Among other things, the 1962 amendments gave the FDA the mandate to analyze new drugs for safety and efficacy and allowed the Agency to influence the design of clinical trials.⁸

1. Pub. L. No. 59-384, 34 Stat. 768 (1906); see generally FDA History—Part I, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm> (last visited May 9, 2010).

2. *Id.*; Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1758 (1996).

3. Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER MAGAZINE, June 1981, <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/ucm2007257.htm>.

4. *Id.*; 21 U.S.C. § 355 (2009).

5. Merrill, *supra* note 2 at 1761-62.

6. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended at 21 U.S.C. §§ 301-381 (2002)).

7. Merrill, *supra* note 2 at 1764 n.35. See Richard Harris, THE REAL VOICE 184-99 (1964).

8. Merrill, *supra* note 2 at 1765-66.

A series of Supreme Court decisions in 1973 made it clear that generic drugs (*i.e.*, less expensive copies of brand name drugs) needed to pass the same safety and efficacy requirements as brand name drugs.⁹ Generic manufacturers had piggy-backed on the safety and efficacy studies submitted by brand manufacturers, and the FDA for the first time created an Abbreviated New Drug Application (“ANDA”) to standardize and facilitate this process.¹⁰ However, as occurs today, brand manufacturers saw the “free-riding” generics as a threat to their profits and took action. A lawsuit brought by a major brand manufacturer resulted in a ruling that decimated the then-existing generic industry.¹¹ A federal judge held that generic manufacturers could not rely on the branded manufacturers’ studies and were required to submit full sets of their own data and studies, making the generic model at that time much less efficient and viable.¹² “As a result of the dearth of generic drugs in the ‘monopolized’ pharmaceutical marketplace, patients, as drug consumers, faced steadily increasing costs.”¹³

As the market for drugs matured, the government, having addressed safety and efficacy, turned its focus to escalating drug costs. The Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch–Waxman Act” or the “Act”) was compromise legislation that sought to balance the dual goals of (1) facilitating and streamlining access to less expensive generic drugs and (2) ensuring that the system maintained sufficient incentives for brand manufacturers to develop new products.¹⁴

Given the enormous amount of money at stake, it is unsurprising that the Hatch-Waxman Act has had mixed success in meeting its objectives. The Act was a complicated, highly compromised piece of legislation that left open loopholes that were later exploited by brand and generic manufacturers

9. See *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); *Ciba Corp. v. Weinberger*, 412 U.S. 640 (1973); *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645 (1973); *USV Pharm. Corp. v. Weinberger*, 412 U.S. 655 (1973); see generally Note, *Protecting Public Health from Outside the Physician’s Office: A Century of FDA Regulation from Drug Safety Labeling to Off-Label Drug Promotion*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 117, 137–43 (2007) (detailing the history of the generic drug industry).

10. See Note, *supra* note 9 at 139–40.

11. See *id.* at 141; *Hoffmann–LaRoche, Inc. v. Weinberger*, 425 F. Supp. 890, 892–93 (D.D.C. 1975).

12. *Hoffmann*, 425 F. Supp. at 892, 894–95.

13. See Note, *supra* note 9 at 142.

14. Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc (2000) and 35 U.S.C. §§ 156, 271, 282 (2000)). See generally Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch–Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 590 (2003); *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1326 (Fed. Cir. 2001).

to circumvent the goals of the Act. Among other things, these loopholes “create[d] perverse incentives for brand name and generic drug companies to enter into collusive agreements, with possible antitrust implications, to the detriment of the public.”¹⁵ Subsequent amendments in 2003 sought to cure certain egregious loopholes,¹⁶ but new anticompetitive schemes emerged to preserve and extend monopoly profits from drug sales.¹⁷

The iterative nature of the government’s role in regulating drugs, as shown by this brief history, gives context both to the limitations that have arisen in the Hatch–Waxman framework and the institutional willingness to occasionally remake the system in response to new problems. Will history repeat itself and cure what ails the current system of generic drug entry? Could the limitations of Hatch-Waxman cause a rethinking of current policy and a paradigmatic shift toward new approaches to further the Act’s goals? In this Article we argue that it should.

In Part II of this Article we provide a brief overview of the Hatch–Waxman Act’s role in ensuring efficient generic entry and we explore two of the key compromises in the legislation: the thirty-month automatic stay of FDA approval while infringement litigation is pending; and the 180-day exclusivity period for certain generic filers. In Part III we focus on two major continuing problems with the Hatch–Waxman Act that persist even after the 2003 amendments. And in Part IV we analyze and propose different solutions to further the Hatch–Waxman Act’s goals, which are just as relevant today as they were in 1984. We analyze these proposals with an eye toward how they address current failings and whether they can adapt to cover new challenges like fostering competition within the emerging market for biologic drugs.

15. *The Hatch–Waxman (Im)Balancing Act*, Legal Electronic Document Archive at Harvard Law School, available at <http://leda.law.harvard.edu/leda/data/551/Paper1.html>.

16. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066 (2003) (codified in scattered sections of 42 U.S.C. and 26 U.S.C.).

17. Yana Percersky, *To Achieve Closure of the Hatch–Waxman Act’s Loopholes, Legislative Action is Unnecessary: Generic Manufacturers are Able to Hold Their Own*, 25 CARDOZO ARTS & ENT L.J. 775, 786 (2007).

II. MAKING THE SAUSAGE: THE HATCH-WAXMAN ACT COMPROMISE

A. *The Simmering Problem*

The legislation that eventually became the Hatch–Waxman Act in 1984 had its origins in the late 1970s under the Carter Administration.¹⁸ Branded pharmaceutical manufacturers complained that lengthy FDA review caused a wasting of patent life, and reduced the statutory term to a substantially shorter “effective” patent term.¹⁹ At the same time, the 1962 amendments to the FDCA that required safety and efficacy testing for all drugs through clinical trials presented a barrier to competition from less expensive generic drugs.²⁰ The FDA later described this requirement for duplicate studies as “unethical because it requires that some sick patients take placebos and be denied treatment known to be effective.”²¹ However, the framework created by the 1962 amendments so inhibited efficient generic entry that by 1984 there were approximately 150 drugs that were off patent and had no generic equivalent.²²

B. *A Compromise Solution to Speed Generic Entry*

The Hatch–Waxman Act—aptly named the Drug Price Competition and Patent Term Restoration Act of 1984—attempted to address both of these problems.²³ “The purpose of Title I of the [Act] is to make available more

18. Gerald J. Mossinghoff, *Overview of the Hatch–Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 188 (1999).

19. H.R. Rep. No. 98–857, pt. 2, at 3 (1984); *see also* FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* 4 (2002), <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (hereinafter “FTC Study”).

20. FTC Study, *supra* note 19, at 3–4.

21. H.R. Rep. No. 98–857, pt. 1, at 16 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649.

22. *Id.* at 17.

23. In this Article we discuss discrete sections of the Hatch–Waxman Act, specifically focusing on the expedited approval process for generic drugs, the thirty-month stay, and the 180-day exclusivity period. We do not rehash the existing comprehensive studies surrounding the legislation. To the extent that this presentation makes it seem, counterfactually, that the balance of the Hatch–Waxman Act compromise tilted in favor of generic manufactures, readers should consult more detailed analyses of each piece of the legislation, and especially the incredibly valuable patent term restoration and extension provisions. *See* 35 U.S.C. § 156 (2006); *see also* *Bristol–Myers Squibb Co. v. Royce Labs.*, 69 F.3d 1130, 1132 (Fed. Cir. 1995) (noting the “balance” struck by the Hatch–Waxman Act); *Mylan Pharm., Inc. v. Thompson*, 139 F. Supp. 2d 1, 5 (D.D.C. 2001) (“The Hatch–Waxman Act represented Congress’s efforts to strike a compromise between the competing interests of pioneer

low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs[.]”²⁴ and “[t]he purpose of Title II . . . is to create a new incentive for increased expenditures for research and development . . . [by restoring] some of the time lost on patent life while the product is awaiting pre-market approval.”²⁵ In this Article we focus on Title I.

In Title I, the Hatch–Waxman Act sought to streamline the process for generic drugs to come to market. Because mere experimentation—not even marketing—by generic companies prior to patent expiry was held to be “a violation of the patent laws in the guise of ‘scientific inquiry,’”²⁶ generic manufacturers had to wait until the patent expired before beginning to develop generic versions. This delay effectively extended patents for two years beyond their statutory lives with no benefit to consumer welfare.²⁷

In response to these hurdles, the Hatch–Waxman Act created a new, quicker, and less expensive ANDA process.²⁸ Whereas makers of new molecular entities still were required to submit detailed New Drug Applications (“NDAs”) supported by safety and efficacy studies, generic drugs could be approved pursuant to ANDAs that demonstrated, *inter alia*,

pharmaceutical companies and generic manufacturers.”); *Mylan Pharm., Inc. v. Henney*, 94 F. Supp. 2d 36, 52–53 (D.D.C. 2000) (noting that interpretation of Hatch–Waxman must take into account the compromise nature of the statute); *Fisons Corp. v. Shalala*, 860 F. Supp. 859, 862 (D.D.C. 1994) (“A variety of federal courts have recognized that this Act represents a compromise, and aids both sets of drug manufacturers.”); *Tri-Bio Labs. v. United States*, 836 F.2d 136, 139 (3rd Cir. 1987); *Weiswasser & Danzis*, *supra* note 14, at 590–93 (detailing the Hatch–Waxman Act’s increased incentives for brand manufacturers).

24. H.R. Rep. No. 98–857, pt. 1, at 14 (1984).

25. *Id.* at 15. Despite its stated purpose, the Act contains no requirement that branded manufacturers actually devote any additional resources, available because of the restoration of patent life, to research and development. Given comparatively larger profit margins in the pharmaceutical industry, it remains an open question whether the additional resources resulting from the Hatch–Waxman Act went, as intended, toward research and development, or just went to the bottom line. For example, in 2002, the top ten drug companies in the United States had a median profit margin of seventeen percent, while the median profit margin in other industries in the Fortune 500 was merely 3.1%. PUB. CITIZEN CONGRESS WATCH, 2002 DRUG INDUSTRY PROFITS: HEFTY PHARMACEUTICAL COMPANY MARGINS DWARF OTHER INDUSTRIES 2–4 (2003), www.citizen.org/documents/Pharma_Report.pdf. Interestingly, the delta between pharmaceutical industry profit margins and the profit margins of the rest of the Fortune 500 was relatively steady in the fifteen years prior to the passage of the Hatch–Waxman Act but grew substantially in the two decades following the Act’s passage. *Id.* at 9.

26. *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984).

27. *See* H.R. Rep. No. 98–857, pt. 2, at 8–9 (1984) (noting that waiting until patent expiry to begin development of generic products “would result in delays of about two years after the expiration of the patent before a generic could go on the market”).

28. 21 U.S.C. § 355(j) (2006).

bioequivalence to the existing branded drug.²⁹ For a generic drug to be bioequivalent it must not deliver a “significant difference” in the amount of active ingredient to a patient’s blood stream over time when compared to the brand drug.³⁰ The ANDA applicant thereby relies on the branded manufacturer’s safety and efficacy studies, speeding approval and reducing the cost of bringing generic drugs to market.

An ANDA applicant must certify that marketing its generic drug will not infringe any existing patents. Though an applicant has four options—(I) certifying that no patent is claimed to cover the drug, (II) certifying that the patent has expired, (III) certifying that the patent will expire on a date in the future, or (IV) certifying that the patent that purportedly covers the drug is invalid or not infringed—the first three options are relatively straightforward, and therefore most of the litigation regarding ANDAs concerns the final option, known as a Paragraph IV certification of invalidity or non-infringement.³¹

A Paragraph IV certification triggers an elaborate mechanism created to give the branded manufacturer the ability to test whether the patent that purportedly covers the branded product indeed is invalid or is not infringed.³² The ANDA applicant must notify the branded manufacturer of the Paragraph IV certification,³³ and within 45 days the branded manufacturer can bring an infringement suit against the applicant.³⁴ Branded manufacturers were concerned that an immediate generic launch would decimate the markets for their products³⁵ and lobbied Congress to include a provision automatically staying FDA approval of the generic drug for thirty months or while the infringement litigation is pending, whichever is shorter.³⁶

Interestingly, and illustrative of the larger compromises that the drafters of the Hatch–Waxman Act had to navigate, one finds scant mention of the (now well-known) thirty-month stay in the legislative history of the Act.

29. 21 U.S.C. § 355(j)(2)(A)(iv) (2006).

30. 21 C.F.R. § 320.1(e) (2009).

31. See 21 U.S.C. § 355(j)(2)(A)(vii) (2006). The final option is called a Paragraph IV certification because it is found in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006).

32. FTC Study, *supra* note 19, at 6–7.

33. 21 U.S.C. § 355(j)(2)(B) (2006) (enumerating notice requirements).

34. 21 U.S.C. § 355 (j)(5)(B)(iii) (2006). While development of a generic product no longer constitutes infringement, as it did under the 1962 amendments, the filing of an ANDA technically is an act of infringement that gives the brand manufacturer the opportunity to bring an infringement suit. 35 U.S.C. § 271(e)(2)(A) (2006); *Eli Lilly Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (describing the ANDA filing as a “highly artificial act of infringement”).

35. See H.R. Rep. No. 98–857, pt. 1, at 28 (1984).

36. *Id.* at 27–28.

Throughout the drafting process the automatic stay, to the extent that it was thought necessary at all, was to be limited to eighteen months.³⁷ It seemed that both the brand and generic manufacturers “were willing to live with an eighteen-month rule because of other provisions of the bill.”³⁸ However, “through the work of the research industry [*i.e.*, branded manufacturers], that time period was changed to thirty months.”³⁹ The thirty-month stay—which has been the source of numerous litigations and scholarly articles—was, until a late change, intended to be an eighteen-month stay.

Even an eighteen-month stay would have been a fairly radical departure from the standard rule allowing the plaintiff in an infringement suit to seek a preliminary injunction or other emergent relief, but it does not set the default as an automatic stay of the defendant’s action. If a generic launches before a court decision on the patent, “and it is later determined that the patent is valid, the patent owner may still recover damages from the generic. Therefore, in most cases the bill affords greater protection for patent holders than current law.”⁴⁰ Branded manufacturers extracted a last-minute change from eighteen to thirty months that resulted in the redistribution of billions of dollars from drug purchasers to branded manufacturers, as generic products that otherwise would have launched after eighteen months were prohibited from launching for another full year.

In an effort to create incentives for generic manufacturers to challenge or design around patents purportedly covering branded drugs, the Hatch–Waxman Act offered the applicant filing the first ANDA its own 180-day exclusivity period during which the FDA would not approve any other ANDAs.⁴¹ In exchange for challenging the patent and defending the likely infringement suit, the generic manufacture is awarded its own period of exclusivity from other generic competition during which it can earn supracompetitive profits.⁴²

37. *Id.* at 4, 27 (discussing approval stay of eighteen months). Congress defeated an amendment that would have created an automatic stay for the duration of the patent infringement litigation, regardless of how long it lasted. H.R. Rep. No. 98–857, pt. 2, at 7 (1984) (rejecting Sawyer Amendment).

38. *See id.* at 10.

39. Mossinghoff, *supra* note 18, at 190.

40. *See* H.R. Rep. No. 98–857, pt. 2, at 10.

41. 21 U.S.C. § 355(j)(5)(B)(iv) (2006); *Teva USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1328 (Fed. Cir. 2005).

42. *See* FTC Study, *supra* note 19, at 57–58. During this period the only other generic that can be launched is an “authorized” generic made or licensed by the brand manufacturer.

C. Unintended Consequences

The Hatch–Waxman Act established a complex framework to try to accomplish its goals. Given the competing interests and highly regulated nature of the industry, the vast amount of money at stake, and the talented and creative people seeking to exploit different provisions to their benefit, it is unsurprising that certain goals were perverted. Manufacturers quickly realized that the Act created valuable new property rights. As manufacturers sought to gain advantage, both the thirty-month stay and the 180-day exclusivity period showed signs of stress.

The thirty-month stay was subject to open abuse as branded companies began to file seriatim infringement suits, each addressing a different patent that purportedly covered the drug at issue, and availed themselves of multiple thirty-month stays.⁴³ During the NDA process, a branded manufacturer provides the FDA with a list of the patent(s) that purportedly cover the drug.⁴⁴ The FDA lists those patents in the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence” (also referred to as the “Orange Book”).⁴⁵ Following the passage of the Hatch–Waxman Act, branded manufacturers began listing additional patents in the Orange Book even *after* ANDAs were filed. These late listings caused the ANDA applicants to recertify invalidity or non-infringement of those patents, and it allowed new infringement suits by the brand manufacturers and new thirty-month stays.⁴⁶ In one of the more egregious cases, GlaxoSmithKline received, through various patent litigations, a total of five thirty-month stays that delayed FDA approval of generic versions of the prescription drug Paxil by sixty-five months.⁴⁷ Given Paxil’s \$1 billion in annual sales at the time of the second thirty-month stay,⁴⁸ the delay in FDA approval of generic Paxil cost drug purchasers dearly.

The 180-day exclusivity period, originally awarded as a tool to incentivize generic manufacturers to challenge existing patents, was similarly susceptible to abuse. Brand and generic manufacturers realized that the 180-

43. *See id.* at 39–56.

44. 21 U.S.C. § 355(b)(1) (2006).

45. 21 U.S.C. § 355(j)(7)(A) (2006).

46. FTC Study, *supra* note 19, at 40.

47. *Id.* at 51–52; *see also* Apotex, Inc. v. Thompson, 347 F.3d 1335, 1339–40, 1345 (Fed. Cir. 2003) (Paxil case); Watson v. Bristol Myers Squibb, 194 F. Supp. 2d 442, 444–45 (D. Md. 2001) (discussing multiple stays concerning FDA approval of generic versions of prescription drug Buspar).

48. FTC Study, *supra* note 19, at 49.

day exclusivity period provided by the Hatch–Waxman Act to the first ANDA filer could block later generic entrants.⁴⁹ The 180-day period was triggered either by the first sale of the generic drug or by a court decision finding invalidity or no infringement.⁵⁰ However, a patent settlement agreement between the brand manufacturer and first ANDA filer whereby the generic would agree not to launch would create a bottleneck preventing later generic filers from coming to market, at least until a much later finding of invalidity or non-infringement in a subsequent patent suit.

Agreements concerning the drug Cardizem CD put this theory into practice. In 1995, generic manufacturer Andrx filed an ANDA for approval of a generic version of brand manufacturer Hoechst’s drug Cardizem CD.⁵¹ Andrx filed a Paragraph IV certification and Hoechst sued for infringement, triggering the thirty-month stay. In September 1997, twenty-one months into the stay, the parties entered into an agreement whereby Andrx agreed not to launch its generic version until the litigation resolved, effectively extending the thirty-month stay.⁵² In return, Hoechst would pay \$10 million quarterly following approval of Andrx’s ANDA and \$60 million annually if Hoechst lost the litigation.⁵³ The FTC challenged this agreement and Hoechst and Andrx entered into a consent order,⁵⁴ but similar agreements were rife.⁵⁵

D. A Patch for the Act

By the early 2000s, the limitations of the Hatch–Waxman Act were well documented and the need for a fix became clear.⁵⁶ Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

49. See 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

50. *Id.*

51. See *In re Hoechst Marion Roussel, Inc.*, No. 9293, Compl. ¶ 17 (F.T.C. Mar. 16, 2000), available at <http://www.ftc.gov/os/2000/03/hoechstandrxcplaint.htm>; see also FED. TRADE COMM’N, CONSENT AGREEMENT RESOLVES COMPLAINT AGAINST PHARMACEUTICAL COMPANIES HOECHST MARION ROUSSEL, INC. & ANDRX CORP. (Apr. 2, 2001), <http://www.ftc.gov/opa/2001/04/hoechst.htm>.

52. *In re Hoechst*, No. 9293, Compl. ¶ 18.

53. *Id.* at ¶ 23.

54. *Id.* at ¶ 24.

55. FTC Study, *supra* note 19, at 58 (explaining that “14 of the 20 final settlements obtained through the study . . . had the potential, at the time they were executed, to ‘park’ the first generic applicant’s 180-day exclusivity for some period of time, thus preventing FDA approval of any eligible subsequent applicants”).

56. See FTC Study, *supra* note 19, at i–ii.

(the “MMA”),⁵⁷ which, among other things, tightened the loopholes in the Hatch–Waxman system and recalibrated the Act to foster quicker generic entry, in accordance with one of its original purposes.⁵⁸

Among other things, the MMA aimed to correct the abuses described above of the thirty-month stay and 180-day exclusivity periods. The MMA limited the practice of successive thirty-month stays.⁵⁹ It also ended the most serious bottleneck problem by providing that, for ANDAs filed after the MMA’s enactment, the 180-day exclusivity period is forfeited if the ANDA applicant does not market its product within seventy-five days of ANDA approval,⁶⁰ and by providing other provisions intended to halt similar gamesmanship.⁶¹

III. CONTINUING WEAKNESSES IN THE HATCH-WAXMAN SYSTEM

Despite the widespread recognition of cracks in the Hatch–Waxman Act’s framework and the MMA’s attempts at patches, problems remain. In part because the MMA was not a comprehensive reform of the Hatch–Waxman Act and dealt only with certain of the emerging issues—and even then some of its provisions applied only prospectively—several important issues were left unresolved. Nor have drug manufacturers capitulated, and their attempts to extend periods of exclusivity have creatively evolved. In this section we examine two areas of concern that collectively cost drug purchasers billions of dollars: (1) reverse payment settlements, including settlements involving agreements by the brand manufacturer not to launch an “authorized generic” during the first ANDA filer’s 180-days of exclusivity; and (2) continued abuse of the thirty-month stay. These examples demonstrate the need for additional rethinking of the Hatch–Waxman Act regulatory scheme.

57. Pub. L. No. 108–173, 117 Stat. 2066 (2003) (codified in scattered sections of 42 U.S.C. and 26 U.S.C.).

58. See generally Comment, *The Hatch–Waxman System: Suffering a Plague of Bad Behavior*, 5 Hous. Bus. & Tax L.J. 369, 389–90 (2005); S. 1225, 108th Cong. (2003).

59. 21 U.S.C. § 355(j)(5)(B)(iii) (2006); see also 21 C.F.R. 314.53(b)(1) (2006).

60. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (2006); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 659–61 (2009).

61. See, e.g., 21 U.S.C. § 355(j)(5)(D)(i)(V) (Supp. 2009) (providing for forfeiture in the case of anticompetitive agreements proven by successful government action, an admittedly high bar).

A. *Reverse Payments Agreements: Win–Win. Lose*

Reverse payment settlements of patent infringement suits—wherein branded manufacturers agree to provide something of value to generic manufacturers, who in return agree not to launch their generic products—are the most hotly contested issue in the Hatch–Waxman framework.⁶² However, “[f]ive years after the MMA’s passage . . . there is little evidence that settlements featuring both payment and delayed entry have become less popular.”⁶³

In its simplest form, under a reverse payment agreement the brand manufacturer drops the patent infringement suit, thereby avoiding a possible finding of invalidity or no infringement. In return, the generic manufacturer agrees not to launch its product or seek a declaratory judgment. Both manufacturers agree to split the monopoly profits received by effectively extending the period of patent protection. Those monopoly profits are greater than both firms’ combined profits in the presence of generic competition, making this a classic win–win situation for the drug manufacturers. Only drug purchasers lose.

Manufacturers have realized that naked reverse payment settlements could be viewed as agreements to allocate a market and not to compete—violations of the Sherman Act—and have become more creative in structuring these settlements. Instead of a simple payment to stay off the market, in the newer agreements the brand agrees to settle the patent litigation and concomitantly enters into an agreement to compensate the generic for the provision of ostensibly “valuable services” like back-up manufacturing capabilities or sales force co-promotion.⁶⁴ At times even the payments themselves are disguised, such as when the brand agrees to trade its right to launch an “authorized” generic, which *can* be launched during the

62. See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1329 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 205 (2d Cir. 2006); *Schering–Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 899–900 (6th Cir. 2003). These settlements are called “reverse payment” settlements because the brand manufacturer (the plaintiff in the patent litigation) pays the generic manufacturer (the defendant) to settle the litigation, a reverse of the normal course where payments flow from the defendant to the plaintiff.

63. Hemphill, *supra* note 60, at 660.

64. See *id.* at 632. The payments by brand manufacturers, which maintain large, experienced sales forces, to generic manufacturers, which have anemic sales-forces, for alleged co-promotion are especially telling. Unsurprisingly, such agreements between brand and generic manufacturers outside the context of patent settlements are exceedingly rare. *Id.*

first ANDA filer's 180-day exclusivity period, in exchange for delayed generic entry.⁶⁵

The fundamental economics of reverse payment schemes remain unchanged regardless of their window-dressing. Such schemes all involve agreements to delay generic entry and split monopoly profits achieved by the brand drug during that delay. Eliminating such schemes would in no way inhibit pro-competitive settlements of patent infringement litigation. Pro-competitive settlements generally would involve a split patent term or immediate generic entry with a royalty or license paid by the generic to the brand. Tellingly, such settlements predominated in the time following the *Cardizem* decision holding reverse payments *per se* illegal,⁶⁶ but have fallen off after subsequent decisions in other circuit courts have taken a more generous view of the legality of such agreements.⁶⁷

B. Delay Caused By the Thirty-Month Stay

The MMA addressed an egregious abuse of the thirty-month stay—multiple stays on the same product—but left unchanged the basic thirty-month stay that brand manufacturers use as a powerful weapon to delay generic entry. The FDA does not regulate the listing of patents in the Orange Book that later form the basis for infringement suits and the automatic thirty-month stay.⁶⁸ This creates “a powerful incentive for the holder of an NDA to list any and every patent related to a drug product irrespective of whether

65. See FED. TRADE COMM'N, AUTHORIZED GENERICS: AN INTERIM REPORT 1, 3 (June 2009), <http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf>. As one would expect, authorized generics take substantial profits from the generic manufacturer during its lucrative 180-day exclusivity period. *Id.* at 3. Even a simple agreement by a brand not to launch an authorized generic during that period represents a substantial transfer of value from the brand to the generic—even with no money changing hands—which is repaid by the generic's agreement to delay its entry. *Id.* Schemes involving authorized generics have increased in number and complexity. *Id.*

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

67. FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FTC UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 7 (2008), <http://www.ftc.gov/os/2008/05/mmaact.pdf> (finding zero such agreements in 2004, three in 2005, and fourteen in 2006; *Cardizem* was decided in 2003).

68. FTC Study, *supra* note 19, at v (“[T]he FDA does not review the propriety of patents listed in the Orange Book, and courts have ruled that generic applicants have no private right of action to challenge those listings. As a result, there is no mechanism to delist an improperly listed patent from the Orange Book. The lack of such a mechanism may have real world consequences in that the Commission is aware of at least a few instances in which a thirty-month stay was generated solely by a patent that raised legitimate listability questions.”).

such patent was a significant barrier to legitimate competition.”⁶⁹ Instead of being penalized for wrongfully listing a patent in the Orange Book, brand manufacturers are rewarded in the form of the automatic thirty-month stay that extends their monopoly power over the listed drug and permits continued monopoly profits.⁷⁰

The thirty-month stay process repeatedly has been used to delay generic competition. While, in general, the generic eventually comes to market,⁷¹ the delay itself is worth many millions of dollars to the brand manufacturers.

69. Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 415 (1999).

70. *Id.* (explaining that the thirty-month stay allows a “patent owner to prevent competition irrespective of the merits of the patent being asserted and without any meaningful penalty for a wrongful assertion save for the possible award of the opposing party’s legal fees [which] are nominal as compared to the hundreds of millions of dollars in monopoly profits that can be earned during the thirty months a competitor is held off the market”). The citizen petition process has seen similar abuses. Percersky, *supra* note 17, at 784–85 (noting that “pharmaceutical companies have been know to file groundless citizen petitions and effectively delay the FDA’s approval of the pending ANDA”). Individuals and companies can petition the FDA to raise concerns about pharmaceutical products that it regulates. 21 C.F.R. § 10.30. Brand manufacturers have used this process to raise safety and efficacy concerns, often involving bioequivalence measurements, on generic products. FTC Study, *supra* note 19, at 65. “Since there are no penalties or sanctions for filing meritless citizen petitions, and generic drug approval cannot occur until these petitions are resolved, the incentives for filing frivolous petitions are high.” Bryan A. Liang, *Regulating Follow-on Biologics*, 44 HARV. J. ON LEGIS. 363, 421 n.434 (2007). Between 2003 and 2007 twenty of the twenty-one citizen petitions filed by brand manufacturers were rejected. *Id.* Nonetheless, the filings were worthwhile for the brand manufacturers, as the review process resulted in additional delays to FDA approval of competing generic drugs. *Id.* Recent legislation attempted to ameliorate this problem, see 21 U.S.C. § 355(q) (2006), but it is too early to judge its success.

71. While the generics generally come to market, sophisticated brand firms have devised ways to essentially nullify generic entry through product hopping—making marginal changes and switching from a product that faces imminent generic competition to a purportedly “new and improved” product that does not face generic competition. *See, e.g.*, *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 415 (D. Del. 2006) (describing allegations that Abbott Laboratories engaged in product hopping by changing the formulation of a drug and withdrawing the prior version of the drug to prevent generic competition). *See generally* Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 709–17 (2009) (describing product hopping as “a dangerous, market-distorting regulatory game” and “precisely the sort of behavior the Sherman Act condemns”). Product hopping concerns continue, and often are part of a larger scheme including, for example, infringement litigation and reverse payments. *See, e.g.*, *FTC v. Watson Pharm.*, No. 09–598 (C.D. Cal. filed Jan. 29, 2009) (alleging product hopping as part of scheme to defeat generic entry).

IV. “WHERE DO WE GO / WHERE DO WE GO NOW / WHERE DO WE GO”?⁷²

Twenty-five years later the Hatch–Waxman Act appears to be both a ringing success *and* a significant failure. Both analyses are correct. The Act streamlined the ANDA process and enabled wider access to generic drugs. In 1984, before passage of the Act, 150 off-patent brand name drugs had no generic competition⁷³ and only thirty-five percent of the top selling drugs with expired patents faced generic competition.⁷⁴ Today, virtually all off-patent drugs have generic competitors.⁷⁵ In 2007, according to IMS Health, generics accounted for more than two-thirds of total prescriptions dispensed nationally and, due to their lower prices, only one-fifth of spending on prescription drugs.⁷⁶ The Hatch–Waxman Act’s success in bringing less expensive generic drugs to market is undeniable.⁷⁷

This success, however, has been mitigated. As described above, drug manufacturers continue to exploit loopholes and engage in “market-distorting regulatory gam[ing]”⁷⁸ that costs drug purchasers billions of dollars.⁷⁹ If the Act has succeeded beyond all expectations in bringing more generics to market, it also has failed spectacularly by creating a complex framework that has been exploited to delay generic entry of some of those same drugs. The legislative history reveals that Congress expected the ANDA process to save consumers approximately \$1 billion.⁸⁰ Yet as one commentator notes, reverse payment agreements alone—an exploitation of a loophole created by the Hatch–Waxman Act—today cost drug purchasers over \$16 billion annually.⁸¹

72. Guns N’ Roses, *Sweet Child O’ Mine*, on *APPETITE FOR DESTRUCTION* (Geffen Records 1988).

73. H.R. Rep. No. 98–857, pt. 1, at 16.

74. CONGRESSIONAL BUDGET OFFICE, *HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICE AND RETURNS IN THE PHARMACEUTICAL INDUSTRY* xii (1998), <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf>.

75. *Id.*

76. Sarah K. Nothelfer, *Generic Drugs the Prescription for Saving Money*, THE SAGINAW NEWS, March 28, 2008, http://blog.mlive.com/saginawliving/2008/03/generic_drugs_the_prescription.html.

77. Spending on research and development—the second goal of the Hatch–Waxman Act—also has increased. See Weiswasser, *supra* note 14, at 607.

78. Dogan, *supra* note 71, at 717.

79. Hemphill, *supra* note 60, at 650–51.

80. H.R. Rep. No. 98–857, pt. 1, at 20 (1984). In 1983, the government spent a total of \$2.4 billion on prescription drugs. *Id.* at 18.

81. Hemphill, *supra* note 60, at 661 (estimating that the annual “buyer overcharge from pay-for-delay settlements likely exceeds \$16 billion”).

The Act's dual purposes—speeding entry of less expensive generic drugs and providing sufficient incentives for development of new drugs—remain as important today as they were twenty-five years ago. We believe that the Hatch–Waxman framework need not tolerate the destructive rent-seeking behavior that currently exists and, with the full benefit of twenty-five plus years of actual experience, we suggest three options for closing the loopholes.⁸² We present these options in order, from most- to least-likely. Whether they are also arranged in ascending order of efficacy is an open question.

A. Another Patch: Ending Reverse Payment and Thirty-Month Stay Abuses

Additional legislative patches are the most obvious way to end continuing abuses of the Hatch–Waxman Act. Arguments exist for courts to prohibit reverse payments based on both the text and the legislative history of the Hatch–Waxman Act,⁸³ however, as the somewhat tortured history of antitrust challenges to reverse payments has made clear,⁸⁴ a legislative fix is far more efficient than piecemeal judicial determinations. Happily, legislation addressing reverse payments is currently pending.⁸⁵

82. Certain mechanisms do exist for reining in the worst abuses. For example, courts find cognizable antitrust allegations of anticompetitive conduct when manufacturers file baseless patent infringement suits or citizen petitions that are merely shams to delay generic entry. See *Louisiana Wholesale Drug Co., Inc. v. Sanofi–Aventis*, No. 07–CV–7343, 2008 WL 4580016 (S.D.N.Y. Oct. 14, 2008) (denying defendants' motion for summary judgment). The sham standard, however, is exacting, as it requires a plaintiff to prove both subjective and objective baselessness. See *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993). Reliance on such a limited tool to police misconduct has left manufacturers with nearly free reign to exploit the Hatch–Waxman Act.

83. Comment, *Prognosis Negative: Why the Language of the Hatch–Waxman Act Spells Trouble for Reverse Payment Agreements*, 56 CATH. U. L. REV. 155, 177–184 & n.153 (2006) (arguing that the Hatch–Waxman Act “list[s] what remedies are available for parties to a patent infringement suit . . . [and] the textual canon of *expressio unius est exclusio alterius* demands that things absent from a list, like the availability of reverse payments, be excluded from that list” and that “[r]everse payment agreements have anti-competitive effects that seem counter to the drafters' intent to encourage an environment where generic drugs are more easily approved for market”).

84. Compare *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 911 (6th Cir. 2003) (finding reverse payments *per se* illegal), with *Schering–Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1300 (11th Cir. 2003).

85. See, e.g., Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009) (prohibiting “any person to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which an ANDA filer receives

While ending the practice of reverse payments would be a welcome step, it would do nothing to ameliorate the abuses of the thirty-month stay. As discussed *supra*, the Hatch–Waxman Act’s automatic thirty-month stay provides great incentive for brand manufacturers to list patents in the Orange Book and then file patent infringement cases on even the most questionable patents. Absent the thirty-month stay, this perverse incentive to engage in dubious patent litigation disappears.

The legislative history reveals that the drafters of the Hatch–Waxman Act did not intend to modify substantive patent law.⁸⁶ The thirty-month stay was included as a procedural tool to “balance[] the rights of a patent owner to prevent others from making [] its patented product and the rights of third parties to contest the validity of a patent.”⁸⁷ Congress rejected amendments prohibiting ANDA approval until the patent litigation was finally resolved because it was feared that such a rule would “substantially delay” generics from coming to market.⁸⁸ From the drafters’ perspective, the thirty-month stay would have little “practical” effect, as “it was believed the [thirty-month] time period would not affect when generic manufacturers would begin to market their drugs.”⁸⁹

The practice has been just the opposite. In reality, brand manufacturers have used the thirty-month stay as an additional patent extension strategy. With even the most questionable patent providing a brand manufacturer that lists it in the Orange Book with thirty-months of additional exclusivity, brand manufacturers have exploited the stay in ways that the drafters of the Hatch–Waxman Act never envisioned or intended. The drafters’ stated desire not to change substantive patent rights has not been given effect, as the automatic stay effectively extends patent terms by up to thirty months. In the case of a blockbuster drug, this results in monopoly profits worth hundreds of millions

anything of value; and the ANDA filer agrees not to research, develop, manufacture, market, or sell, for any period of time, the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim”); the companion bill in the Senate is the Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009) (making it illegal for parties involved in pharmaceutical patent litigation to sign a settlement agreement in which the generic company receives “anything of value” and agrees not to come to market for any period of time).

86. H.R. Rep. No. 98–857, pt. 1, at 28.

87. *Id.*

88. H.R. Rep. No. 98–857, pt. 2, at 10.

89. Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Applications of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676, 36,694 (June 18, 2003).

or even billions of dollars. The cleanest fix for abuses of the thirty-month stay is simply to write the stay out of the Act.

Patent holders will not be defenseless if the automatic thirty-month stay is removed. To the contrary, patent holders will be able to bring the very same infringement actions and recover the very same treble damages that are found sufficient in all other patent litigation.⁹⁰ Patent holders will still be able to apply for preliminary injunctions or temporary restraining orderings to block imminent generic launches, but the stay will not be automatic.⁹¹ Ironically, the same brand manufacturers who, in the reverse payment context, tout the need for settlements to quickly resolve litigation use the automatic thirty-month stay to delay patent litigation. Congress should amend the Hatch–Waxman Act to end this practice. We predict that such an amendment would significantly cut back on patent litigation and encourage early pre-competitive compromises between brand and generic manufacturers.

90. See 35 U.S.C. § 284 (2006) (providing for award of treble damages in infringement actions); *Yurman Studio, Inc. v. Castaneda*, 591 F. Supp. 2d 471, 503 n.191 (S.D.N.Y. 2008) (“Treble damages are available for willful infringement of a patent under 35 U.S.C. § 284.”). To the extent that brand manufacturers complain that smaller generic manufacturers are not able to satisfy potentially large judgments, bonding can address that problem.

91. Though brand manufacturers have argued that generic launch causes irreparable injury justifying emergent equitable relief, real-world experience refutes that argument. For example, in 2006, after the thirty-month stay had expired, but before its patent litigation against brand manufacturer Bristol Myers Squibb (“BMS”) was resolved, generic manufacturer Apotex launched a generic version of the prescription drug Plavix. Apotex flooded the market with as much as six months’ supply of generic Plavix before BMS sought and won a preliminary injunction barring further sales of the generic product. *Sanofi–Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 321, 325, 350 (S.D.N.Y. 2006). To win the preliminary injunction BMS argued that it would suffer irreparable injury if the generic sales continued because—for some unexplained reason—BMS would be unable to recapture the market if its patent ultimately were upheld. In reality, after Apotex was ordered to halt its sales, BMS regained its monopoly position and pricing power despite the fact that the market had already seen six months’ of generic supply that supposedly would cause irreparable injury. A quick look at BMS’s sales of Plavix confirms the absurdity of BMS’s argument. Plavix’s 2005 sales were \$3.82 billion, and its 2006 sales—affected by the Apotex launch—fell to \$3.26 billion, but sales then recovered and indeed far surpassed prior sales, as 2007 sales were \$4.76 billion and 2008 sales topped \$5.6 billion. *Bristol Myers Squibb Co.*, 2007 Annual Report (Form 10-K at 48) (filed Feb. 22, 2008); *Bristol Myers Squibb Co.*, 2008 Annual Report (Form 10-K at 4) (filed Feb. 20, 2009). And, all this occurred at the same time that BMS was undergoing a criminal investigation, guilty pleas, removal of its CEO and other senior executives and a general public relations nightmare concerning its attempt to enter into secret reverse payment deals with Apotex and its lies to the government concerning those deals. That is, BMS’s position to recapture sales could not have been worse, yet its sales could not have been higher.

Even if legislation were explicitly to prohibit reverse payments and end the automatic thirty-month stay we are not convinced that all the problems would be solved or that new and greater problems would not materialize. As experience with the MMA has shown, well-intentioned fixes are not always successful. For example, following the MMA's prohibition on consecutive thirty-month stays,

[brand manufacturers] took a different tack: rather than stacking patents, they stacked products[,] making trivial changes to their product formulation and pulling the old drug from the market. This product hopping delays generic competition in two ways. First, . . . product hopping can prompt a whole new set of Orange Book filings, ANDA Paragraph IV certifications, and litigation-triggered thirty-month stays. Second, even without new patent claims, product hopping delays generic substitution for the new branded product because the generic firm must file a second ANDA, which faces the same lengthy FDA review as the first one. The generic firm may, of course, continue to offer the first drug, for which it already gained approval. That means nothing, however, if the branded firm has pulled that drug from pharmacy shelves and convinced doctors to write scripts for its new product. Until the ANDA for that new product is approved (with its AB-rating), state laws limit the ability of pharmacists to substitute the "old" generic for the "new" branded drug."⁹²

The amount of money at stake is so great, and the stakeholders are so sophisticated, that any legislative fix is likely to be temporary at best while the players regroup and consider new ways to game the system.

B. Let's Call in the Experts: An Argument for Regulatory Expertise

The evolution of the drug regulatory system, the Hatch–Waxman Act, and the drug industry itself suggests that we may need new, or at least different, tools to address the current problems. C. Scott Hemphill persuasively argues that courts, the traditional arbiters in antitrust rule-making, suffer from structural deficiencies that render them poorly suited to address the ever-changing issues created by the Hatch–Waxman Act, and especially reverse payment agreements.⁹³ Hemphill explains that while courts necessarily focus only on the case at hand, regulatory agencies like the

92. Dogan, *supra* note 71, at 711–12.

93. Hemphill, *supra* note 60, at 674.

FTC, to whom the terms of settlements must be reported pursuant to the MMA,⁹⁴ stand in a superior and indeed unique position. Because the FTC is able to aggregate information and promulgate more effective rules, we should rely on it instead of on courts as the primary rule-maker for drug manufacturers' conduct, and we should grant it the authority to carry out those functions.⁹⁵

Hemphill's points are sound and his proposal for a greater regulatory role to combat reverse payment agreements is welcome.⁹⁶ Though we agree that the FTC should play an important and likely the central role, other agencies, such as the FDA and potentially the Patent and Trademark Office ("PTO"), also have expertise that could be valuable. For instance, one can imagine expanded roles for the FDA and PTO working together to serve as gatekeepers for the Orange Book listing process. Using agency expertise to resolve expeditiously some of the issues in the current system is a compelling argument, but the FTC is likely not the only agency that could have important input.

C. And the Winner Is . . . Prizes?

The problems stemming from the Hatch–Waxman Act system arguably call not just for the normal legislative tinkering, but for a paradigmatic rethinking of how best to ensure access to less expensive drugs while still providing sufficient incentives for drug development. As the brief history set forth at the beginning of this Article makes clear, such seismic shifts do occur every generation or two and the time may be ripe for a fundamental rethinking of the Hatch–Waxman regulatory system.

The very structure of the Hatch–Waxman Act, in which Title I addresses the streamlined ANDA process while Title II focuses on patent restoration, establishes these goals as conflicting and the legislation as a balance between the two goals. These goals, however, are not necessarily at odds. A prize-based system would foster both goals directly, simultaneously, and arguably far more efficiently than the current system.

94. Pub. L. No. 108–173, § 1112, 117 Stat. 2066 (2003) (codified in scattered sections of 42 U.S.C. and 26 U.S.C.).

95. Hemphill, *supra* note 60, at 688 (concluding that the FTC is “uniquely positioned”).

96. *Id.* Hemphill also argues for “a presumption of illegal payment where a side deal is reached contemporaneously with delayed entry.” *Id.* Such a presumption, while likely factually accurate in most cases, arguably would require even greater progress than the legislative patch of abolishing the automatic thirty-month stay, discussed *supra*.

A prize-based system offers numerous benefits over the current system of drug development. Prizes can directly link rewards to improved health outcomes, whereas the current patent-based system creates valuable property rights that often have little relation to improved health outcomes.⁹⁷ Line extensions⁹⁸ and “me-too” drugs, for example, offer little treatment value compared to existing drugs, yet consume substantial resources. “The corollary effect to giving prizes based on health outcomes of medicines rather than monopoly pricing is that incentives for drug discovery would then be aligned with finding medicines that will improve the health of the most people,” instead of “narrowly focusing on incremental improvements to medicines which only benefit a narrow group that can afford to pay the highest prices.”⁹⁹ The deadweight loss from the current system of monopoly drug pricing has been estimated to be up to \$30 billion annually.¹⁰⁰

The prescription drug industry lacks the price discipline present in most industries because of its tripartite nature in which the drivers of demand (physicians) are largely insulated from the economic purchasers (government or private health plans).¹⁰¹ In most industries, an incremental improvement would justify only an incremental change in price. If, for example, the new model-year car contained a minor improvement, *e.g.*, a navigation system, the manufacturer could not price the new model 900% higher than the prior-year model and expect to make many sales. Drug manufacturers, on the other hand, are able to maintain market share while launching line extensions that offer only minimal benefits over older, now-generic versions even though the new products cost 900% more than older generic products.¹⁰² Prizes could

97. See Marlynn Wei, *Should Prizes Replace Patents? A Critique of the Medical Innovation Prize Act of 2005*, 13 B.U. J. SCI. & TECH. L. 25, 26 (2007) (discussing how the patent system leads to “the production of drugs that have little incremental therapeutic value, such as follow-on drugs that are substantially similar to established blockbuster drugs (so-called ‘me-too’ drugs)”).

98. *E.g.*, Wellbutrin SR and Wellbutrin XL.

99. Sara E. Crager, Ethan Guillen & Matt Price, *University Contributions to the HPV Vaccine and Implications for Access to Vaccines in Developing Countries: Addressing Materials and Know-How in University Technology Transfer Policy*, 35 AM. J.L. & MED. 253, 274 (2009).

100. Wei, *supra* note 97, at 27.

101. Patients, as consumers, constitute the third leg.

102. Because of the tripartite nature of the domestic health care system and the presence of generic automatic substitution laws, meaningful price competition for prescription drugs occurs generally only within a molecule, *i.e.*, between a brand and generics than can be automatically substituted for that brand in the pharmacy. See *Teva Pharm. USA v. Abbott Labs.*, 580 F. Supp. 345, 354–55 (D. Del. 2008) (explaining price competition dynamic for prescription pharmaceuticals). Automatic substitution laws normally facilitate swift and

restore price discipline to drug manufacturing and create a more rational reward system for innovation.

Prizes would spur direct expenditures on research and development (“R&D”), often in a greater amount than the prize itself. In a “race towards a common prize[, i]f an uncoordinated group of individuals [is] each seeking the prize, and the prize has a known value, then each individual rationally might elect to spend up to just less than the value of the prize to get it, which would mean that as a group they are spending more in aggregate than the value of the prize.”¹⁰³ The Hatch–Waxman Act aims to foster research and development, yet takes no steps to ensure that the fruits of the patent term extension—the valuable carrot offered to brand manufacturers—would actually be devoted to R&D. Given outsized profits in the pharmaceutical industry,¹⁰⁴ and the fact that the industry spends nearly twice as much on marketing as on R&D, it seems that much of the surplus that was awarded to brand manufacturers through the patent term restoration was devoted to areas other than R&D. Money spent on prizes would directly spur investment in R&D.

Prizes have a favorable historical legacy. From the discovery of a method to measure longitude,¹⁰⁵ to the Orteig Prize won by Charles Lindbergh in 1927,¹⁰⁶ to the 2009 Netflix prize for improving movie

efficient conversion of the market from the brand to the generic product. *See* Barr Labs., Inc. v. Abbott Labs., 978 F.2d 98, 103 (3d Cir. 1992) (discussing mandatory substitution laws). However, brand manufacturers can frustrate these laws with minor tweaks to their products—*e.g.*, changing the drug from a capsule to a tablet formulation, which prevents automatic substitution—and thereby defeat the system of efficient generic entry and continue to charge monopoly prices.

103. F. Scott Kieff, *Coordination, Property, and Intellectual Property: An Unconventional Approach to Anticompetitive Effects and Downstream Access*, 56 EMORY L.J. 327, 371 (2006). This multiplier effect is evident with the Ansari X PRIZE, which offered \$10 million to “the first private team to build and launch a spacecraft capable of carrying three people to 100 kilometers above the earth’s surface, twice within two weeks.” The \$10 million prize spurred “26 teams from 7 different nations [to collectively] spen[d] more than \$100 million to win the prize.” Ansari X PRIZE, <http://space.xprize.org/ansari-x-prize> (last visited Oct. 17, 2009). For other recent examples of the use of prizes, *see* Lee Davis & Jerome Davis, *How Effective Are Prizes as Incentives to Innovation? Evidence from Three 20th Century Contests*, Paper for the Druid Summer Conference on Industrial Dynamics, Innovation and Development, Elsinore, Denmark (2004), <http://www.druid.dk/conferences/summer2004/papers/ds2004-114.pdf> (unpublished manuscript, presented at DRUID Summer Conference).

104. *See supra* note 25 and accompanying text.

105. *See* DAVA SOBEL, *LONGITUDE: THE TRUE STORY OF A LONE GENIUS WHO SOLVED THE GREATEST SCIENTIFIC PROBLEM OF HIS TIME* (Penguin Books 1996) (1995).

106. Wei, *supra* note 97, at 30.

preference recommendations,¹⁰⁷ prizes have a long and successful history. While a prize-based system for pharmaceuticals is unlikely to completely supplant the patent system anytime soon,¹⁰⁸ support for the idea is growing,¹⁰⁹ and the idea should not be rejected because it seems new or untested.

Prize-based systems can take many different forms and we do not offer an opinion on which method is best.¹¹⁰ What we do offer, having seen first-hand the effects of the Hatch–Waxman Act, is strong encouragement for a prize-based system to be considered and incorporated as part of the solution to the problem of affordable drug development.

We suggest that legislators consider a hybrid approach that does not require a wholesale revision of the current framework governing generic drugs but employs prizes to combat some of the worst abuses in the current system. For example, a hybrid system that awards patents to drugs that are indeed new molecular entities while providing appropriately-sized prizes for line-extensions or substantially similar formulations of the same active ingredient¹¹¹ would help avoid the deadweight losses discussed above while still rewarding innovation. It would also likely refocus R&D dollars from projects that result in minor tweaks to existing drugs in favor of development of new molecules that might have more substantial impacts on patient health.

D. *Biologics*

More ambitiously, a system incorporating prizes could aid in the developing framework for follow-on biologics (“FOB”). Unlike the simpler small molecule drugs regulated by the Hatch–Waxman Act, “biologics are produced using living cells[,] the structure of the end product is highly dependent on the production process, and different production pathways

107. Steve Lohr, *And the Winner of the \$1 Million Netflix Prize (Probably) Is . . .*, NEW YORK TIMES, June 26, 2009, <http://bits.blogs.nytimes.com/2009/06/26/and-the-winner-of-the-1-million-netflix-prize-probably-is/?scp=3&sq=netflix%20award&st=cse>.

108. *But see* Medical Innovation Prize Fund Act of 2007, S. 2210, 110th Cong. (2007).

109. *See, e.g.*, Joseph E. Stiglitz, *Prizes, Not Patents*, POST-AUTISTIC ECON. REV., May 18, 2007, at 48–49, *available at* www.paecon.net/PAERReview/issue42/Stiglitz42.pdf; and Scott Woolley, *Prizes Not Patents*, FORBES, April 18, 2006, http://www.forbes.com/2006/04/15/drug-patents-prizes_cx_sw_06slate_0418drugpatents.html.

110. *See generally* Wei, *supra* note 97, at 29–38 (discussing the benefits and pitfalls of different prized-based systems).

111. *E.g.*, bioequivalent formulations that differ only in form or dosage.

cannot necessarily be expected to yield identical end products.”¹¹² Demonstrating bioequivalence between small molecule drugs is a well-established and relatively simple process, but, according to one commentator, “it is difficult to demonstrate that two biologic products are exactly identical. Biologics are orders of magnitude larger and far more complex than small molecule drugs, and it is currently not possible to characterize their structure with the same degree of precision.”¹¹³

The Hatch–Waxman Act does not cover biologics,¹¹⁴ and though there are a number of competing bills addressing FOB,¹¹⁵ none are in the final stages of passage. Given the lack of an entrenched system for FOB and the greater difficulty in making replicas of pioneer drugs, FOB may offer another area in which a prize-based system could be useful.¹¹⁶ While maintaining the general benefits of prizes, a prize-based system for FOB could avoid some of the hurdles in replicating these more complex products. If the initial R&D were compensated by a substantial prize, the system could be structured so that the pioneer developer would then sell the original version—not a FOB—at marginal cost. We stress that these are not the only (or even necessarily the best) ideas for leveraging the benefits of prizes, but we do believe that experimentation with prizes should be part of the discussion.

112. Crager, *supra* note 99, at 255.

113. *Id.* at 263; *see also id.* at 264–67 (discussing possible safety issues with follow-on biologics).

114. One commentator notes that because biologics are not covered by the Hatch–Waxman Act, to date there have been no reverse payment agreements between brand and FOB manufacturers. He further posits that if the bill more favorable to the brand manufacturers passes it will create incentives similar to the Hatch–Waxman Act and reverse payment agreements are likely to appear. Chris Holman, *Reverse Payment Settlements and Biotechnology*, HOLMAN’S BIOTECH IP BLOG, May 7, 2009, <http://holmansbiotechblog.blogspot.com/2009/05/reverse-payment-settlements-and.html>.

115. *See, e.g.*, Promoting Innovation and Access to Life-Saving Medicine Act, H.R. 1427, 111th Cong. (2009) (pro-generic proposal); Pathway for Biosimilars Act, H.R. 1548, 111th Cong. (2009) (pro-brand proposal); Promoting Innovation and Access to Life-Saving Medicine Act, S. 726, 111th Cong. (2009).

116. Crager, *supra* note 99, at 274 (proposing a hybrid system of prizes and patent pools, and explaining that “[w]hile both approaches could be used separately—patent pools to reduce transaction costs and streamline provision of IP to generic producers, and prize funds to motivate research that better reflects global need while ensuring generic production of resulting products—used in conjunction they create an opportunity to simplify production and lower the cost of follow-on biologics”); *see also Knowledge Ecology International, Prizes to Stimulate Innovation*, http://www.keionline.org/index.php?option=com_content&task=view&id=4&Itemid=1 (listing reports on the use of prize funds and patent pools to spur innovation while lowering costs) (last visited May 9, 2010).

V. CONCLUSION

The Hatch–Waxman Act is best thought of as a mixed blessing. At the same time that it spurred the development of the modern generic drug industry, it created a labyrinth that is exploited by brand and generic manufacturers to the tune of billions of dollars annually. Creativity on the part of drug manufacturers, spurred by the extremely high stakes involved, has outpaced the enforcement ability of the courts and regulatory agencies. Legislative and regulatory fixes can and should address current stress-points in the Act, but likely will cause further evolutions and gamesmanship by the drug manufacturers. Given the magnitude of the problem and the vast sums involved, we suggest consideration of a paradigmatic shift toward incorporating parts of a prize-based system that would offer efficiencies not found in the current patent-only system, especially when applied to line extensions and other minor changes to existing drugs. As lawmakers consider amending the Hatch–Waxman Act and new regulations governing FOB, we hope that they will consider this.