Intellectual Property Brief

Volume 1
Issue 1 *Spring 2010*

Article 12

1-1-2010

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Keywords
Patents, Pharmaceutical patents, Drug patetnt, Drug patent litigation, Hatch-Waxman Amendments

Pharmaceutical Patents, Paragraph IV, and Pay-for-Delay: The Landscape of Drug Patent Litigation and the Lessons Provided for the Recently Passed Biosimilar Approval Pathway

By Brett Havranek[1]

The Hatch-Waxman Amendments created a three-way intersection between pharmaceutical, intellectual property, and antitrust law, but there is no stop sign, and collisions are common. The laws governing generic drug approval incentivize the filing of patent infringement suits, which often lead to reverse settlements where the manufacturers of patented drugs pay their generic competitors to remain off the market. In 1984, Congress passed the Hatch-Waxman Amendments, a major revision to the Food, Drug, and Cosmetic Act, which hoped to strike the difficult balance between encouraging research and development of new drugs and the desire for a robust generic drug industry that could supply the public with inexpensive medication.[2] To bolster the generic industry, Congress created a unique exception to patent exclusivity, allowing generic drug manufacturers to research, develop, and test their products to prepare them for submission to the FDA, all without infringing the innovator's patents.[3] The generic's new privileges are counterbalanced in part by allowing the patent holder to immediately and unilaterally halt the FDA's approval of the generic for up to thirty months.[4] This gives the patentee[5] an advantageous legal position to exploit, where, by filing for patent infringement, a competitor is automatically prevented from entering the market. The unique economics of the pharmaceutical industry provide a wide set of legal options for the patentee, from simply buying monopoly time by pursuing the infringement action, to actually paying the defendant to settle the case and refrain from competing in the drug market. These so-called "reverse settlement" or "pay-for-delay" cases have drawn the attention of government antitrust regulators[6] and Congress,[7] while causing some inconsistencies between the circuits and some ambiguity as to where each circuit stands on the legality of reverse payments.[8]

Part I of this Article briefly discusses pharmacoeconomics and the drug development process to elucidate why infringement actions are so common and why reverse settlements are relatively unique to the pharmaceutical industry. Part II details the generic drug approval process originally set up by the Hatch-Waxman Act and explains how the law bypasses the usual judicial balancing of equities in the preliminary injunction process, which ultimately incentivizes filing infringement suits. Part III explores the eventual results of drug patent infringement suits and the legal issues they create: Once filed, these suits are difficult for the generic to challenge and may last for a long time,

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2. *See* Andrx Pharm., Inc. v. Biovail Corp., 276 F.3d 1368, 1370-71 (Fed. Cir. 2002) ("Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the 'Hatch Waxman Amendments' to the Federal Food, Drug and Cosmetic Act ('FFDCA')), Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.").

3. *See* 35 U.S.C. § 271(e)(1) (2009) (excluding the use of a patented invention for purposes related to an FDA submission from the definition of infringement).

4. 21 U.S.C. § 355(c)(3)(C) (2009).

5. This Article uses the terms "patentee," "innovator," and "brand" interchangeably, as is common in the drug industry. In some circumstances, a generic can actually be its own brand, and these are called "branded generics," but here, "brand" refers only to the innovator.

6. *See, e.g.*, Health Care Div., Fed. Trade Comm'n, Overview of FTC Antitrust Actions in Pharmaceutical Services and Products (2009).

7. *See, e.g.*, Tracy Staton, *Congress Grills Generics Firms on Pay-for-Delay*, FiercePharma, June 4, 2009, *available at* http://www.fiercepharma.com/story/congress-grills-generics-firms-pay-delay/2009-06-04 for excerpts of recent Congressional hearings on pay-for-delay.

8. *See infra* Part III.

thereby creating favorable conditions for the generic to enter into a mutually beneficial reverse settlement agreement with the brand. In these agreements, the brand pays the generic not to market its product, and in doing so, the brand guarantees its profitable market exclusivity. These agreements can straddle the line between an exercise of the innovator's lawful patent monopoly rights and an antitrust injury to other generic competitors and consumers. Part IV applies the lessons learned from twenty-five years under the Hatch-Waxman approval regime to Congress's latest legislation: the new approval process for generic biologic medicines. The current biosimilar pathway contains a set of provisions that can be used together in conjunction with a reverse settlement to prolong an innovator's exclusivity period while providing a defense to antitrust challenges.

Part I — Drug Development and Pharmacoeconomics

Unlike virtually all other patented products, new drugs[9] have an especially long development[10] process and require FDA approval before they can be lawfully marketed.[11] Three to six years before involving the FDA, the research process typically begins by screening between 5000 and 10,000 potential drug molecules, followed by further laboratory and animal studies on approximately 250 of the most promising candidates.[12] Of these 250 candidates, only about five are suitable for human trials, for which the sponsor must file an Investigational New Drug Application (IND) to notify the FDA of its intent to initiate clinical trials.[13] Filing an IND triggers a significant set of regulatory requirements that apply throughout the remainder of the drug's testing,[14] burdening the innovator without providing any guarantee of success. Once the IND is in effect, the five potential drugs are subjected to three successive phases of clinical trials[15] over the next six to seven years. Statistically, only one and a half of the candidates progress to the final stage (phase III) of the trial process[16] where they are able to accumulate data demonstrating safety and substantial evidence of effectiveness[17] that supports the filing of a New Drug Application (NDA) with the FDA.[18] Another six months[19] to two years pass during the FDA's typical review of the NDAs, and on average, only one drug ultimately receives approval for sale and marketing.[20] Even when the NDA is approved, the FDA requires additional post-approval (phase IV) research[21] in 72% of new drugs.[22]

The entire process, resulting in one FDA-approved drug, typically takes ten to fifteen years to complete.[23] There is some disagreement about the average cost to develop one approved new drug, but the most recent estimates include $802 million in a 2002 study[24] (excluding an additional $95 million for post-approval research costs, adjusted down to approval-year dollars),[25] $1.3 billion in a 2005 study,[26] and $1.7 billion in a 2002 study (including the costs of preparing

9. The terms "drug" and "pharmaceutical" are sometimes used nonspecifically in the literature and may encompass both biologics/biopharmaceuticals and traditional small-molecule drugs/pharmaceuticals. A significant part of this Article deals with the legal interactions between generic manufacturers and patentees, but as of this writing, there are no approved generic biologics. Therefore, when possible, the statistics presented here disaggregate the two markets. In this Article, "drug" and "pharmaceutical" are used to refer to traditional small-molecule drugs.

10. When discussing the development of a new drug in this Article, the author assumes the new drug to be a new chemical entity, not just a reformulation of an existing product.

11. 21 U.S.C. § 355(a) (2009).

12. Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile 2009 36 (2009) [hereinafter PhRMA Profile].

13. *See id.*; *see also* 21 C.F.R. § 312.20 (2009) (explaining when an IND is required to be submitted to the FDA).

14. *See*, *e.g.*, 21 C.F.R. pt. 312 (2009).

15. *See* 21 C.F.R. § 312.21 (2009) (listing the phases of clinical trials).

16. *See* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 162 (2003) (estimating that the probability of phase III entry is 31.4%).

17. *See* 21 U.S.C. § 355(d) (2009) (requiring that proof of safety and substantial evidence of effectiveness).

18. *See* 21 C.F.R. § 314.50 (2009) (listing all the requirements for an NDA).

19. *See* 21 U.S.C. § 355(c)(1) (2009) (requiring a decision by the FDA on drug applications within 180 days, but allowing a longer period if the applicant agrees).

20. PhRMA Profile, *supra* note 12, at 36.

21. *See* 21 C.F.R. § 312.85 (2009) (allowing the FDA to tie marketing approval with the applicant's agreement to conduct phase IV research).

22. *See* Accenture, The Pursuit of High Performance Through Research and Development – Understanding Pharmaceutical Research and Development Cost Drivers 17 (Pharmaceutical Research Manufacturers of America 2007) *available at* http://www.phrma.org/files/Accenture%20R&D%20Report-2007.pdf ("The FDA is increasingly requiring companies to commit to post-approval activities. In 2005, 13 (72 percent) of the 18 new molecular entities approved required post-marketing activities, ranging from a single human in vivo drug interaction study to a large randomized safety study to assess major clinical outcomes.").

23. *See* PhRMA Profile, *supra* note 12, at 36.

24. *See* DiMasi, *supra* note 16, at 166 ("Our base case out-of-pocket cost per approved new drug is US$ 403 million, while our fully capitalized total cost estimate is US$ 802 million.").

25. *See id.* at 173. The total out-of-pocket capitalized cost in approval-year dollars is broken down so that the pre-approval cost is $802 million and the post approval cost is $95 million. The money spent on post-approval research does include an average of 15% on improvements to already-approved drugs. *Id.*

26. PhRMA Profile, *supra* note 12, at 39.

to market the drug).[27] These extremely high research and development costs are reflected in the industry's overall research spending of approximately $52 billion in 2005.[28]

The high cost of initial development stands in stark contrast to the relatively simple and inexpensive process of gaining approval for a generic drug. The most important element of the Hatch-Waxman Amendments to the pharmaceutical industry was its creation of an expedited method for generic manufacturers to gain FDA approval for their products.[29] Generic manufacturers are allowed to file an Abbreviated New Drug Application (ANDA) in which they need only to demonstrate that their generic is the same as a branded drug (bioequivalence) and do not have to re-prove that the drug is safe and effective.[30] Under the more lenient ANDA requirements, the cost of obtaining FDA approval for a generic drug is only a few million dollars, which creates a major dichotomy in development costs between innovators and generics.[31]

As an incentive for generic manufacturers to challenge innovator patents, the law gives the first generic applicant to submit a substantially complete ANDA 180 days of marketing exclusivity before other ANDAs can be approved by the FDA.[32] Originally, the first Paragraph IV ANDA filer was required to successfully defend against a patentee's infringement suit to qualify for the 180 days of exclusivity,[33] but this requirement was officially eliminated in 1998.[34] Now, successful judgment on the patent for a subsequent ANDA filer can force the first filer to either begin or forfeit its exclusivity period.[35]

The extremely high costs associated with developing a single marketable pharmaceutical product only begin to set the stage for reverse settlements and other arguably anticompetitive behavior. The market for pharmaceuticals is extremely lopsided, where the "blockbuster" drugs comprising the top decile of the market generate eighty percent of all drug sales.[36] In fact, the drug market is so lopsided that eighty percent of all pharmaceuticals will never recoup their own research and development costs.[37] The extreme profitability of a small proportion of drugs creates a powerful incentive for brand name manufacturers to preserve their marketing exclusivity, resulting in unique legal strategies such as pay-for-delay.

While innovators have a strong financial reason to preserve their monopolies, generic manufacturers have comparatively much less to gain by entering the market. Although a generic is supposed to be equivalent in efficacy to its brand-name competitor, the prices charged by generics and brands are very different. The decrease in the innovator's profits due to the generic's arrival is normally much higher than the generic's potential profit were it to enter the market. Thus, if the innovator were to pay its potential generic competitor the entire amount of the generic's expected profit in exchange for an agreement to stay off the market or to delay entry, the innovator would still see higher profits than if it were competing with the generic.[38] An examination of the national drug market is illustrative: while branded

27. *See* Accenture, *supra* note 22, at 4 ("Though estimates differ, one source suggests that the cost of an approved pharmaceutical drug, including average launch costs, has gone up from 1.1 billion in 1995-2000 to 1.7 billion in 2000-2002.").

28. *See* Accenture, *supra* note 22, at 4 ("Approximately $51.8 billion was spent by US biopharmaceutical companies alone in 2005. R&D spending by Pharmaceutical Research and Manufacturers of America (PhRMA) member companies, representing the top pharmaceutical and biotechnology companies in the United States, went up 53.5 percent, from $26 billion in 2000 to $39.9 billion in 2005.") (citation omitted). This aggregate statistic may include spending on the development of biologics as well as traditional drugs but is nevertheless illustrative of the massive costs of researching new medicines.

29. *See* 21 U.S.C. § 355(j) (2009).

30. *See id.* § 355(j)(2)(A).

31. *See* Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries, in* Science and Cents: Exploring the Economics of Biotechnology 87, 90 (John V. Duca & Mine K. Yucel eds., Federal Reserve Bank of Dallas) (2003) ("Generic firms can file an abbreviated new drug application (ANDA). The ANDA process only takes a few years and typically costs a few million dollars.").

32. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2009).

33. *See* 21 C.F.R. § 314.107(c)(1) (1998); *see also In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1339 (Fed. Cir. 2008) ("FDA regulation in effect conditioned the first Paragraph IV ANDA filer's right to the 180-day exclusivity period on a 'successful defense' of its Paragraph IV ANDA against the patent holder.").

34. *See* 63 Fed. Reg. 59710 (Nov. 5, 1998).

35. *See* 21 U.S.C. §355(j)(5)(D)(i)(I)(bb)(AA); *See also* Caraco Pharm. Lab. v. Forest Lab., 527 F.3d 1278, 1284 (Fed. Cir. 2008) ("Only the first Paragraph IV ANDA filer can trigger its 180-day exclusivity period via the commercial-marketing trigger. However, subsequent Paragraph IV ANDA filers can trigger the first Paragraph IV ANDA filer's 180-day exclusivity period via the court-judgment trigger.") (citation omitted).

36. *See* Congressional Research Service, Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act"), Congressional Research Service 38-39 (2005).

37. *See* PhRMA Profile, *supra* note 12, at 39.

38. *See* FTC, Generic Drug Entry Prior to Patent Expiration, Federal Trade Commission viii (2002) ("a generic applicant's potential liability for lost profits on the brand-name drug usually will vastly exceed its own potential profits after market entry.").

drugs make up only 28.5% of prescriptions dispensed, they still account for 78.4% of the money spent on prescriptions.[39] On an individual drug level, brand name prescriptions sold for an average of 3.5 times more than their generic counterparts in 2007.[40] In only one-year's time, the 2008 innovator-to-generic price ratio has risen to 3.9[41] despite the preexisting disparity.

The substantial price differences between innovators and generics, the high research and development costs associated with new pharmaceuticals, and the uncertainty that any drug candidate in the innovator's development pipeline will attain blockbuster profitability give patentees a strong incentive to preserve and prolong market exclusivity. These factors allow for reverse settlements in which the brand and the generic both make more money if the generic stays off the market. The increasing prices of branded drugs compared to their generic counterparts should make these settlements even more profitable in the future. From an economic perspective, as long as the innovator's potential loss vastly exceeds the generic manufacturer's potential gain, reverse settlements will offer a Pareto improvement[42] for pharmaceutical suppliers when the number of potential generic entrants is small. Accordingly, the industry association representing generic manufacturers supports reverse patent settlements[43] as does the industry association for innovators.[44]

Part II — The Unique Legal Status of Pharmaceutical Patents

Patents typically afford the holder twenty years of exclusivity to market a product.[45] However, when the patented article is a drug, the patent holder must also wait for the FDA's approval before selling it.[46] For the pharmaceutical patent holder, this means the actual amount of sales exclusivity before a generic becomes available is typically between ten and fifteen years.[47] Not surprisingly, the increased incentive to challenge the patents on blockbuster drugs results in these drugs having average exclusivity periods toward the bottom of this range.[48]

As part of the tradeoff for allowing generics to rely on the original safety and efficacy data in the innovator's NDA, the generic is required to submit:

(A) a certification . . . with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed . . .

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) *that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .*[49]

To generic manufacturers, the most important of these certifications is the Paragraph IV certification because it potentially leads to a challenge

39. *See* Generic Pharmaceutical Association, Celebrating the Past Defining the Future 28 (2009).

40. *See* Facts at a Glance | Generic Pharmaceutical Association, *available at* http://www.gphaonline.org/about-gpha/about-generics/facts (last visited Nov. 5, 2009) ("In 2007, the average retail price of a generic prescription drug was $34.34. The average retail price of a brand name prescription drug was $119.51. (source: The National Association of Chain Drug Stores, 2007)").

41. *See* Industry Facts-at-a-Glance, National Association of Chain Drug Stores, http://www.nacds.org/wmspage.cfm?parm1=6536 (last visited Nov. 5, 2009) (stating that the average brand name prescription price in 2008 was $137.90, and the average generic price in 2008 was $35.22).

42. A Pareto improvement is a situation where resources are allocated to make one entity better off without hurting anyone else. Here, the brand can afford to pay its generic competitors all of the money they would have made by selling their products, or could even agree to pay *more* money than the generics could have possibly made in the market, all while still remaining better off than if it were competing with the generics. Because no one is worse off and some (or all) are better off, these reverse settlement agreements that create a Pareto improvement are a natural occurrence. The allocations analyzed here which result in a Pareto improvement are only the potential supply allocations and resulting profits among drug manufacturers, not the allocations among suppliers and consumers.

43. Patent Settlements | Generic Pharmaceutical Association, http://www.gphaonline.org/issues/patent-settlements (last visited Oct. 18, 2009) ("GPhA opposes an outright ban on settlements as a means of resolving patent litigation.").

44. *See* PHRMA – PhRMA Statement on Authorized Generics, http://www.phrma.org/news_room/press_releases/phrma_statement_on_authorized_generics (last visited Nov. 5, 2009) ("[I]t is unfortunate that the FTC used this potentially valuable report . . . to further its attack on patent settlements. Neither authorized generics nor patent settlements have discouraged the availability of generics to patients.").

45. 35 U.S.C. § 154(a)(2) (2009).

46. *See* 21 U.S.C. § 355(a) (2009).

47. *See* Henry G. Grabowskia & Margaret Kyleb, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 Managerial & Decision Econ. 491, 493 (2007) ("The NMEs [(New Molecular Entities)] in the two smallest [market] size categories have the longest MEPs [(Market Exclusivity Periods)] with averages of approximately 15 years. By contrast, the average MEPs for market size categories above $100 million are in the 10.5–12.5 year range.").

48. *See id.*

49. 21 U.S.C. § 355(b)(2)(A) (2009) (emphasis added).

of the innovator's patent.[50] When generics make this certification, they must agree to notify the patent holder of their intention to seek approval of the drug.[51] This notice must include a statement of the legal and factual basis for the generic's belief that it will not infringe the innovator's patent.[52] When the generic makes a Paragraph IV certification, the FDA cannot make any approval effective for forty-five days, giving the patentee an opportunity to file an infringement suit.[53] If the patentee files an infringement suit against the generic, the FDA cannot approve the generic's ANDA for thirty months,[54] unless the generic wins the infringement case.[55]

The key effect of Paragraph IV is to dramatically increase the innovator's incentive to file suit because the existence of an infringement suit alone has the same ultimate effect as a judicially-granted injunction: the generic manufacturer is prevented from selling its product because it cannot gain the necessary approval.[56] The law does not provide any way for a generic with a strong case for non-infringement to continue with the approval process, except to get a ruling that the patent is invalid or has not been infringed.[57] Still, a ruling may take considerable time, usually not less than thirty months.[58] By contrast, in a normal patent infringement proceeding, the patentee would have to petition the court for a preliminary injunction, and the court would weigh the following four factors, the first two of which are required: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest."[59] A recent case illustrated the inconsistency of the two approaches when an innovator pharmaceutical company's thirty-month Hatch-Waxman "injunction" expired, and the innovator had to request a judicially-imposed preliminary injunction.[60] The district court found that the patentee failed to establish a likelihood of success on the merits and irreparable harm,[61] and on appeal, the Federal Circuit affirmed the district court's denial of injunctive relief.[62] In this case, the automatic thirty-month stay gave the patentee a significant amount of market exclusivity that would have never been available to a non-pharmaceutical patentee.

Part III — Pay-for-Delay and Antitrust

The economics of the pharmaceutical market combine with the Hatch-Waxman generic approval scheme to incentivize and facilitate reverse settlement payments from patentees to generics. In any case, innovators can decide to file an infringement suit irrespective of any intent to settle, opting simply to prolong the litigation and enjoy thirty months of exclusivity before the FDA can approve the generic. In either of these situations, little recourse is available to competing generics and the public.

Challenges to the legality of reverse payments have been made on antitrust grounds, and challenges to the patentee's filing of an infringement suit have been made on both antitrust and Rule 11 grounds. Except in cases where fraud is alleged, neither approach has been particularly successful. If the innovator's initial filing of an infringement suit is fought under an antitrust theory of delaying generic competitors from coming to market, the innovator is often immunized from antitrust liability because it is only trying to enforce its constitutional patent exclusivity rights.[63] If the filing of suit is contested under Rule 11, two legal facts, that patents are presumed valid and that filing an ANDA is a technical act of

50. *See id.* § 355(b)(2)(A)(iv).
51. *See id.* § 355(b)(3)(A); *id.* § 355(b)(3)(C).
52. *See id.* § 355(b)(3)(D)(ii).
53. *See id.* § 355(c)(3)(C).
54. *Id.*
55. *See id.* § 355(c)(3)(C)(i).
56. *See id.* § 355(c)(3)(C); *id.* § 355(a).
57. *See id.* § 355(c)(3)(C)(i).
58. *See* FTC, *supra* note 38, at iv ("The data also do not indicate that court decisions in ANDA-related patent litigation typically are reached much earlier than 30 months from notice of the generic's ANDA."). See also, for example, Altana Pharma AG v. Teva Pharm. USA, Inc., 566 F.3d 999 (Fed. Cir. 2009), where the infringement proceedings were still in progress after the expiration of the Hatch-Waxman stay.
59. *See Altana,* 566 F.3d at 1005.
60. *See id.* at 1004 ("On or about April 6, 2004, Teva filed an Abbreviated New Drug Application ('ANDA') pursuant to the Hatch-Waxman Act . . . . Sun filed similarly directed ANDA applications on or about March 1, 2005, and June 25, 2005. Both Teva and Sun filed paragraph IV certifications in conjunction with their respective ANDA applications. . . . Altana filed a motion for preliminary injunction on June 22, 2007.").
61. *See id.* at 1005 ("Based on Altana's failure to establish either a likelihood of success on the merits or irreparable harm, the district court denied the motion for preliminary injunction.").
62. *See id.* at 1011.
63. *See* Andrx Pharm., Inc. v. Elan Corp., 421 F.3d 1227, 1234 (11th Cir. 2005) ("Based on this precedent, we agree with the district court that the Noerr-Pennington doctrine shields Elan from antitrust liability for filing two patent infringement suits against Andrx in relation to the manufacture and sale of controlled release naproxen. The United States Constitution expressly permits the government to grant exclusive monopolies in the form of patents, and therefore the Sherman Act cannot be read to impede a litigant from seeking to defend constitutionally-permitted patent rights.") (citation omitted).

infringement, combine such that there is usually a non-frivolous basis for filing suit.[64] Therefore, in many cases, the act of filing an infringement suit cannot be challenged with any reasonable expectation of success, leaving only the settlement agreements themselves potentially vulnerable to attack.

By the very nature of a lawsuit, a claimant files suit alleging some harm in the hopes of getting a favorable legal determination, money, or both. Therefore, when a claimant alleging patent infringement in a Paragraph IV suit offers money to the alleged wrongdoer, the settlement seems puzzling. When the patentee actually pays the infringing generic more money to settle the case than the generic could possibly have made selling its product, the result becomes downright "suspicious"[65] in light of the Sherman Act, which bars contracts and combinations that restrain trade[66] and prohibits any attempt to monopolize commerce.[67] Nevertheless, the courts of appeals, except possibly the Sixth Circuit whose position is particularly ambiguous,[68] have upheld the legality of some of these agreements, as long as their terms stay "within the exclusionary zone of the patent."[69]

The confusion over pay-for-delay began when the Sixth Circuit first declared a reverse settlement agreement illegal. The Sixth Circuit decided the first Paragraph IV settlement antitrust case, *In re Cardizem CD Antitrust Litigation*, where an innovator agreed to pay the first-filing generic manufacturer $40 million per year not to sell any generic equivalent of the patented drug and to not relinquish its right to the 180-day exclusivity period.[70] The court classified the agreement as a per se antitrust violation, noting that the 180-day exclusivity provision acted to delay other potential entrants and that the agreement inhibited competition by paying the innovator's only potential competitor to stay out of the market.[71] The court said that "HMR's agreement to pay Andrx $40 million per year not to bring its generic product to market . . . is a naked, horizontal restraint of trade that is per se illegal."[72] The Sixth Circuit's reasoning looks more to the character of the settlement agreement and its actual effects on competition, rather than focusing as intently on the scope of the agreement with respect to the patent.

Unlike the Sixth Circuit, the Eleventh Circuit took a more lenient stance on reverse settlements. Shortly after the Sixth Circuit's decision, the Eleventh Circuit weighed in on reverse settlements in *Valley Drug Co. v. Geneva Pharmaceuticals Inc.*, when an innovator entered into reverse payment settlements with two of its generic competitors.[73] Though the terms of these settlements were similar to those in *Cardizem*,[74] the Eleventh Circuit decided that settlements were not per se antitrust violations.[75] When determining if there was antitrust liability, the court examined whether the settlement agreements extended beyond the exclusionary power granted by the patent.[76] Although at least one agreement contained a provision protecting the generic's 180-day exclusivity[77] and the agreements might have gone beyond prohibiting only infringing generics, the court felt the per se label was still not appropriate.[78] On its face, the Eleventh Circuit's precedent appears to conflict with the Sixth Circuit's holding. The Eleventh Circuit noted that "[t]he failure to produce the

64. *See, e.g.,* Celgene Corp. v. KV Pharm. Co., No. 07-4819, 2008 WL 2856469 at *3 (D.N.J. July 22, 2008) ("[T]he act of infringement alleged in the complaint is the filing of an ANDA—***not*** the manufacture or sale of the product. Because the Act has made the act of submitting an ANDA itself an act of infringement, in a Hatch-Waxman ANDA case, the attorney can conduct a reasonable and competent inquiry into the act of infringement by investigating whether a relevant ANDA has been filed.").

65. *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 208 (Fed. Cir. 2006) ("There is something on the face of it that does seem 'suspicious' about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent holder. Why, after all—viewing the settlement through an antitrust lens—should the potential competitor be permitted to receive such a windfall at the ultimate expense of drug purchasers?").

66. *See* 15 U.S.C. § 1 (2009).

67. *See id.* § 2.

68. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1335 (Fed. Cir. 2008) ("To the extent that the Sixth Circuit may have found a per se antitrust violation based solely on the reverse payments, we respectfully disagree.").

69. *See id.* at 1336 ("The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits . . . and we find it to be completely consistent with Supreme Court precedent.").

70. 332 F.3d 896, 902 (6th Cir. 2003).

71. *Id.* at 907-08.

72. *Id.* at 911.

73. 344 F.3d 1294, 1300 (11th Cir. 2003).

74. *Id.* at 1311 n.25.

75. *Id.* at 1309.

76. *See id.* at 1305-06.

77. See *id.* at 1300 ("Geneva agreed not to transfer or sell its rights under its ANDAs, including its right to the 180-day exclusivity period. Geneva also agreed to oppose any subsequent ANDA applicant's attempt to seek approval of its application based on Geneva's failure to satisfy the then-existing successful defense requirement and to join and support any attempt by Abbott to seek an extension of the 30-month stay of FDA approval on Geneva's tablet ANDA.").

78. *Id.* at 1306 n.18.

competing . . . drug, rather than the payment of money, is the exclusionary effect,"[79] highlighting the Eleventh Circuit's interest in the scope of the agreements rather than the size of the payments or their practical effect.

The Second Circuit was the next court to decide a pay-for-delay case, and it followed the Eleventh Circuit's approach. The Second Circuit made its ruling on reverse settlements in *In re Tamoxifen Citrate Antitrust Litigation*, when an innovator agreed to pay a generic manufacturer $9.5 million dollars immediately and $35.9 million over ten years for the generic to change its Paragraph IV certification to a Paragraph III certification, thereby allowing the generic to market the infringing drug only after the innovator's patent had officially expired.[80] The settlement occurred while an appeal was pending after a district court had declared that the patent was invalid,[81] the agreement did not cover non-infringing products,[82] and the agreement was made while the 180-day exclusivity period's successful defense requirement was in effect.[83]

The Second Circuit followed the Eleventh Circuit and decided that reverse payments by a patentee designed to protect its patent monopoly were not per se antitrust violations,[84] even though the settlement took place after the patent was declared invalid but was on appeal.[85] The court noted that the successful defense requirement meant the generic would not block other competitors,[86] but even if the agreement was "designed to manipulate the 180-day exclusivity period," any injury was caused by the "valid patent and the inability of other generic manufacturers to establish that the patent was either invalid or not infringed."[87] As long as the original infringement suit is not objectively baseless, the settlement does not expand the patentee's monopoly beyond the patent's scope, and there is no fraud, then "[p]ayments, even 'excessive' payments, . . . [are] not necessarily unlawful."[88] Like the Eleventh Circuit, the Second Circuit's analysis focused primarily on the scope of the agreement, not the size of the payments or the effect on competition.

In the most recent precedential case decided by an appeals court, the Federal Circuit also upheld a pay-for-delay agreement. *In re Ciprofloxacin Hydrochloride Antitrust Litigation* was the Federal Circuit's chance to speak on reverse payments, when it took an appeal involving a settlement agreement worth $398.1 million.[89] The generic agreed to change its Paragraph IV certification to a Paragraph III certification,[90] reserved the right to revert to Paragraph IV if a court ever declared the patent invalid or unenforceable,[91] and agreed "not to market a generic version of Cipro until the" patent at issue expired.[92] Although the generic retained its right to change certifications, the Federal Circuit ignored this factor in its antitrust analysis because the settlement agreement predated the change in the successful defense requirement, and a prior court had already determined the generic had lost its exclusivity right under the law at the time.[93]

With this "bottleneck" element out of the way, the Federal Circuit decided the agreement was not a violation of antitrust law and essentially adopted the Second and Eleventh Circuits' holdings that reverse payments alone were not per se antitrust violations.[94] Also, it explicitly held that:

[when] all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent.[95]

With this statement, the Federal Circuit foreclosed the possibility of using its exclusive jurisdiction over patent cases[96] to funnel Paragraph IV antitrust cases away from the other circuits.[97]

79. *Id*. at 1309.
80. 466 F.3d 187, 193-94 (Fed. Cir. 2006).
81. *Id*. at 193.
82. *Id*. at 213-14.
83. *Id.* at 219.
84. *Id*. at 205.
85. *Id*. at 206.
86. *Id*. at 214.
87. *Id*. at 219.
88. *Id*. at 213.
89. 544 F.3d 1323, 1329 n.5 (Fed. Cir. 2008).
90. *Id*. at 1328-29.
91. *Id*. at 1329 n.4.
92. *Id*. at 1333.
93. *Id*. at 1339.
94. *See id.* at 1335-36.
95. *Id.* at 1336.
96. 28 U.S.C. § 1295(a)(1) (2009).
97. *See Ciprofloxacin,* 544 F.3d at 1336 ("[T]he court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment."). Because the basis of a reverse settlement is a generic's technical infringement of an innovator's patent by filing the ANDA and Paragraph IV certification, if the Federal Circuit had ruled that patent validity mattered when analyzing a reverse settlement, the Federal Circuit's exclusive jurisdiction over patent cases would have brought all future pay-for-delay cases to it. The possible exception would be if a case somehow did not raise substantial issues of patent law.

There is confusion among the courts[98] and even strong disagreement among commentators[99] concerning the state of the law in each circuit on reverse payments. Some commentators characterize the Sixth Circuit as employing the per se approach against the practice of the Second and Eleventh Circuits,[100] others lump the Sixth and Eleventh Circuits' approaches together and contrast them with the Second and Federal Circuits' holdings,[101] and still others argue that all the circuits' holdings are consistent.[102] One of the chief impediments to comparing the different circuits' approaches is that the slightly different features of the settlement agreements in each case may be significant to each court's respective holding, but the opinions do not disentangle and separately analyze the elements of the agreements clearly enough to allow for a convenient comparison. For example, the Federal Circuit attempted to distinguish its *Cipro* decision from the Sixth Circuit's per se holding in *Cardizem* by pointing out that in *Cardizem* the generic had agreed not to market non-infringing versions of the drug.[103] The difficulty with this approach is that the Federal Circuit characterizes the settlement agreement in *Cipro* as preventing the generic from manufacturing or marketing "a generic version" of the drug, language that appears to prevent non-infringing versions as well.[104] One way to reconcile the Federal Circuit's characterization of the *Cipro* agreement with its holding is to assume the court was relying on the fact that the patent in *Cipro* was on the underlying drug molecule[105] and not the pharmaceutical's formulation. Therefore, presumably, a non-infringing generic was not possible,[106] and the settlement agreement could cover all possible generics without exceeding the scope of the patent. Nevertheless, the exact basis for the court's holding is ambiguous.

An analysis of each circuit's antitrust approach reveals that, despite the conflicting interpretations, there appear to be a set of settlement terms that would satisfy each court, including the Sixth Circuit, whose per se holding was the strictest. The Sixth Circuit's per se holding rests on only two facts: the reverse payments to keep the generic off the market and the use of the 180-day exclusivity period to prevent additional entrants to the market.[107] The Sixth Circuit does not necessarily declare all patent settlements per se illegal; rather, it appears that the per se label attaches once the agreement goes beyond enforcing patent rights and "bolster[s] the patent's effectiveness,"[108] because, in *Cardizem*, the

98. *See id.* at 1335 ("To the extent that the Sixth Circuit may have found a per se antitrust violation based solely on the reverse payments, we respectfully disagree.").

99. *Compare* Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases* 18 Alb. L.J. Sci. & Tech. 441, 462-63 (2008) ("In addressing the antitrust issues of the patent settlement agreements between brand-name and generic pharmaceutical companies, the federal courts have adopted two different approaches. The Court of Appeals for the Sixth Circuit held that a settlement agreement between a brand-name drug company and a generic drug company to delay marketing until resolution of the patent infringement case in exchange for a 'reverse payment' is classical restraint of trade and per se illegal. The Eleventh and Second Circuits rejected this 'per se rule' but instead considered the exclusionary power of the patent and addressed whether the settlement agreements exceeded the exclusionary power awarded by the patent law.) (citations omitted), *with* Brief Amici Curiae of 54 Intellectual Property Law, Antitrust Law, Economics, and Business Professors, the American Antitrust Institute, the Public Patent Foundation, and the AARP in Support of the Petitioner, Arkansas Carpenters Health and Welfare Fund v. Bayer, 129 S. Ct. 2828, 2 (2009) (No. 08-1194), 2009 WL 1144190, *cert. denied*, [hereinafter Brief Amici Curiae] ("The Second/Federal Circuit Rule Is Unprecedented and Conflicts With the Approaches of the Sixth Circuit, the Eleventh Circuit, and the Federal Trade Commission"). *But see* Christopher M. Holman, Patently-O, *Holman: A Contrarian Law Professor's Two Cents on the Arkansas Carpenter's (Ciprofloxacin) Petition for Certiorari,* http://www.patentlyo.com/patent/2009/05/holman-a-contrarian-law-professors-two-cents-on-the-arkansas-carpenters-ciprofloxacin-petition-for-certiorari.html (last visited Oct. 18, 2009) ("[T]he decisions by the Second Circuit and the Federal Circuit in *Tamoxifen* and *Ciprofloxacin* are both entirely consistent with earlier decisions by the other circuits . . . .").

100. Liu, *supra* note 99.

101. Brief Amici Curiae, *supra* note 99.

102. Holman, *supra* note 99.

103. *Ciprofloxacin*, 544 F.3d at 1335.

104. *See id*. at 1329 ("In return, Barr agreed not to manufacture, or have manufactured, a generic version of Cipro in the United States."). *See also id.* at 1333 ("[T]he generic defendants agreed not to market a generic version of Cipro until the '444 patent expired . . . .").

105. *See id*. at 1329.

106. *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 214 (Fed. Cir. 2006) ("Like the patent for the compound ciprofloxacin hydrochloride, which was the subject of dispute in the Cipro cases, and unlike the patents at issue in Cardizem and Valley Drug, Zeneca's tamoxifen patent is not a formulation patent, which covers only specific formulations or delivery methods of compounds; rather, it is a patent on a compound that, by its nature, excludes all generic versions of the drug.").

107. *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 907 (6th Cir. 2003) ("[T]he following facts are undisputed and dispositive. The Agreement guaranteed to HMR that its only potential competitor at that time, Andrx, would, for the price of $10 million per quarter, refrain from marketing its generic . . . the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer.").

108. *See id.* at 908 ("[T]he Agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation. As the plaintiffs point out, it is one thing to take advantage of a monopoly that naturally arises

"agreement's restrictions extended to non-infringing and/or potentially non-infringing versions of generic Cardizem."[109] A reverse settlement agreement would probably withstand the tests set forth by any of the circuits, including the Sixth, if it promised *only* that the generic would not infringe the listed patents, did not block non-infringing generics from being marketed, and forced the generic to abandon its Paragraph IV certification and 180-day exclusivity period. In cases where the listed patents included one on the drug molecule itself, this settlement effectively prevents the generic's entry into the market without incurring antitrust liability under the Sixth Circuit's logic. The result is that competitors and other affected parties have little ability to challenge properly designed reverse payments under an antitrust theory.

Part IV — Lessons from Hatch-Waxman for the New Biosimilar Pathway

For over twenty years, drug companies have lived with the compromises built into the Hatch-Waxman Amendments, but the new healthcare reform bill passed by Congress created an approval pathway for biosimilars[110] and is the future of generic medicines. Spending on biologic products is growing by fifteen to twenty percent annually and has already risen to about $40 billion in 2006.[111] Congress failed to learn from the weaknesses of the Hatch-Waxman regime when designing the new biosimilar approval process, but Congress still has the opportunity to amend the pathway before biosimilars begin to utilize the new system. Presently, the biosimilar pathway contains a set of provisions that can be used together to facilitate reverse settlements and to help justify them to courts.

For perspective, it is helpful to compare the current biosimilar pathway with an older proposal that was not enacted. During the 111th Congress, the House of Representatives' approach to biosimilars in H.R. 1548 grants twelve years of marketing exclusivity to new biologics[112] and gives a twenty-four-month exclusivity period to the *first biosimilar*.[113] When a generic biologic submits an application to the FDA, it must send detailed information about the biogeneric and its production,[114] and the reference product sponsor (i.e., the innovator biologic) responds with a list of its patents[115] and reasons why they have been infringed.[116] In turn, the biosimilar either decides not to go to market before the innovator's patent expires, or certifies that it believes that the innovator's patent will not be infringed, is invalid, or is unenforceable.[117] The House bill makes submitting the certification an act of infringement.[118] Importantly, the House bill only empowers the FDA to delay approval of the generic biologic *after* a court has ruled against the biosimilar.[119]

The new biosimilar pathway passed by Congress is similar to the House bill but with two important additions. First, it requires participation in negotiations over which patent claims should be litigated before the alleged infringer can be subject to an infringement action.[120] Second, the current biosimilar pathway offers variable amounts of exclusivity for the *first biosimilar* to be approved: the first biosimilar never has more than one year of actual marketing exclusivity, but biogenerics seeking approval afterward can be delayed up to forty-two months if the first is involved in infringement litigation and decides not to risk marketing its product.[121]

Both the failed House bill and the enacted biosimilar legislation make several important improvements over the generic drug approval scheme. First, they eliminate the delays associated with Paragraph IV certification by allowing biosimilars to be approved without facing a statutorily-mandated halt in the FDA's issuance of an approval in response to an innovator's infringement suit. Once approved, biogenerics can market their potentially infringing products at their own

from a patent, but another thing altogether to bolster the patent's effectiveness.").

109. *See id.* at 909 n.13.

110. In this Article, the terms "biosimilar," "biogeneric," and "generic biologic" are used interchangeably.

111. Congressional Budget Office, Congressional Budget Office Cost Estimate S. 1695 Biologics Price Competition and Innovation Act of 2007 5 (2008).

112. Pathway for Biosimilars Act, H.R. 1548, 111th Cong. § 101(a)(2) (2009) (amending § 351(k)(7) of the Public Health Service Act) (as introduced in the House on Mar. 17, 2009).

113. *See id.* (adding § 351(k)(6) to the Public Health Service Act).

114. *See id.* (adding § 351(l)(4)(A)(i) to the Public Health Service Act).

115. *See id.* (adding § 351(l)(4)(A)(ii) to the Public Health Service Act).

116. *See id.* (adding § 351(l)(4)(C)(i) to the Public Health Service Act).

117. *See id.* (adding § 351(l)(4)(D) to the Public Health Service Act).

118. *See id.* § 201(3) (amending 35 U.S.C. § 271(e)(2)).

119. *See id.* § 101(a)(2) (adding § 351(l)(5) to the Public Health Service Act).

120. Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, sec. 7002, § 351(l)(4), 124 Stat. 119, 811 (to be codified at 29 U.S.C. § 262).

121. *See id.* § 351(k)(6)(C)(i) at 806.

risk, similar to all other non-pharmaceutical products, and the equitable injunctive power of the court hearing the patentee's infringement case will presumably ensure that biogenerics with weak claims will not take away an innovator's rightful market share. Both bills have long exclusivity periods for the first biosimilar, which provides a strong incentive for these companies to develop their products quickly.

Unlike the unsuccessful House legislation, the actual biosimilar pathway affords innovators extra incentives to game the system and gain extra exclusivity time over second-to-file biogenerics. For example, if the infringement action by the innovator against the first biosimilar is dismissed or a final decision is reached, the first biogeneric's total potential exclusivity time is actually extended to eighteen months *after* the dismissal or decision, provided the biogeneric does not come to market.[122] Therefore, the strategy that is beneficial for both the first generic biologic and the innovator is to settle an ancillary patent to begin the reverse payment process and then move toward a final decision or dismissal. From this point, the parties would have a reverse payment regime in place, with the biosimilar qualified for the extended eighteen-month exclusivity period. The settlement would provide the innovator with at least eighteen months of exclusivity and the first biosimilar with at least eighteen months of reverse payments. Unless the economics of the biogeneric market diverge dramatically from the traditional generic drug market, reverse payments exchanged for eighteen months of innovator monopoly should clearly result in an improved financial outcome for both the biogeneric and innovator when compared with the alternative: twelve months of shared marketing exclusivity.

These reverse payments would avoid accruing antitrust liability because the heightened exclusivity period attaches even if the first biosimilar loses the infringement suit brought by the innovator.[123] There is no certification analogous to Paragraph IV on file with the FDA for the first biosimilar to amend that would relinquish its right to exclusivity, so a biosimilar that chose not to come to market may not be at fault for delaying others. However, even if a court decides that a biosimilar violates antitrust law if it accepts reverse payments without beginning its marketing exclusivity period as soon as permitted, the enacted biosimilar approval pathway provides a way to escape liability. A biogeneric could strategically use a statutorily-mandated 180 days notice to the innovator prior to commercial marketing[124] to ensure that its minimum of one year of market exclusivity[125] plus the additional 180 days of required waiting results in exactly the same eighteen-month delay[126] for all other generic entrants regardless of whether reverse payments are made. This prevents the biogeneric from accruing antitrust liability for causing a bottleneck in the approval of additional biogenerics. In this situation, a court could not justly hold the biosimilar responsible for the delay because the statute requires the biogeneric to give the notice, which prevents the biogeneric from initiating its marketing exclusivity period sooner.

Under this strategy, all additional entrants can be delayed eighteen months, but the only way for the generic biologic to get eighteen months of heightened profit instead of twelve months of shared exclusivity is to enter into a reverse settlement. By providing a longer exclusivity period for biogenerics that do not immediately enter the market, the current biosimilar law sets up an approval process that strongly incentivizes reverse payments.

Conclusion

The ANDA process under Hatch-Waxman, especially Paragraph IV, facilitates reverse settlements. The result is an explosion of litigation: patent infringement suits, followed by reverse payments, followed by antitrust suits. Pharmaceutical companies reasonably respond to the incentives created by the law, and this process, beginning with an infringement suit and ending in murky antitrust waters, is unlikely to abate any time soon. It appears as though all the circuits allow at least some reverse settlements, and short of new legislation banning them, they will remain prominent in pharmaceutical patent litigation. The new biosimilar

122. *See id.* § 351(k)(6)(B) at 806.

123. *See id.*

124. *See id.* § 351(l)(8)(A) at 813 ("Notice of commercial marketing. The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."). The applicant can give notice after submitting an application, and must give the innovator 180 days before marketing the biogeneric, but the applicant should otherwise be able to choose when to give this notice, and it reasonable for the biogeneric to wait if it is embroiled in a lawsuit with the innovator. If the biogeneric does not give notice until a settlement agreement with reverse payments is in place, the notice requirement can act to preclude the biogeneric from ending its exclusivity period for eighteen months, whether it does eighteen months of reverse payments or six months of required waiting and then twelve months of shared exclusivity.

125. *See id.* § 351(k)(6)(A) at 806.

126. *See id.* § 351(k)(6)(B) at 806.

approval process passed by Congress is designed in a way that encourages reverse settlements, so biogenerics will probably be subjected to the same quantity of unnecessary litigation as ANDA generic drugs.

If Congress chooses to reexamine the biosimilar pathway it passed as part of healthcare reform, it should avoid incentivizing reverse settlements. Pay-for-delay agreements should be discouraged by giving the first biosimilar extra exclusivity time if it begins selling its product immediately upon FDA approval. If the biosimilar either accepts reverse payments and stays off the market or waits for any infringement litigation to conclude before coming to market, it should be ineligible for extra exclusivity time. Under this scheme, at least one generic product will reach the market quickly, lowering prices for consumers. A longer exclusivity period for the first biogeneric will partially mitigate the loss to the innovator, because the innovator will have half of a duopoly for the lengthened exclusivity period and will be able to postpone the full onslaught of generic competition. A longer exclusivity period for the first biosimilar, applying only if it comes to market quickly, will shift the economic incentives away from reverse settlements.

The three-way intersection between patent, antitrust, and drug law exists because the road to generic drug approval was not ideally designed. The new biosimilar pathway had the chance to become a detour to innovation and efficiency, but is currently just another road at the intersection.