Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act[1]

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A quarter-century ago, Congress fundamentally changed the way the FDA approves pharmaceuticals for the market. The Hatch-Waxman Act gave additional protection to the inventors of new drugs, both by lengthening patent terms and by providing guaranteed periods of data exclusivity.[4] In exchange, Hatch-Waxman made it easier for generic drug manufacturers to enter the market with a copy of the drug, either by waiting until the patent expires or by challenging weak patents. To encourage generic manufacturers to identify and challenge weak patents, Hatch-Waxman offered a sort of "mini-patent" to the generic challenger. The first generic manufacturer to file for approval with the FDA, with caveats discussed below, is entitled to 180 days of "generic exclusivity" when the generic first enters the market. During that period, other generic drug makers are prohibited from entering the market. The idea was to offer a carrot, encouraging a race among generic firms to challenge and invalidate bad patents (or invent around them), and accordingly get generic drugs on the market earlier.

It isn't working. Pharmaceutical patent owners have responded to Hatch-Waxman with a sophisticated program of "product lifecycle management," which is code for finding ways to extend exclusivity as long as possible. They have filed multiple patents on variants of the same

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4 Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.). In 2003, Congress amended this scheme in Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, tit. XI, subtits. A–B, 117 Stat. 2066, 2448–64 (codified at 21 U.S.C. § 355 (2006)).

drug, listed patents with the FDA that don't cover the product, taken advantage of litigation rules to stay generic entry, and "product-hopped" (made small changes to a product timed to prevent generic entry). Most of all, they have paid their potential generic competitors to abandon their challenges, keeping weak patents intact and preventing market competition.

These "reverse" or "exclusion" payments to settle pharmaceutical patent lawsuits are facilitated because the Hatch-Waxman Act has been interpreted to give 180 days of generic exclusivity to the first generic company to file for FDA approval, whether or not that company succeeds in invalidating the patent or finding a way to avoid infringement. As a result, the patentee can "buy off" the first generic entrant, paying them to delay their entry into the market while still offering them the valuable period of generic exclusivity.[5] And if that first generic is entitled to its 180 days, no one else can enter until after the exclusivity period has expired or been forfeited.[6]

The result is that the 180-day exclusivity period is not serving its purpose of eliminating weak patents. True, it is encouraging lots of *challenges* to those patents. But it is encouraging

[5] That exclusivity period is quite valuable; generics often make more than half of their total profits on a drug during the period of generic exclusivity. "In general, most generic companies estimate that 60% to 80% of their potential profit for any one product is made during this exclusivity period." Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective*, 25 **Biotech. L. Rep.** 525, 525–26 (2006). See also Martin A. Voet, **The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management** 61 (2005) (arguing that the 180 days often provides the majority of total profits).

[6] This description applies to drugs with "new ANDAs"—that is, drugs whose first ANDA with a Paragraph IV certification was filed after December 8, 2003. For old ANDAs, the relevant event is the triggering of the first filer's exclusivity, rather than forfeiture.

the challengers to accept compensation to drop those challenges, rather than taking them to judgment and benefiting the rest of the world.

To be sure, many of these "lifecycle management" strategies have been challenged as violations of antitrust law. The results have been mixed. As we explain below, antitrust challenges have arguably succeeded in curbing certain types of behavior, but have been less successful, at least thus far, in curbing anticompetitive settlements. Meanwhile, a large literature has accumulated that considers the appropriate treatment of various tactics under existing antitrust law, or else evaluates the merits of new antitrust prohibitions to fill any existing gaps.

Our approach is different. We propose to resolve these questions of antitrust policy by changing the Hatch-Waxman statutory scheme itself. After all, the point of 180-day exclusivity was to encourage challenges to patents because the invalidation of bad patents benefits society as a whole.[7] Society doesn't benefit from a private deal to drop a challenge. That doesn't mean settlement is never a good idea; it is a commonplace in our legal system. But it seems bizarre to insulate a company from competition just because it settles the case. Indeed, we expect that our proposal, if implemented, would facilitate more rational settlements, in which the settlements that result accurately reflect the likelihood of success in litigation.

Our alternative is straightforward: first-filing generic drug companies should be entitled to 180 days of exclusivity only if they successfully defeat the patent owner, for example, by

[7] See Christopher R. Leslie, The Anticompetitive Effects of Unenforced Invalid Patents, 91 **Minn. L. Rev.** 101 (2006).

invalidating the patent or by proving that they did not infringe that patent. We suggest that this change could be implemented without any legislative action, for example, by the FDA in interpreting the Hatch-Waxman Act, and by the Federal Trade Commission (FTC) in its enforcement of the FTC Act. The FDA took this view briefly in the 1990s, but the D.C. Circuit held that the statute did not support it. Accordingly, we propose a simple change to the statute to limit 180-day exclusivity to those who have earned it.[8] Doing so won't solve every threat to competition in the pharmaceutical industry, but it will make a significant start.

We provide the background of the Hatch-Waxman Act in Part I. In Part II, we discuss the ways patent owners have circumvented the purpose of the statute, the various efforts—principally as a matter of antitrust—that courts, agencies, and Congress have made to close those loopholes, and why they haven't solved the problem. Part III sets out our basic proposal. Part IV considers the effects of requiring generic challengers to earn their exclusivity, some possible objections to the proposal, and how earned exclusivity compares to other suggested alternatives.

I. The Hatch-Waxman Act and Generic Challenges

A. Paragraph IV Challenges

Generic drug challenges target brand-name drugs that are already on the market. Under federal law, a brand-name firm must demonstrate that a new drug is safe and effective before

[8] As explained *infra*, our approach is more generous than the FDA's successful defense requirement in significant respects. For example, we would grant exclusivity where a first-filing generic firm is never sued and therefore permitted to enter the market immediately.

the FDA will approve it for marketing. Making that demonstration as part of a so-called New Drug Application (NDA) is a lengthy, expensive process, consuming years and many millions of dollars to conduct the necessary clinical trials.[9]

Once the brand-name firm places a new drug on the market, a generic firm may seek to market a competing, "therapeutically equivalent" version of the same drug by filing an Abbreviated New Drug Application, or ANDA, with the FDA. The generic firm must demonstrate that its proposed drug is "bioequivalent" to the brand-name drug—that it uses the same active ingredient, and will be absorbed by the body at the same rate and to the same extent as the brand-name drug.[10] New clinical trials, however, are not required. An ANDA costs around $1 million to prepare.[11]

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[9] Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. **Health Econ.** 151 (2003), estimates that the costs of clinical tests constitute more than half the total cost of drug development. See id. at 162 tbl.1 (estimating out-of-pocket costs of $130 million per successful drug, which rises to $467 million if an estimate of the cost of failure is attributed to the successes and applying an eleven percent discount rate to the later outlays); id. at 166 (separately estimating out-of-pocket and capitalized preclinical costs to be $121 million and $355 million respectively). Other cost estimates for the entire drug discovery and development process range from $110 million to $500 million; the latter is an industry figure. Compare Pharm. Research & Mfrs. of Am., Why Do Prescription Drugs Cost So Much . . . (June 2000), http://www.phrma.org/publications/publications/brochure/questions/ (2000) (reporting the average cost of bringing one new drug to market as $500 million) with Pub. Citizen, Rebuttals to PhRMA Responses to Public Citizen Report Rx R&D Myths: The Case Against the Drug Industry's "Scare Card," at http://www.citizen.org/congress/reform/drug_industry/corporate/articles.cfm?ID=6514 (last visited Dec. 30, 2010) (criticizing industry estimates and offering the lower figure).

[10] 21 U.S.C. § 355(j)(8)(B) (2006). The applicant must also demonstrate that the generic drug contains the same conditions of use, route of administration, dosage form, strength, and labeling. § 355(j)(2)(A).

[11] See Requirements for Submission of In Vivo Bioequivalence Data; Proposed Rule, 68 Fed. Reg. 61,640, 61,645 (Oct. 29, 2003) (reporting estimates of ANDA preparation and filing costs between $300,000 and $1 million).

Most new drugs are protected by one or more patents. Those patents are listed by the brand-name firm in an FDA document commonly known as the Orange Book.[12] The generic firm, faced with this array of patents, may choose not to challenge any patents, in which case the FDA delays ANDA approval until expiration of the last listed patent.

In many cases, however, the generic firm attempts to enter prior to the expiration of the brand-name patents. A generic firm seeking pre-expiration entry files an ANDA containing a "Paragraph IV" certification, asserting that applicable patents are invalid or not infringed by the proposed generic product.[13] The filing of such an ANDA is an act of patent infringement.[14] In response to the ANDA, the brand-name firm may file a patent infringement suit to establish validity and infringement. ANDA-based patent litigation has a special feature, an automatic statutory stay that blocks FDA approval of the generic drug while the litigation is pending for up to 30 months.[15] This pattern—launch, challenge, sue—is frequent for major drugs, and it has

[12] The official name is the Approved Drug Products with Therapeutic Equivalence Evaluations. The Orange Book also lists, for each brand-name drug, any unexpired regulatory exclusivity and approved therapeutically equivalent generic drugs.

[13] 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006). There are three alternative certifications, called Paragraphs I, II, and III. See § 355(j)(2)(A)(vii)(I)-(III). Except where otherwise noted, we limit our attention to ANDAs with Paragraph IV certifications.

[14] 35 U.S.C. § 271(e)(2)(A) (2006).

[15] § 355(j)(5)(B)(iii). The stay takes effect provided that the brand-name firm files suit within 45 days of receiving notice of the certification. Receipt of notice starts the 30-month clock, so the maximum duration of the stay is generally slightly less than 30 months. Under certain special circumstances, the stay lasts for more than 30 months.

become the norm for the top-selling drugs.[16] Litigation raises the expense of a Paragraph IV challenge to $10 million or more.[17]

Once multiple generic firms enter the market, prices fall, often dramatically. Consider the case of simvastatin, a blockbuster treatment for high cholesterol sold under the brand name Zocor. The first generic firm received approval in June 2006. By early 2007, a month's worth of generic simvastatin sold for as little as $7, compared to more than $150 for Zocor.[18] As prices fall, quantities may increase too. In the 18 months after the arrival of generic simvastatin, for example, prescriptions increased by more than 70 percent.[19]

B. The 180-Day Exclusivity Period

[16] C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?* (Columbia Law & Econ. Working Paper No. 379, Aug. 2010), available at http://ssrn.com/abstract=1640512.

[17] Marc Goodman et al., Quantifying the Impact from Authorized Generics (Morgan Stanley Research Report 2004). Nonetheless, challenging patents frequently pays quite handsomely, either in profits from sales in the market or in the form of reverse payments to stay out of the market.

[18] Sarah Rubenstein, *Why Generic Doesn't Always Mean Cheap*, **Wall St. J.**, Mar. 13, 2007 (reporting $154.99 retail price for 30 tablets of 20-mg dose of Zocor at CVS, compared to $6.97 for simvastatin at Sam's Club). The average retail price during this period was higher, given a great deal of variation in the retail price for simvastatin. Id.

[19] Murray Aitken, Ernst R. Berndt & David M. Cutler, *Prescription Drug Spending Trends in the United States: Looking Beyond the Turning Point*, **Health Affairs**, Dec. 16, 2008, at w151, w156-w158 & exh. 5 (reporting increase from 2.8 million to 4.8 million annual prescriptions).

From a social welfare perspective, there are two offsetting effects. First, the quantity of other drugs in the same class may fall. For example, in the case of Zocor, the quantity of another cholesterol-lowering drug, Lipitor, fell as simvastatin use increased. Id. Second, brand-name drug makers reduce marketing in response to generic entry, which reduces utilization. See Frank R. Lichtenberg & Guatier Duflos, *Does Patent Protection Restrict U.S. Drug Use? The Impact of Patent Expiration on U.S. Drug Prices, Marketing, and Utilization* (working paper 2009); Darius Lakdawalla, Thomas Philipson & Y. Richard Wang*, Intellectual Property and Marketing* (National Bureau of Economic Research Working Paper No. 12577, 2006). *Cf.* Gideon Parchomovsky & Peter Siegelman, *Towards an Integrated Theory of Intellectual Property*, 88 **Va. L. Rev.** 1455 (2002) (observing that brand-name drug makers sometimes raise prices upon generic entry, relying on the brand to drive a few sales at the higher price).

Generic firms have a special incentive to challenge a patent, particularly patents that are likely to be invalid or not infringed. That is due to a second special feature of the Hatch-Waxman regime: The first generic firm to file an ANDA is entitled, upon FDA approval, to a 180-day exclusive right to market its product in competition with the brand-name firm before other generic firms may enter. This exclusivity period provides a bounty to generic firms that incur the costs of Paragraph IV challenges, and helps to overcome a collective action problem in challenging patents, since a successful invalidity challenge can be exploited by other generic drug makers.[20]

The bounty is akin to a mini-patent for certain generic firms. Like a patent, it has two key features. First, it is a profitable source of exclusion of competitors. During the 180-day period, only the first generic and the brand-name firm are in the market.[21] For many drugs, the exclusivity period offers the majority of the profits available to the generic firm, since profits fall sharply once other generic firms enter the market.[22] In some cases, the falloff in sales can be

[20] Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation, 402 U.S. 313, 349 (1971); Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 **Berkeley Tech. L.J.** 667, 687–88 (2004) (recognizing public-good characteristic of patent challenges); Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 **Berkeley Tech. L.J.** 943, 952 (2004) (similar); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 **U. Ill. L. Rev**. 305, 333 (similar). Noninfringement claims are more complicated, because they may be specific to the reverse engineering strategy pursued by a particular firm.

[21] As discussed *infra*, in some cases the brand-name firm also authorizes an additional generic firm as an additional competitor.

[22] See note 5 *supra*.

extreme.[23] Often, the exclusivity period also provides a head-start in signing up customers that carries over after exclusivity expires and other firms enter.[24]

Second, the profits come at the expense of high prices for consumers. During the exclusivity period, the price discount from monopoly is slight. The FDA has estimated an average relative price decrease of just 6% when there is only one generic manufacturer competing with the brand-name firm.[25] In the case of Zocor, the difference in retail prices after entry of the exclusive generic was about 10%.[26] The entry of additional competitors reduces the price quite sharply, and the more generic competitors, the lower the price.[27]

The lessons of patent policy apply to the generic firm's mini-patent. One of these lessons is that legal exclusivity ought to be doled out sparingly, and only where it can be expected to induce desirable behavior. Otherwise, the public will suffer high prices and deadweight loss from exclusion, without any compensating benefit from innovative firm

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[23] Gardiner Harris & Joanna Slater, *Bitter Pills: Drug Makers See "Branded Generics" Eating into Profits*, **Wall St. J.**, Apr. 17, 2003, at A1 (reporting that Barr's generic version of Prozac had revenue of $366 million during the 180-day period, and $4 million in subsequent six months).

[24] Voet, *supra* note 5, at 61 (noting that generic firm that enjoys exclusivity often maintains a majority of sales even once the other firms enter).

[25] Food and Drug Administration, Generic Competition and Drug Prices, http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm. The FDA analyzed retail sales data for drugs sold between 1999 and 2004. They found that in markets with a single generic drug maker, the relative price of the generic firm was 94% of the brand-name firm.

[26] Shannon Pettypiece & Justin Blum, *Merck's Zocor Gets Additional Generic Competition*, **Bloomberg News**, Dec. 27, 2006 (noting, at the end of the exclusivity period, that 20-milligram Zocor sells for $4.53 per pill, compared to $4.16 for Teva's generic version).

[27] According to the FDA's calculations, for markets with two generic drug makers, the relative price fell to 52%, and with five, 33%, of the original price. The price continued to fall with additional drug makers. See also Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition and Consumers' Welfare*, 26 **Health Affairs** 790 (2007) (as number of generic firms rises, price falls to 20% of brand-name price or less).

behavior. In the case of patents, that means granting a patent where it will induce socially valuable R&D into developing new drugs.[28] In the case of generic-firm mini-patents, we would like to design the mini-patent so that it is limited to situations where the generic drug maker is doing something that merits a reward.

In the early years of the Hatch-Waxman Act, the FDA applied this lesson in restricting the availability of the mini-patent. In particular, the agency awarded a mini-patent only to generic drug makers that "successfully defended" a patent suit. In other words, to win the bounty, a generic drug maker must file a Paragraph IV certification, be sued by the brand-name firm, and win the subsequent suit. If the generic drug maker settled the case, or was never sued, no mini-patent was awarded. During this period, awards of exclusivity were rare. The FDA awarded the bounty just three times between 1984 and 1998, all of them before 1992.[29]

In 1998, the courts rejected this limitation on the mini-patent as an impermissible interpretation of the Act's text,[30] and the FDA changed its interpretation accordingly.[31] Since

[28] For scholarly research questioning whether the current patent and regulatory rules actually encourage the development of new drugs, as opposed to incremental changes in existing drugs, see Ron A. Bouchard et al., *The Pas de Deux of Pharmaceutical Regulation and Innovation: Who's Leading Whom?*, 24 **Berkeley Tech. L.J.** 1461 (2009).

[29] These awards were for generic versions of Maxzide (ANDA #71-360 of Vitarine, exclusivity expiring in April 1988), Flexeril (ANDA #71-611, Watson, November 1989), and Procardia (ANDA #72-409, Chase, March 1991). Exclusivity awards are recorded in old versions of the Orange Book, collected and furnished by Bhaven Sampat. See also FTC, **Generic Drug Entry Prior to Patent Expiration** vi (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (reporting three awards between 1984 and 1992).

[30] Mova Pharm. Corp. v. Shalala, 955 F. Supp. 128, 130 (D.D.C. 1997), aff'd, 140 F.3d 1060 (D.C. Cir. 1998) ("The language of the statute . . . is plain and unambiguous. It does not include a 'successful defense' requirement, and indeed it does not even require the institution of patent litigation."); see also Granutec, Inc. v. Shalala, 46 U.S.P.Q.2d (BNA) 1398, 1401 (4th Cir. 1998) (similar).

1998, a first-to-file generic drug maker is eligible for the bounty provided that it does not lose the patent suit, even if it never actually won the patent litigation. Indeed, it may earn the exclusivity even if was never sued, so long as it was the first to file an ANDA.

Zocor again provides a useful illustration. The generic challenger did not challenge the basic composition of matter patent, but did file Paragraph IV certifications challenging two additional ancillary patents that the brand-name firm had listed on the Orange Book. The brand-name firm declined to sue on those ancillary patents. The FDA approved the generic product upon the expiration of the basic patent, and awarded exclusivity thanks to the Paragraph IV certification on the other two patents.[32] As a result, despite not having invalidated a patent or accelerated generic entry, the generic firm enjoyed the bounty, thereby delaying further entry on a multibillion dollar drug for 180 days.

C. Effects of 180-Day Exclusivity

To better understand the role 180-day exclusivity plays in encouraging patent challenges and generic entry, we studied the use generics actually made of that exclusivity. To do this, we

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[31] Ctr. for Drug Evaluation & Research, FDA, Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act 4 (1998) (stating that "FDA will not enforce the 'successful defense' provisions" and "intends to formally remove" them from Code of Federal Regulations).

[32] Letter from Gary Buehler, FDA, to Patricia Jaworski, IVAX Pharmaceuticals, Inc. 2-3 (June 23, 2006) (approving ANDA 76-052 as to 5, 10, 20, and 40 mg strengths, noting the absence of any suit, and awarding exclusivity as to these strengths). The text omits one complexity, that there was another generic drug maker that was first to file on one strength that represented about 10% of Zocor sales. Letter from Gary Buehler, FDA, to Abha Pant, Ranbaxy Laboratories Ltd. 2-3 (June 23, 2006) (approving ANDA 76-285 as to 80 mg strength, noting absence of any suit, and awarding exclusivity as to this strength).

collected every instance where 180-day exclusivity was officially awarded by the FDA and triggered by the generic firm over a four-year period between 2005 and 2009.[33] We cleaned the data set, dropping awards on three over-the-counter drugs[34] and several others where a close look at the award demonstrated its irrelevance.[35] The final set contained 49 drugs, with some drugs having awards to multiple generic drug companies. The multiple awards arise where several firms share eligibility for exclusivity, generally because they filed ANDAs on the same day.

For each of these drugs, we determined which patent or patents supported the 180-day award using FDA approval letters, and assessed the circumstances of the award using a variety of sources. We categorized each award as a win in litigation, launch at risk,[36] settlement, or no suit.[37] Some of these were not straightforward to determine. In a few cases where a drug had awards to multiple generic firms, and the different firms received awards in different

[33] In particular, the set contains every award in which exclusivity expired between October 2005 and October 2009.

[34] Generic competition in over-the-counter drugs takes an entirely different form. Consumption of generic prescription drugs, unlike over-the-counter drugs, is promoted by state automatic substitution laws and the reimbursement policies of insurance companies.

[35] For example, two involved an award for a drug that had already seen generic entry. In addition, for several drugs with separate exclusivity awards for different dosages, we coded the dosage for which exclusivity was awarded first.

[36] A generic launches "at risk" if the 30-month stay of entry has expired, but the lawsuit against it has not yet been resolved. If the generic nonetheless enters the market and ultimately loses the suit, it will owe damages that may far exceed what it made from marketing the drug. We coded a launch as "at risk" only if the launch occurred before the district court ruled.

[37] A "no suit" outcome is one in which the patentee didn't file a lawsuit in response to a Paragraph IV ANDA filing on that patent, in effect conceding the right of the generic to enter. We counted the outcome as no suit in four cases in which there was a lawsuit on some patents, but not on any patent that gave rise to the exclusivity award.

circumstances, we resolved the uncertainty in favor of the outcome that supported the exclusivity system.[38]

We found that for most drugs, the generic drug maker did little or nothing to earn the exclusivity award. Almost half of the awards (23) are no-suit awards, meaning that the generic firm didn't have to spend money on litigation or face uncertainty about the outcome of the suit. Indeed, in some cases the basis for the award was a patent that was arguably irrelevant to the product described in the ANDA, in which case little or no effort was needed to develop a legal or design-around strategy. Another 10 are settlements, which we reviewed.[39] The particular settlements in these cases did nothing to open up the market to other generic entrants. Seven more were launches at risk. Only 9 included a win by the generic firm, all but one of which

[38] For instance, where one generic settled and another won a case, we coded the drug as one involving a win.

[39] One settlement, Lamictal CD, did provide for early generic entry, but the overall terms of the settlement did not promote entry. Lamictal CD is a chewable version of a blockbuster drug, Lamictal. At the time of settlement, annual sales of Lamictal CD were about $50 million, compared to about $1 billion for Lamictal tablets. Teva, the first filing generic for both versions, was sued—as to the same patent—for both drugs. In early 2005, Teva settled. Press Release, Teva Pharms. USA, Teva Announces Settlement of Lamictal Litigation with GlaxoSmithKline (Feb. 17, 2005). Under the settlement, Teva secured early (June 2005) entry with exclusivity on Lamictal CD, and the early completion of the exclusivity period might have opened the way to other generic firms. (As it turned out, Teva's entry was delayed until June 2006, see Letter from Gary Buehler, Dir. of Office of Generic Drugs, FDA, to Philip Erickson, TEVA Pharmaceuticals USA (Aug. 30, 2006) (approving ANDA with exclusivity), but so far as appears this was not due to the settlement.) At the same time, Teva accepted a delay of entry until July 2008 on the blockbuster version of the drug, six months prior to patent expiration. Thus the expiration of Teva's exclusivity coincided with the expiration of the Lamictal patent, blocking generic entry on the blockbuster version.

included an invalidation or unenforceability determination as to at least one brand-name patent.[40]

The fact that the 180-day "mini-patent" isn't actually encouraging many patent invalidations may come as a surprise. To be sure, we don't observe every instance in which the 180 days matters. We only see cases where the 180-day award is triggered. We don't observe instances where the generic is eligible for the award but never actually got it, or will eventually trigger the award but hasn't done so yet. The classic case of the latter situation is a settlement with delayed entry, in which the generic firm will enter eventually, but has not done so yet.[41] But we observe the set of cases in which 180-day exclusivity works the way it is supposed to. And there aren't very many of them.

Do these awards block entry by other generic firms? To answer this question, we need to know whether there are additional generic firms that would have entered before the end of the 180-day period but for the fact that they were blocked by the unexpired exclusivity. If a subsequent approval coincides with the end of exclusivity, the timing of approval is unlikely to be a coincidence. It is highly likely that the timing of entry was the result of exclusivity delay.

[40] Of the nine drugs, eight included a determination of invalidity or unenforceability, and one centered on a judgment of noninfringement. In two of the eight coded as an invalidity case, the initial invalidity determination occurred on appeal to the Federal Circuit. (The district court had ruled in one of these two that the patent was valid and infringed, and in the other that the patent was valid but not infringed.)

[41] Consider, for example, the case of Xopenex, an important asthma treatment. The first filer was sued over five method of use patents, with expiration dates ranging from January 2010 to August 2013, and one formulation patent expiring in March 2021. Shortly after the generic firm received FDA approval, the parties settled the litigation. The settlement agreement provides for a generic launch in August 2012. The generic firm retains exclusivity, without triggering it, in the meantime. For a discussion of the litigation history, see Dey, L.P. v. Sepracor, Inc., 595 F. Supp. 2d 355, 359 (D. Del. 2009).

(That said, we cannot rule out the possibility that some additional cause, such as technical problems raised by the FDA, would have prevented ANDA approval even without the delay.) If a subsequent approval occurs long after the end of exclusivity, then the 180-day period is not a direct impediment to subsequent entry.

To determine this, for each drug, we looked at the approval dates of therapeutically equivalent generics. We coded a block if the subsequent approvals occurred on the day of exclusivity expiration or within ten days after that.[42] For the 180-day awards on non-suit drugs, twelve blocked other generic approvals, with the effect of keeping prices high for longer than would otherwise be the case. Moreover, in most cases, the award blocked approval of a large number of other generics, the earlier entry of which would have reduced prices even more. Five of the ten settlements also blocked subsequent approvals. In other words, when the exclusivity associated with the settling generic firm expired, there were immediate approvals of at least one other generic firm. Of the generic wins, five blocked subsequent generics.

II. Drug Maker Strategies and Policy Responses

As Paragraph IV certifications have continued to rise,[43] brand-name drug makers have employed a variety of tactics to extend the duration of exclusivity. Both of the unusual features of generic drug entry – the 30-month stay of generic drug approval and the 180-day bounty –

[42] We omitted one drug in which the end of exclusivity coincided with patent expiration, raising the possibility that the subsequent entrants had declined to challenge the patent, and hence been blocked from approval by the unexpired patent rather than the 180-day exclusivity period.

[43] See Hemphill & Sampat, *supra* note 16.

are vulnerable to manipulation. The long lead time needed to secure generic drug approval provides additional opportunities for abuse. These tactics have met with counter-measures—judicial, statutory, and regulatory—to curb their use, with varying degrees of success.

A. Three Strategies for Delaying Generic Entry

1. Multiple 30-month stays

One of the earliest strategies for avoiding generic entry focused on the operation of the 30-month stay. Brand-name firms listed additional patents in the Orange Book after the generic firm filed its ANDA in order to secure multiple, overlapping stays for a single drug. This practice became known as "evergreening,"[44] because the patentee could refresh its stay by periodically adding a new patent to the Orange Book, no matter how weak the patent or how little it related to the defendant's product. For example, in the case of Paxil, a blockbuster antidepressant, the brand-name drug maker initially listed a single patent in the Orange Book. A generic firm filed a Paragraph IV certification for the patent, which attracted a patent suit and triggered an initial stay. While that lawsuit was pending, the drug maker obtained additional patents and listed them on the Orange Book. These patents were further ammunition in the fight with the generic firm. They obliged the generic firm to file additional Paragraph IV

[44] For discussion of evergreening, *see, e.g.,* Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 **B.U. L. Rev.** 63, 81-83 (2004); Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 **IDEA** 227, 233-35 (2001); Christine S. Paine, *Brand-Name Drug Manufacturers Risk Antitrust Violations By Slowing Generic Production Through Patent Layering*, 33 **Seton Hall L. Rev.** 479, 497 (2002); Frederick Tong, *Widening the Bottleneck of Pharmaceutical Patent Exclusivity*, 24 **Whittier L. Rev.** 775, 787-88 (2003).

certifications, which triggered additional patent suits—and more stays, for a total of five overlapping stays that stretched out over 65 months.[45] Paxil was far from unique. For six other drugs, brand-name drug makers secured multiple stays.[46]

Resolving the multiple stay problem entailed a mix of regulatory attention and legislative change. The FTC investigated and obtained antitrust consent decrees in several multiple stay cases,[47] and publicized findings about the problem[48] that prompted an FDA decision to limit drug makers to a single stay for each drug, regardless of how many patents are listed in the Orange Book.[49] In 2003, Congress passed legislation confirming that view.[50] The problem has attracted private antitrust suits as well.[51] But since 2003, evergreening of this form won't work for new cases.

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[45] FTC, *supra* note 29, at 49.

[46] Id. The FTC lists 8 drugs including Paxil, but one of them, Platinol, involved a single stay caused by a late-added patent, rather than multiple stays. In addition to these drugs, the product-hopping conduct described in the next section can have the consequence of generating multiple automatic stays.

[47] See, e.g., In re Biovail Corp., 2002 WL 727033 (FTC No. 011 0094, Apr. 23, 2002); In re Bristol-Myers Squibb Co., No. C-4076, 2003 WL 25797221 (F.T.C. Apr. 14, 2003) (describing improper multiple stays).

[48] FTC, *supra* note 29, at ii-v, 48-52.

[49] Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application 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; Final Rule, 68 Fed. Reg. 36676 (June 18, 2003).

[50] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §1101(a)(2)(A)(ii), 117 Stat. 2066, 2449-50.

[51] The multiple stays in Paxil were the subject of antitrust class action suits by indirect and direct purchasers that resulted in settlements of $65 million and $100 million, respectively. See Nichols v. SmithKline Beecham Corp., No. Civ. A. 00-6222, 2005 WL 950616, at *1, *26–27 (E.D. Pa. Apr. 22, 2005) (indirect); Stop & Shop Supermarket Co. v. SmithKline Beecham Corp., No. Civ. A. 03-4578, 2005 WL 1213926, at *1 (E.D. Pa. May 19, 2005) (direct). A competitor claim was recently settled too. Press Release, GlaxoSmithKline, GlaxoSmithKline Legal Update, July 15, 2010 (reporting that antitrust litigation with Apotex over Paxil is now "fully resolved").

2. Product switches

A second brand-name tactic for extending the life of drug patents takes advantage of the long lead time needed for a generic firm to secure FDA approval of a competing drug, including establishing bioequivalence, making Paragraph IV certifications, and conducting litigation. By the time a generic drug is approved, the brand-name firm may have developed a new formulation—for example, a tablet instead of a capsule—and switched customers from the old drug to the new drug. Developing a generic version of the new drug then requires the generic firm to go through the process all over again, with further delays. In the meantime, the generic firm may sell its version of the old drug, but that is often small comfort, because pharmacists cannot substitute the old drug for the new brand-name drug.[52]

Not all product switches are created equal. A single enantiomer version, or once-a-day-formulation, may offer significant improvements over the original, and the differences may lead patients and doctors to prefer the new drug. But product switches that involve significant changes in the product generally require a new NDA by the brand-name company, which means that they are not a very useful tool for raising rivals' costs. Manipulation of the switch is more troubling if the improvement on the original drug is less significant: if the new drug is bioequivalent to the old, no new clinical studies are required. In the extreme case, there is no

[52] For analyses, see 1 **Herbert Hovenkamp et al., IP and Antitrust** §15.3c1 (2d ed. 2010); Stacey L. Dogan & Mark A. Lemley, *Regulatory Gaming*, 87 **Tex. L. Rev.** 685, 709-17 (2009); Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 **Rutgers L.J.** (forthcoming 2010); **Robin Feldman, Rethinking Patent Law** (book manuscript 2010).

improvement, and the product design change is made purely to create an incompatibility that avoids competition.

In some cases, the drug maker's product-switching or "product-hopping" conduct goes even further. For example, the drug maker, after accomplishing the switch, may go to great lengths to withdraw the older drug from the market, making it more difficult for pharmacists to fill prescriptions for the old drug using the generic product.[53] Another tactic is to execute multiple switches, for example, from a capsule form to a tablet form, and then a second switch—as the generic firm again closes in on approval—to a third, slightly different tablet form.[54] The second (or third, or fourth) switch compounds the consumer harm of the first switch.

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[53] For example, in the course of protecting the brand-name drug Tricor, the brand-name drug maker not only stopped selling the capsules, but also bought all existing stock from pharmacies and changed the code for TriCor capsules in the National Drug Data File (NDDF) to "obsolete." Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 416 (D. Del. 2006). The code switch converted the generic version of the old product—the only version of the old product still available—to a brand-name product in the view of some health plans. That lowered the reimbursement rate and inhibited pharmacies from requesting to switch new tablet prescriptions to Teva's capsule product. It also prevented pharmacists from automatically substituting the generic capsules for Abbott capsule prescriptions under state generic substitution laws. See Second Amended Answer, Affirmative Defenses, and Counterclaims, Abbott Labs. v. Teva Pharm. USA, Inc., No. 02-1512, 2005 WL 6155984 (D. Del. July 29, 2005); First Amended Counterclaims at 9, Abbott Labs. v. Impax Labs., No. 03-120 (D. Del. Sept. 30, 2005); Teva Pharms. USA v. Abbott Labs., 580 F. Supp. 345, 355 (D. Del. 2008) (noting plaintiffs' allegation that code change resulted in higher insurance copayment). Teva's sales were thus limited to those few doctors who wrote prescriptions specific to Teva's own (Lofibra) brand of the product. Disclosure: Lemley represented Impax, an antitrust plaintiff in this case.

A similar strategy is for the brand owner to deactivate the NDA with the FDA, forcing the ANDA filer to seek a declaration from the FDA that the original drug approval was not withdrawn for safety and efficacy reasons.

[54] Abbott Labs., 432 F. Supp. 2d at 416-17.

The primary countermeasure in response to product hopping has been private antitrust enforcement. Courts applying antitrust law are properly skeptical of claims that purported innovations have harmed consumers, but not every claim of innovation is entitled to deference, and the proper legal standard is a matter of ongoing dispute.[55] In the leading case, the plaintiff presented evidence that multiple switches with no significant benefits for consumers, combined with withdrawal of the older drug from the market, were made specifically to fend off competition from generic drug makers. The case reached trial, and the brand-name firm settled.[56] The court's willingness to consider the product-hopping claim may have curbed similarly egregious behavior by other brand-name firms.

3. Manipulation of the 180-day bounty

Multiple stays and product hopping are unilateral actions by a brand-name firm made at the expense of the generic firm. Manipulation of the 180-day bounty, by contrast, relies on

[55] Compare id. with Walgreen Co. et al. v. AstraZeneca Pharmaceuticals, 534 F. Supp. 2d 146 (D.D.C. 2008) (dismissing antitrust claim involving switch from Prilosec to Nexium); see United States v. Microsoft Corp., 253 F.3d 34, 65 (D.C. Cir. 2001) (per curiam) (en banc) (noting that courts are skeptical of antitrust claims based on product design changes because "firms routinely innovate in the hope of appealing to consumers, sometimes in the process making their products incompatible with rivals," and imposing liability on dominant firms that do so would "inevitably deter a certain amount of innovation"); 1 **Herbert Hovenkamp et al., IP and Antitrust** § 15._ (2d ed 2010). For an argument that any plausible claim of benefit must defeat an antitrust claim for product hopping, see Richard Gilbert, *Holding Innovation to an Antitrust Standard*, 3 **Competition Pol'y Int'l** 47 (2007).

[56] Abbott Labs., 432 F. Supp. 2d at 434 (denying motion to dismiss); Teva Pharms. USA, Inc. v. Abbott Labs., 580 F. Supp. 2d 345, 369 (D. Del. 2008) (denying summary judgment). For endorsement of antitrust liability in this circumstance, see Dogan & Lemley, *supra* note 52. For an argument that product hopping should violate antitrust laws, but using a different approach than *Abbott Labs.*, see generally Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 **Colum. L. Rev.** 1471 (2008).

collusion between the brand-name and generic firm. As discussed in Part I, a brand-name drug maker has a lot at risk in patent litigation with a generic firm. If a court strikes down the brand-name patent, the result is a sharp decline in profit. A generic firm eligible for the 180-day bounty, for its part, has a lot to lose too. Its potential mini-patent disappears if the court decides that the patent is valid and infringed.

These complementary risks set the stage for a peculiar form of non-aggression pact. Both brand-name drug makers and generics gain by settling the pending patent litigation without resolving the status of either the patent or the mini-patent. The brand-name firm is much better off because it has eliminated a near-term threat to its monopoly. And because the FDA regulates entry without evaluating the scope or strength of the relevant patents, settling that suit will enable it to keep even a dubious patent intact for some period of time. The generic drug maker is also much better off. When it eventually enters the market, usually but not necessarily before patent expiration set by mutual agreement of the drug makers, it will reap the 180-day bounty. Thanks to the lack of a successful defense requirement, the generic firm need not win a patent suit to receive the bounty. Consumers, however, suffer from the elimination of a chance at early generic entry, and from higher prices during the 180 days of generic exclusivity.

Such non-aggression pacts have become common. Dozens of settlements of drug patent litigation include this feature.[57] In some cases, the deal includes an additional troubling feature, a payment by the brand-name firm to the generic firm to secure an even later generic entry date. Settlements with cash payments have received a great deal of attention, creating enormous controversy and a large literature considering their effects.[58] The role of the non-aggression pact as a source of delay even absent payment, by contrast, has been mostly

[57] C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 **Colum. L. Rev.** 629, 651-53 (2009) [hereinafter Hemphill, *Aggregate Approach*].

[58] For analyses of the controversy, see, e.g., 1 Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley & Christopher R. Leslie, **IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law** §15.3a1 (2d ed. 2010); Hemphill, *Aggregate Approach*, *supra* note 57; Robin Cooper Feldman, **The Role of Science in Law** 167 (Oxford 2009); Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in 4 **Innovation Policy and the Economy** (Adam B. Jaffe et al. eds. 2004); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 **Mich. L. Rev.** 37 (2009); Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, **Annals of Health Law**, Winter 2010, at 367; Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?,* 98 **Am. Econ. Rev.** (2008); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 **NYU L. Rev.** 1553 (2006) [hereinafter Hemphill, *Paying for Delay*]; Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 **Minn. L. Rev.** 1719 (2003); Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 **J. Econ. Perspectives** 75 (2005); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, **Antitrust**, Spring 2003, at 68; Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 **Rand J. Econ.** 391 (2003); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 **Fla. L. Rev.** 747, 779-96 (2002); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 **Antitrust Bull.** 491, 534-38 (2002); Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 **Minn. L. Rev.** 1767, 1781-82 (2003); Catherine J.K. Sandoval, *Pharmaceutical Reverse Payment Settlements: Presumptions, Procedural Burdens, and Covenants Not to Sue Generic Drug Manufacturers*, 26 **Santa Clara Comp. & High Tech. L.J.** 141 (2009); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 **Antitrust L.J.** 1033 (2004); Robert D. Willig & John P. Bigelow, *Antitrust Policy Towards Agreements that Settle Patent Litigation*, 49 **Antitrust Bull.** 655 (2004).

neglected.[59] That is a serious omission, for as one generic drug CEO has explained, "[e]limination of the risk of losing by the generic company is not just a payment in and of itself, but *the primary* form of payment in Hatch-Waxman settlements."[60]

Settlement by non-aggression pact has other bad consequences for generic entry beyond delaying the entry of the first filer. Later filers—generic drug makers that file ANDAs with Paragraph IV certifications after the first filer—are blocked from FDA approval while the first filer's bounty is pending. That is because the approval of later generic applicants is delayed until 180 days after the date of "first commercial marketing" by the first filer,[61] which in turn is delayed thanks to the settlement. The delay is limited by the possible forfeiture of exclusivity, as explained below. But settlement itself does not amount to such a forfeiture.

Breaking through the resulting bottleneck is difficult, costly, and time-consuming. Under current law, the later filer can force the first filer to use the bounty (i.e., enter with exclusivity) or else lose it, but only if the later filer wins a patent suit of its own. That is difficult and time consuming and, to make matters worse, it is not enough to win in the district court. Only an appellate win by the later filer triggers the first filer's obligation to enter with exclusivity, which it must do within 75 days or else forfeit the bounty.[62] The resulting delay from this process—file

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[59] For exceptions, see Hemphill, *Aggregate Approach*, *supra* note 57, at 651-53; Hemphill, *Paying for Delay*, *supra* note 58, at 1588-94.

[60] Protecting Consumer Access to Generic Drugs Act of 2009: Hearing Before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce, 110th Congress, Mar. 31, 2009 (statement of Bernard Sherman), p. 9.

[61] See 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2006). The description in text applies to new NDAs. For a comparison of this regime to the pre-MMA regime, see Hemphill, Aggregate Approach, at 658-59.

[62] 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (2006).

the ANDA, conduct the district court suit, win the appeal, wait until just before the end of 75 days, then wait another 180 days—can easily stretch for several years.[63] Moreover, in some cases, the settlement with the first filer permits the first filer to launch upon approval of the later filer's ANDA, further reducing the incentive to pursue this strategy. In the meantime, consumers pay monopoly prices.

This account presumes that there is a patent lawsuit between the brand-name firm and the later filer. Often, that cannot be taken for granted because the brand-name firm declines to sue the later filer, even if it sued the first filer. Without a suit, the later filer is bottled up behind the first filer, unable to secure FDA approval. In response, some generic firms file declaratory judgment suits in an effort to trigger (eventually) the first filer's use-it-or-lose-it obligation. A declaratory judgment action, however, is a chancy thing, because there is often a dispute about whether the generic firm has standing to bring its suit.[64] That complication makes this route an even more time consuming, costly, uncertain affair.

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[63] See Dey, L.P. v. Sepracor, Inc., 595 F. Supp. 355, 357 n.1 (D. Del. 2009) (describing this outcome). This description applies to drugs with new ANDAs. For old ANDAs, the result of a later filer's appellate win is not a forfeiture, but a triggering of the first filer's exclusivity. Pub. L. No. 108-173, § 1102(b)(3), 117 Stat. 2066, 2460 (2003) (codified as a note to 21 U.S.C. § 355).

[64] Prior to 2007, the Federal Circuit took the view that declaratory judgment actions were inappropriate in these cases. After the Supreme Court cast serious doubt on this view in MedImmune v. Genentech, 549 U.S. 118, 132 n. 11 (2007), the Federal Circuit changed course. Today, some cases are allowed to move forward, while others are not. Compare Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330, 1334 (Fed. Cir. 2007) (generic firm has standing); Caraco Pharm. Labs., Ltd., v. Forest Labs., Ltd., 527 F.3d 1278, 1288 (Fed Cir. 2008) (same); Teva Pharms. USA v. Eisai Co., 620 F.3d 1341 (Fed. Cir. 2010) (same); Dey, 595 F. Supp. 2d 355 (same); Pfizer Inc. v. Apotex Inc., No. 08-7231 (N.D. Ill. June 30, 2010) (same); with Janssen Pharmaceuticals, N.V. v. Apotex, Inc., 540 F.3d 1353, 1362-63 (Fed Cir. 2008) (generic firm lacks standing); Merck & Co. v. Apotex, Inc., 2008 WL 3992460 (Fed Cir. 2008) (per curiam) (Cosopt) (same); Merck & Co. v. Apotex, Inc., 488 F. Supp. 2d 418 (D. Del. 2007), vacated as moot, 287 Fed. Appx. 884 (Fed. Cir. 2008) (Fosamax) (same). See also Dr. Reddy's

B. Policy Responses to Manipulation of the 180-Day Bounty

There are several possible policy responses to non-aggression pacts and the resulting blocking of later filers. An intervention is possible before, during, or after the Paragraph IV challenge and award of a bounty. Before the challenge occurs, we can limit the set of patents that can provide a basis for the bounty in the first place. Once the challenge occurs, we can either narrow the types of generic-firm conduct that qualify for exclusivity or reduce the effect of exclusivity on later filers. After the challenge is complete, we can use antitrust law to deter and neutralize the effect of manipulation.

1. After the challenge

Most of the current policy attention to this issue concentrates on ex post measures. Private plaintiffs and government enforcers have looked mainly to antitrust law to clean up and, it is hoped, deter manipulation of the bounty. The major focus has been "pay-for-delay" settlements in which the brand-name firm not only reaches a non-aggression pact with the generic firm, but makes a large additional cash payment to the generic firm in exchange for

Laboratories, Ltd. v. AstraZeneca AB, 2008 WL 4056533 (D.N.J. 2008) (generic firm lacks standing as to some patents), order vacated on reconsideration, 2009 WL 3241699 (D.N.J. 2009) (denying dismissal); Ivax Pharmaceuticals, Inc. v. AstraZeneca AB, 2008 WL 4056518 (D.N.J. 2008), order vacated in part on reconsideration, 2009 WL 3208656 (D.N.J. 2009) (same). This time-consuming litigation over standing delays generic entry even when it is ultimately resolved in favor of the generic firm.

delaying the entry date. In these cases, the cash payment has been the centerpiece. The effect of manipulation of the 180-day bounty on later filers has also played a role in some cases.[65]

Antitrust law has so far met with poor to mixed results in cases with a large cash payment.[66] New legislation has been proposed to clarify that pay-for-delay settlements violate either the Clayton Act or the FTC Act.[67] We think that pay-for-delay settlements violate existing antitrust law, and that antitrust properly applies to cases in which the settlement takes the form of a non-aggression pact.[68] The struggle to establish liability in cash payment cases, however, means that a standalone manipulation case without a cash payment is unlikely to be an enforcement priority in the near term.

2. Before the challenge

[65] See, e.g., King Drug Co. v. Cephalon, Inc., No. 06-1797, 2010 WL 1221793, at *19 (E.D. Pa. 2010) (denying motion to dismiss, in part, because plaintiffs alleged that agreement created a bottleneck that blocked subsequent filers).

[66] The Second and Federal Circuits have declined as a matter of law to impose antitrust liability even in cases in which the payment was quite large. See Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 110 (2d Cir. 2010) (per curiam); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1341 (Fed. Cir. 2008). The Eleventh Circuit has applied a somewhat different standard, but with substantial deference to the patent and the settlement. Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294 (11th Cir. 2003); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005). The Sixth Circuit has concluded that some settlements are per se illegal. See In re Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003); see also Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 809–12 (D.C. Cir. 2001) (reaching similar conclusion in dicta); Arkansas Carpenters, 604 F.3d at 108-10 (opinion by Second Circuit panel, explaining that the panel was bound by Circuit precedent, and urging reconsideration of that view).

[67] See, e.g., Preserve Access to Affordable Generics Act, S.369, 111th Cong. (2010), approved by the Senate Appropriations Committee as part of the Financial Services and General Government Appropriations Bill.

[68] Hemphill, *Paying for Delay, supra* note 58, at 1596; Hovenkamp et al., *supra* note 58. Disclosure: Hemphill has served as a consultant to the FTC on the antitrust issues raised by brand-generic settlements.

A second response is to narrow the set of patents that are subject to Paragraph IV challenges, and hence 180-day awards. The FDA implemented one solution along these lines when it narrowed the set of patents that could be listed on the Orange Book by ruling out patents on chemical variants different from the approved drug.[69] The 2003 statutory amendments to the Hatch-Waxman Act might be thought to offer another step in this direction, by providing for forfeiture of exclusivity if the patent that is the basis for the award is delisted from the Orange Book—for example, because the patent does not sufficiently pertain to the approved drug product to be eligible for inclusion.[70] However, the D.C. Circuit concluded that despite this language, even a delisting cannot deprive the generic firm of its continued entitlement to exclusivity.[71] In any event, these measures leave unaffected a large number of unearned awards, particularly since the listing of a patent on the Orange Book is a ministerial act, not one that involves any evaluation by the FDA of the relevance of the patent.[72]

A more ambitious proposal would be to limit the patent award itself, by evaluating drug patents before they become the basis for 180-day awards. Patents are not carefully scrutinized

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69 Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application 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; Final Rule, 68 Fed. Reg. 36676 (June 18, 2003).

70 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC). Under the pre-MMA regime, which contained no similar forfeiture provision, ANDA filers remained eligible for the exclusivity despite delisting, as in the case of Zocor. Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120, 126 (D.C. Cir. 2006).

71 Teva Pharmaceuticals USA, Inc. v. Sebelius, 595 F.3d 1303, 1318 (D.C. Cir. 2010).

72 *See, e.g.,* In re *Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 369-70 (S.D.N.Y. 2002); Watson Pharm., Inc. v. Nenney, 192 F. Supp. 2d 442, 445 (D. Md. 2001); Mylan Pharm., Inc. v. Thompson, 139 F. Supp. 2d 1, 10-11 (D.D.C. 2001), *rev'd on other grounds*, 268 F.3d 1323 (Fed. Cir. 2001).

by the Patent Office before they are issued.[73] That default could be altered for drug patents, for example, by providing for re-examination of every patent that receives a Paragraph IV certification,[74] or even every patent in the Orange Book. Reexamination has the advantage that, unlike a private suit, it cannot be settled once it has begun.[75] And this additional scrutiny would be consistent with proposals that the PTO focus more attention on the most important patents.[76] But it cannot solve the whole problem. The PTO is oriented towards granting, not denying patents.[77] The reexamination process is limited to certain types of prior art, and excludes things like prior sales or uses that are often the most important types of art.[78] And the PTO cannot assess infringement as opposed to validity.

3. *During the challenge*

The third route is to reduce manipulation of the 180-day bounty by altering its source, the award procedure contained in the Hatch-Waxman Act. For example, one somewhat drastic

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[73] Mark Lemley, *Rational Ignorance at the Patent Office*, 95 **Nw. U. L. Rev.** 1495 (2001).

[74] For a proposal along these lines, see Gregory Dolin, *Of Square Pegs and Round Holes: Using Patent Instead of Antitrust Law to Address the Problem of Reverse Settlements* (working paper 2010).

[75] 35 U.S.C. §§301-305.

[76] *See, e.g.,* Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 **Stan. L. Rev.** 45 (2007); Mark A. Lemley et al., *What to Do About Bad Patents*, **Regulation**, Winter 2005-2006, at 10.

[77] *See, e.g,.* Lichtman & Lemley, *supra* note 76, at __.

[78] 35 U.S.C. § 301.

solution is to simply eliminate the bounty.[79] We don't go that far, though some of the arguments about our proposal, discussed in Part IV, also apply to elimination.

We propose to mend the bounty, not end it. Our basic proposal is to narrow the availability of the bounty to those generic drug makers that have done something substantial to earn it. Our inspiration is the successful defense regime initially maintained by the FDA. This idea has been largely neglected, despite its having been used by the FDA for more than a decade.[80] The neglect is even more surprising given one powerful source of support for such a change: Senator Orrin Hatch. Aside from being a prime mover behind the Hatch-Waxman Act, Hatch was an active participant in the development of the 2003 legislative amendments. During the revision process, he often criticized the "almost unbelievable advantage" given to first filers,[81] and repeatedly urged a version of the successful defense regime.[82] The next Part takes up how to accomplish a partial restoration of that regime.

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[79] See, e.g., Ankur N. Patel, Comment, *Delayed Access to Generic Medicine: A Comment on the Hatch-Waxman Act and the "Approval Bottleneck"*, 78 **Fordham L. Rev**. 1075, 1113-14 (2009); Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 **IDEA** 389, 425 (1999); see also Greater Access to Affordable Pharmaceuticals Act of 2003: Hearing Before the Senate Committee on the Judiciary, 108th Congress, Aug. 1, 2003 (statement of Robert Armitage) (proposing a severe limitation on availability of exclusivity).

[80] An exception is Robin Feldman, who has noted that an alteration of the exclusivity rules to apply only if the generic challenger wins on the merits would amount to a return to the successful defense regime. **Robin Feldman, The Role of Science in Law** 165 (2009).

[81] Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the Senate Committee on the Judiciary, 108th Congress, June 17, 2003 (statement of Sen. Orrin Hatch).

[82] "[I]f we are to legislate in this area, why don't we consider overriding Mova and reinstate the old successful defense requirement?" Id. See also 149 Cong. Rec. S 8686, 8692 (June 26, 2003), 2003 WL 21485369; id. at [149]; Cong. Rec. S 8169, 8195 (June 19, 2003) (proposal under consideration "appears to retain a feature of the current system that grants the 180-day marketing exclusivity period to first filers of generic drug applications rather than those applicants actually successful in defeating the

III. An Earned Exclusivity Proposal

The core of our proposal is that to earn the bounty, a first-filing generic drug maker must exert significant effort to secure early generic entry, with the end result of achieving entry without delay. For example, if the generic firm files a Paragraph IV certification, is sued, and wins the suit, it receives the bounty. If the generic firm instead loses the suit, it loses the exclusivity. Nor can it receive the bounty if it settles for delayed entry.

We do not propose an exact return to the successful defense requirement.[83] That would be difficult as a formal matter, since the statute has changed in important ways since 1984. As a substantive matter, moreover, we would grant exclusivity in circumstances where the FDA did not, as discussed below.

A. Narrowing Eligibility for the Bounty

An easy way to implement our proposal is simply to narrow the set of first filers eligible for the bounty. Under current law, only a "first applicant" is eligible. A first applicant is "an applicant that, on the first day on which a substantially complete application containing a [Paragraph IV] certification is submitted for approval of a drug, submits a substantially

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patents of pioneer drug firms." As discussed *infra*, however, Hatch has expressed sympathy for a variety of proposals that promote entry by later filers, some of which diverge from a return to successful defense.

[83] For such a suggestion, see Timothy Chen Salsbury, *Curbing Pay for Delay: The Case for a Legislative Solution* (working paper 2009).

complete application that contains *and lawfully maintains* a [Paragraph IV certification]."[84] It is not enough simply to have applied under the law; the Paragraph IV certification must be "lawfully maintained." If, for example, a generic firm loses a Paragraph IV challenge in court, it may no longer lawfully maintain the certification.[85]

What if the generic firm instead settles the suit? In this situation, too, we think the Paragraph IV certification is no longer lawfully maintained within the meaning of the statute, because the generic firm is no longer pressing its claim. That interpretation is consistent with the statutory text, though courts to date have not read it that way.[86] We propose that the law be clarified to make this interpretation explicit: if the generic firm settles, it is no longer lawfully maintaining its certification. The FDA has not yet conclusively resolved this question,[87] and

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[84] 21 U.S.C. §355(j)(5)(B)(iv)(II)(bb) (emphasis added). The inartful language here is intended to treat any applicant that files on the same day as another as a first filer.

[85] Letter from Gary Buehler, FDA, to [Unnamed] ANDA Applicant, Docket No. 2008-0483 (Oct. 28, 2008) (interpreting "lawfully maintains" in the course of determining 180-day exclusivity for generic version of Cosopt). The ANDA filer must instead convert the certification to Paragraph III, which acknowledges the validity and infringement of the patent, in which case the FDA must wait until patent expiration to approve the ANDA. For a discussion of "lawfully maintained," see David E. Korn et al., *A New History and Discussion of 180-Day Exclusivity*, 64 **Food & Drug L.J.** 335, 346-47 (2009).

[86] See, e.g., Hemphill, Aggregate Approach, *supra* note 57, at 660 n. 125; David Bickart, **The Hatch-Waxman Act, in Developments in Pharmaceutical and Biotech Patent Law** 205, 274 (Practicing Law Institute 2008) (noting this "conceivabl[e]" interpretation); Erica N. Andersen, Note, *Schering the Market: Analyzing the Debate over Reverse-Payment Settlements in the Wake of the Medicare Modernization Act of 2003 and In re Tamoxifen Citrate Litigation*, 93 **Iowa L. Rev.** 1015, 1051-52 (2008) (advocating this approach).

[87] In a 2008 letter granting exclusivity for generic granisetron, the FDA touched on but did not answer this question. See Letter from Gary J. Buehler, Dir., Office of Generic Drugs, FDA, to Marc A. Goshko, Executive Dir., Teva N. Am. 5 (Jan. 17, 2008). In that letter, the FDA concluded that the generic firm had not forfeited exclusivity under certain "failure to market" provisions discussed infra. Although the facts did not include any settlement, the letter considered what might happen in the case of a settlement. It noted that in that event, there would again be no forfeiture of the exclusivity. Id. at 5 n.6. Moreover, if later filers were unable to initiate a declaratory judgment action, the FDA suggested, "[t]his potential

could accomplish this clarification by issuing a rule that interprets the scope of "lawfully maintained." Alternatively, a simple statutory change would accomplish that result.[88]

A second doctrinal route to the same end is to provide for forfeiture in the event of settlement.[89] Under current law, a first applicant loses all eligibility for the bounty if one of several defined events occurs.[90] One of these pertains to entry-delaying agreements between

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scenario is not one for which the statute currently provides a remedy." Id. At the same time, the letter specifically noted that in the particular facts at hand did not raise any allegation of "parked" exclusivity. Id. at 5 n.5. Thus, the FDA had no occasion to address whether the post-MMA regime contains, either as an interpretation of "lawfully maintained" or the forfeiture provisions, a safety valve for removing such a bottleneck.

An analogous argument—that settlement requires conversion from Paragraph IV to Paragraph III—was rejected by the FDA in Letter from Gary Buehler, FDA, to Carmen M. Shepard, Docket No. 2007-0382 (Jan. 29, 2008) (interpreting availability of 180-day exclusivity for ramipril). The drug at issue there was subject to the pre-MMA statute, which had a different regime for awarding exclusivity, and did not include the "lawfully maintained" requirement. The FDA did consider whether a settlement results in forfeiture under an MMA provision that applies to pre-MMA ANDAs, but had no occasion to consider the operation of "lawfully maintained."

[88] This change, taken alone, might not implement our proposal in all cases. That is because lawful maintenance is determined patent by patent. The brand-name firm might decide to sue on one or more patents, yet strategically refrain from suit on one patent. Settlement as to the litigated patents could result in removal of "lawfully maintained" as to those patents, yet there would still be a lawfully maintained challenge on the unlitigated patent, and so exclusivity would still be available. *See* Erika Lietzan & David E. Korn, *Issues in the Interpreation of 180-Day Exclusivity*, 62 **Food & Drug L.J.** 49, 53 n.16 (2007). One way to close this loophole would be an interpretation in which the changed status of the no-longer-litigated patents is extended to the never-litigated patent.

[89] For brief, general proposals in this vein, see Protecting Consumer Access to Generic Drugs Act of 2009: Hearing Before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce, 111th Congress, March 31, 2009 (statement of C. Scott Hemphill); Protecting Consumer Access to Generic Drugs Act of 2007: Hearing Before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce, 110th Congress, May 2, 2007 (statement of Bernard Sherman); Bulow, *supra* note 58, at 178 ("an optimal rule would require that the exclusivity period be forfeit upon the signing of any agreement for deferred entry"); Alfred B. Engelberg, Eliminating Reverse Payments in Pharmaceutical Patent Challenges 4 (working paper 2009) (on file with authors) (similar).

[90] 21 U.S.C. § 355(j)(5)(D)(i). In some cases, patent owners have delisted challenged patents from the Orange Book, raising the possibility that exclusivity might have been forfeited, opening the way to broad

the brand-name firm and the first applicant.[91] However, the provision is a mainly cosmetic addition to the forfeiture scheme. Triggering the provision requires a final appellate judgment that the settlement violates antitrust law. That is difficult and time consuming; by the time the antitrust case is finished, generic entry will likely have already occurred, even for settlements with a late entry date. It is doubtful that the provision will ever be triggered.[92] The antitrust case is a still less likely prospect where the conduct in question is a non-aggression pact that does not include a cash payment. To beef up the forfeiture provision, we propose to simply delete the language that requires an antitrust violation. That would create a forfeiture in the case of any settlement.[93]

A third way to implement this outcome is for the FTC to induce it indirectly in the course of enforcing section 5 of the FTC Act. The FTC could take the view that if a generic firm settles its suit, yet retains eligibility for the exclusivity, this is a violation of section 5. There is ample judicial support for the proposition that manipulation of entry through retained exclusivity is a

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generic entry. The D.C. Circuit held that the first filer was entitled to 180-day exclusivity in that circumstance. Teva Pharms. v. Sebelius, 595 F.3d 1303 (D.C. Cir. 2010).

91 21 U.S.C. § 355(j)(5)(D)(i)(V). The other forfeiture events are failure to market under certain circumstances, withdrawal of the ANDA, removal of the Paragraph IV certification, failure to receive tentative FDA approval, and expiration of the relevant patents.

92 See Shashank Upadhye, **Generic Pharmaceutical Patent and FDA Law** § 14.11 (2010) (arguing that the provision, "while verbose, has no teeth because . . . the forfeit will only occur after a ridiculously long period of time").

93 Another way to implement the forfeiture is to modify a different forfeiture provision, which gives rise to a forfeiture under certain circumstances in which a generic firm fails to market its drug. § 355(j)(5)(D)(i)(I). The forfeiture is potentially triggered where a court reaches a final judgment of invalidity or non-infringement, or a settlement to the same effect, and certain other conditions are satisfied. § 355(j)(5)(D)(i)(I)(bb)(AA), (BB). That provision could be changed to provide for forfeiture where there is *any* final judgment. This route would not require the grace period discussed in the next paragraph because the failure-to-market provisions already contain a grace period.

violation of antitrust law, even in opinions that take a narrow view of antitrust liability in settlement cases.[94] Even if a settlement with retained exclusivity, thus creating a bottleneck, somehow failed to rise to the level of a Sherman Act violation, the FTC could likely challenge the settlement as a violation of section 5 of the FTC Act. Manipulating the bounty in this fashion is just the sort of activity that section 5's extra breadth, relative to the Sherman Act, was made for.[95] An additional benefit of this approach would be to reinforce the FDA interpretation of "lawfully maintained" proposed above, if it did not extend to never-litigated patents; in that case it would be particularly obvious that the never-litigated patents were being used to manipulate the exclusivity, an act subject to section 5 enforcement. The enforcement could be accomplished through FTC challenges in individual cases, or alternatively through rulemaking.

What if the parties settle in a manner that permits immediate entry? In that rare case, we would grant exclusivity, consistent with the successful defense requirement.[96] To

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[94] Cases that emphasize the presence of a bottleneck as a basis for liability include In re Cardizem CD Antitrust Litigation, 332 F.3d 896, 907-08 (6th Cir. 2003); Valley Drug Co. v. Geneva Pharms., 344 F.3d 1295, 1306 n. 18 (11th Cir. 2003); King Drug Co. v. Cephalon, Inc., 702 F. Supp. 2d 514, 534, 535-36 (E.D. Pa. 2010). Cases that acknowledge the bottleneck as a basis for liability, while emphasizing the absence of a bottleneck on their particular facts, include In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323, 1336 (Fed. Cir. 2008); In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 215 (2d Cir. 2006).

[95] The idea that section 5 reaches more broadly than other antitrust statutes is controversial, however. *See, e.g.,* Richard A. Posner, *The Federal Trade Commission: A Retrospective,* 72 **Antitrust L.J.** 761, 766 (2005); Bruce H. Kobayashi & Joshua D. Wright, *Federalism, Substantive Preemption, and Limits on Antitrust: An Application to Patent Holdup*, 5 **J. Comp. L. & Econ.** 469 (2009).

[96] The regulations appear not to have explicitly provided for settlement, but FDA contemplated an award of exclusivity at least where the settlement included a finding of invalidity or noninfringement. See 54 Fed. Reg. 28872, 28895 (1989) (defining "court decision" trigger date by reference to consent decrees and settlement orders, and noting that "final adjudication on the merits is not required to trigger the 180-day period."). The very first award of exclusivity, involving Maxzide, was predicated on a settlement in which the brand-name firm acknowledged noninfringement. The FDA took the view that

implement this difference, we would add a short grace period after settlement—60 days, say—before the "lawfully maintains" or forfeiture provision took effect, so that generic firms entering settlements that did not delay entry could still receive the bounty.[97]

A difficult question with earned exclusivity is whether to grant exclusivity to drug makers that file a Paragraph IV certification but are never sued. As noted above, this is a significant category of cases, amounting to nearly half of all 180-day-exclusivity approvals over the past four years.[98] There is an argument that the generic firm may not have earned its exclusivity in this case. That was the position taken by the FDA in settling upon a successful defense requirement.[99] Moreover, as discussed in the next Part, in at least some cases the generic would have filed the ANDA anyway, even without the exclusivity. Generics already have an incentive to file quickly, because the first filer will also tend to have first approval, with a significant and valuable head start in signing up customers.

On the other hand, the ANDA filer subjected itself to the risk of suit. The generic firm's actions are not trivial: aside from developing its bioequivalence package, it has developed a

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this sufficed for an award of exclusivity, and a district court affirmed this interpretation, over the objection of another generic firm. See Transcript of Proceedings at 5-6, 11-12, Barr Labs., Inc. v. Bowen, No. 87-4574 (D.N.J. Nov. 20, 1987).

97 This grace period could also be limited to those settlements that do not delay entry.

98 See *supra* Part I.C.

99 "To apply the section [granting exclusivity] where there has been no lawsuit would require that the agency . . . assume that Congress intended, contrary to the goals it stated in the legislative history, to create an incentive for delay in generic competition, without any countervailing benefit to society. Moreover, it would provide a windfall to an applicant who has not devoted the considerable time and money necessary for patent litigation." 59 Fed. Reg. 50338, 50353 (1994).

detailed explanation, as it is required to do, of why the patent is invalid or not infringed.[100] It may have raced to file, with the benefits discussed in the next Part.[101] And it may have made the ANDA investment decision before it knew whether it would face a long, expensive, and uncertain suit or just a straightforward bioequivalence analysis. Just as we grant patents not only to those who face a long road, but to those who happen upon an invention easily, we might grant mini-patents both to those who turned out to have to work hard for generic entry and those for whom it turned out to be easy.[102] The D.C. Circuit has adopted this interpretation, holding that where the patentee delists a challenged patent from the Orange Book the first filer to have challenged that patent is entitled to 180-day exclusivity.[103] While the issue is not free from doubt, we think that an award of exclusivity where there is a challenge but no suit is a reasonable approach.

In some cases, though, the generic firms may in fact know (or at least strongly suspect) that the patentee will not file suit in response to a Paragraph IV challenge, perhaps because it is clear that the patent does not cover the proposed drug product. Certainly that turns out to be the case in a surprisingly large number of Paragraph IV filings. We need to encourage such

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[100] See 21 U.S.C. § 355(j)(2)(B)(iv)(II) (2006) (requiring a "detailed statement of the factual and legal basis" for the Paragraph IV certification).

[101] See Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the Senate Committee on the Judiciary, 108th Congress, June 17, 2003 (statement of Timothy J. Muris) (favoring exclusivity for such firms on the ground that it gives generic firms "an incentive to go ahead and be clever and innovative").

[102] The same is not true of those generic firms that settle rather than resolve a challenge. The question of whether the patentee will file a suit is not in the generic firm's control, so the generic cannot eliminate that uncertainty. Settlement decisions, by contrast, are something the generic firm can control and therefore can plan for.

[103] Teva Pharmaceuticals USA, Inc. v. Sebelius, 595 F.3d 1303, 1318 (D.C. Cir. 2010).

filings only if the generic expects ex ante to face significant expenditure or uncertainty to enter the market. That isn't true in cases of settlement; it might or might not be true in cases where no suit is ever filed.[104]

B. Reducing the Effect of the Bounty

Narrowing the eligibility for the bounty is not the only way to reduce the scope for manipulation. An alternative route would be to reduce the effect of the bounty, by permitting later filers to secure approval in situations in which they must currently wait. The basic approach is to expand the forfeiture provisions, so that when a later filer is ready for approval, and is blocked by the bounty, a forfeiture is triggered.[105] For example, forfeiture could be triggered when the later filer either wins in court or is never party to a lawsuit, and is otherwise ready for approval, as indicated by an FDA grant of "tentative approval."[106] The effect of the 180-day bounty is reduced but not eliminated, because it still prevents approval for some later filers that are pure free riders on the first filer's efforts.

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[104] We would also grant exclusivity if a drug maker launches at risk, but that is unlikely to matter much in practice. The launch triggers the exclusivity period immediately, and later filing generic firms are seldom ready to launch by the time the exclusivity period expires.

[105] For a proposal along these lines, see Ashlee B. Mehl, Note, *The Hatch-Waxman Act and Market Exclusivity for Generic Drug Manufacturers: An Entitlement or an Incentive*, 81 **Chi.-Kent L. Rev.** 649, 672-677 (2006).

[106] Senator Hatch has suggested this too. Greater Access to Affordable Pharmaceuticals Act of 2003: Hearing Before the Senate Committee on the Judiciary, 108th Congress, Aug. 1, 2003. The never-sued case could be limited to situations where the brand-name firm either grants a covenant not to sue or, upon a declaratory judgment action, the action either reaches a substantive judgment or is dismissed for lack of jurisdiction. For bills taking this approach, see H.R. 1706, 111th Cong. § 4 (2009) (forfeiture where dismissed for lack of subject matter jurisdiction or covenant not to sue); H.R. 1902, 110th Cong. § 4(2007) (same).

This forfeiture proposal differs from earned exclusivity in that it depends on the actions of the later filer, which does not have exclusivity, rather than the first filer. Variants of the proposal might eliminate 180-day exclusivity altogether in that situation, or transfer it to the second filer. The forfeiture approach applies even when the first filer diligently pursues litigation, but the later filer is simply faster. A variant is to accord first applicant status to the later filer, thereby making it eligible to share in an exclusivity award.[107] This latter variant would be a form of earned exclusivity; it would simply change who is entitled to that exclusivity from the first to file to the first to succeed in entering. While we think such proposals would likely improve on the current regime, they suffer from several disadvantages compared to an earned exclusivity approach. We discuss the relative merits of those two forms of earned exclusivity below.

IV. Litigation in an Earned-Exclusivity World

What would litigation and settlement incentives look like in a world where generic entrants must earn their 180-day exclusivity? We foresee several effects, most positive but some arguably negative.

[107] See, e.g., 111th Cong., S. 1315. This proposal was advanced in Protecting Consumer Access to Generic Drugs Act of 2009: Hearing Before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce, 110th Congress, Mar. 31, 2009 (statement of Bernard Sherman), p. 9. For an academic analysis advocating this approach, see Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, **Rutgers L.J.** (forthcoming 2010). Sherman's testimony also suggests, as an alternative, sole exclusivity for the successful later filer. Some of Hatch's statements suggest that he would support this approach, though the draft bill discussed *supra* provided only for reductions in the scope and effect of a first-filer's grant, not a new grant of exclusivity to later filers.

A. Taking Cases to Judgment

First, earned exclusivity will reduce the prevalence of anticompetitive settlements in which the patentee pays the generic to stay out of the market. Exclusion payments work because the patentee stands to lose more from the invalidation of its patent than the generic challenger stands to gain. This follows from the higher price patent owners charge during the period of exclusivity. As discussed above, once generic companies enter the market, the average price falls dramatically, with drug purchasers capturing the remaining value. The fact that the generic can settle the case and still obtain 180 days of exclusivity expands the range of settlements that are win-win for the litigating parties, even though they are costly to the public as a whole. If settling the case means that the generic has to give up its 180-day exclusivity – and hence a substantial percentage of its expected profits – fewer generics are likely to settle, at least on the same terms. And while some patentees may simply pay the generic more to compensate for the loss of exclusivity, in equilibrium the narrowing range of joint surplus means that fewer cases will settle.

The same is even more likely true of what we have described as nonaggression pacts. Parties that today settle without payment are basing the entry date on the relative value of exclusivity to both parties. Because the generic can obtain 180 days of exclusivity by settling, and because that exclusivity accounts for a majority of the revenue they receive in many cases, they are willing to delay entry substantially in exchange for keeping their exclusivity. If they

have to earn exclusivity, that kind of delayed-entry settlement will mostly disappear, replaced with cases litigated to judgment.

In this context, litigating more cases to judgment is desirable. As noted above, both the Supreme Court and commentators have observed that the invalidation of patents is a public good: one party bears the costs of invalidation, but lots of others share in the benefits.[108] And like most public goods, the invalidation of patents is likely to be undersupplied. Generic manufacturers who have evidence invalidating a patent are using that evidence to obtain a private sweetheart deal, rather than to benefit the world at large by invalidating the patent.[109] Under earned exclusivity, some – though not all – of those patents will be invalidated. That invalidation provides a substantial social benefit.[110]

Of course, generic firms won't win all the cases that are litigated to judgment rather than settled under earned exclusivity. Sometimes the patent will be held valid and infringed. In that case, the public will continue to have to pay the monopoly price for the drug until the patent expires. But that is as it should be. If the patent is valid and infringed, the patentee should be able to exclude others and command a supracompetitive royalty; that's the benefit of

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[108] See sources cited in note 58 *supra*.

[109] We would ban such sweetheart deals; we think they quite clearly violate the antitrust laws. Hovenkamp et al., *supra* note 58, at _; Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 **Minn. L. Rev.** 1719 (2003); Hemphill, *Paying for Delay*, *supra* note 58. The courts have not so far been receptive to this argument (see sources cited in note 66 *supra*), and we assume in this article that that trend will continue.

[110] While we discuss invalidity here, the same logic applies to a finding of noninfringement. A generic that succeeds in designing around a patent while making a bioequivalent compound has provided a public benefit too.

the patent bargain. And the heightened certainty the decision will bring to other litigants is itself of social value.

In any event, the cost to the public isn't likely to be that great. First, data suggest that pharmaceutical patent owners only win about half of the cases that go to judgment now,[111] and presumably would win even fewer of the ones that defendants didn't settle under an earned exclusivity regime.[112] The patent owner win rate is substantially higher than in the previous decade, when generic firms won 73% of cases that went to judgment.[113] The drop in generic win rate is likely traceable to an increase in settlements in weak-patent cases after the FDA's earned-exclusivity rule was rejected, a fact which further strengthens our view that those settlements are problematic.

Second, the fact that the patentee is paying the defendant a substantial amount to stay out of the market suggests that the parties think there is a significant chance the defendant will win; a patentee confident of victory would not be willing to pay as much to end the challenge.[114] Finally, if the patentee pays the defendant to stay off the market altogether, the patent may as well be valid from the public's perspective; they won't benefit from generic entry

[111] RBC Capital Markets, Pharmaceuticals: Analyzing Litigation Success Rates (Jan. 15, 2010) (concluding that generic firms won 48% of cases that reached judgment between 2000 and 2009).

[112] Settlements that would not happen without retained exclusivity are likely to be disproportionately cases that the generic firm was likely to win absent the settlement. That is because the gain from entry-delaying settlement is so much higher (and hence settlement more likely) when the patent protection is weak, and the brand-name firm has more to lose in litigation. Removing this tool of settlement would likely have a disproportionate effect on strong generic challenges.

[113] See FTC, *supra* note 29, at viii (studying results through June 2002).

[114] To be sure, all litigation is uncertain, so smaller payments may reflect a high but not total degree of confidence that the patentee will win the lawsuit.

regardless. Settlements that pay a generic to delay entry but still allow it before expiration give the public some benefit, but less than they would expect from litigation.[115] Some of the benefit, moreover, is an illusion, because entry is timed to coincide with a product switch. By the time entry has occurred, much or most of the sales may have migrated to the newer product not yet subject to generic entry.[116] And while other generic entrants might eventually invalidate the patent, they both have less incentive to do so and will likely be able to do so only later in the patent term.

Finally, while there are some additional litigation costs that will be incurred as more cases move further towards trial or judgment, those litigation costs are dwarfed by the magnitude of the stakes at issue in these cases. Settling a pharmaceutical patent case might plausibly save each side at most a few million dollars in legal fees; in many cases the settlement occurs so late in the case that the savings are trivial.[117] But even assuming a high end number, the savings from settling *all* the cases in our database are far outweighed by the cost to consumers of a single year without competition in a single large drug.

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[115] This follows from the fact that the patentee had to pay the defendant to agree to the delayed entry; the only function that payment serves is to move the entry date back from what the parties would otherwise have agreed to.

[116] For example, in the case of Provigil, scheduled entry under the settlements was timed to occur after Cephalon switched patients to Nuvigil, a single-enantiomer version of the drug. See Complaint at 23-24, FTC v. Cephalon, Inc., No. 08-244 (D.D.C. Feb. 13, 2008) (making this argument, and asserting further that Cephalon delayed Nuvigil launch to coincide more closely with generic entry on Provigil). For an analysis of the combination of settlements and product switches, see Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product-Hopping*, 62 **Fla. L. Rev.** 1009 (2010).

[117] Cite cyclobenzaprene settlement this week on the last day of trial.

B. Earlier Competitive Entry

Second, an earned exclusivity requirement accelerates the competitive effects of entry even in cases in which the patentee and the first generic entrant do settle. As we said earlier, generic entry results in a sharp drop in the price of a drug, but 180-day exclusivity moderates that effect. Data on drug prices shows that the average price drops only slightly when an exclusive generic firm enters, creating a duopoly.[118] The generic firm usually prices its drug at about 80% of the patent owner's price during this period. When 180-day exclusivity expires and other generics enter, the price drops quite substantially, often to 20% or less of the original patent owner's price. Thus, consumers benefit somewhat from first generic entry, but they benefit more from subsequent entry by other generic firms.

An earned exclusivity requirement deprives the first generic drug maker of 180-day exclusivity if it settles the case with delay rather than winning it. As a result, under our proposal even with an exclusion payment consumers will benefit from lower prices earlier than they do today. The settling generic firm will no longer be able to serve as a bottleneck to the entry by others during the 180-day exclusivity period.

C. Effects on Incentives to Bring Patent Challenges

The previous two effects of our proposal are unambiguously positive. The biggest risk of earned exclusivity is that it will discourage generic firms from challenging patents, leaving weak

[118] See *supra* notes 25-27 and accompanying text.

patents intact. If this happened in a significant number of cases, it could hurt rather than help the public by leading to fewer invalidations and fewer instances of early entry.

We think it likely that earned exclusivity will deter some generic challenges that occur today. Like agricultural subsidies that pay farmers not to grow crops, exclusion payments have conditioned some generic firms to automatically challenge at least one patent on a sufficiently valuable drug,[119] hoping that they can be paid to go away. Generic firms that file for that purpose may still do so under our scheme, but because settlements are less likely under our proposal, so too will be challenges designed to provoke exclusion-payment settlements.

But so what? Generic challenges aren't an end in themselves. We want to encourage them only to the extent they will benefit the public, by invalidating or limiting the scope of bad patents and allowing earlier competition for the corresponding drugs. A generic that files a challenge only in order to be paid to drop that challenge isn't providing such a benefit. Nor is a generic that files a challenge destined to fail. We shouldn't worry about weak generic challenges, because they are unlikely to lead to the invalidation of a patent and hence to early generic entry.

The right question, then, is whether generic companies will be less likely to file challenges that actually lead to early entry if they cannot obtain 180-day exclusivity by settling with the patent owner. For that to be true, the number of challenges must decline so far as to

[119] For the most valuable drugs, almost all of them attract a patent challenge. See Hemphill & Sampat, *supra* note 16.

overwhelm the fact that under an earned exclusivity regime more of the challenges that are filed will go to judgment or be settled on more procompetitive terms.

This is ultimately an empirical question, one we cannot answer definitively without trying our alternative. We might obtain some evidence from the recent practice by pharmaceutical patent owners of authorizing generics to compete with ANDA challengers during the 180-day period.[120] That practice, by adding an additional generic competitor into the market, reduces the profitability of a successful challenge and hence, at least in theory, the incentive to launch a challenge in the first place. Authorized generics likely reduce the incentive to challenge significantly more than an earned exclusivity scheme would, since generic challengers may see their profitability cut by half or more, even if the challenge is successful. Nonetheless, the effect of authorized generics on ANDA challenges can put a sort of upper bound on the risk of reducing generic challenges. If generics aren't shying away from filing Paragraph IV ANDAs against firms that use authorized generics, it suggests they are overcompensated, relative to the minimum needed to induce a challenge. And a recent empirical study concludes that authorized generics have not impeded the flow of ANDA filings.[121]

[120] The 180-day exclusivity period only applies to other ANDA filers seeking entry by means of Paragraph IV certifications. It does not prohibit the brand-name firm from licensing another competing generic firm. Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 53–55 (D.C. Cir. 2005).

[121] A recent study sponsored by PhRMA concludes, "During the recent five-year period of increases in authorized generics, we find little overall change in the number of drugs facing [P]aragraph IV certifications, the total number of [P]aragraph IV certifications filed, or the timing of [Paragraph IV] certifications relative to new chemical entity ("NCE") approvals." Ernst R. Berndt, Richard Mortimer &

In the absence of direct empirical evidence, several factors will drive the likely effect on generic challenges. The first is the size of the market. Hemphill and Sampat find that the more money is at stake for a particular drug, the more likely one or more generics are to file an ANDA challenge to the patents covering that drug. And for the largest drugs, multiple generic firms file challenges, quite often on the same day (the first day the law permits them to do so).[122] Indeed, our survey found that nearly half of the 180-day awards (including 12 of 23 no-suit awards, and 5 of 10 settlement awards) occurred in circumstances in which there was at least one, and often many, other generic challengers waiting in line behind the first generic filer. This suggests there is already an overabundance of incentives to challenge the largest drugs, particularly since if multiple generics file ANDAs on the same day, they must share the 180-day exclusivity if they win. The fact that so many nonetheless bring those challenges suggests that for those drugs, 180-day exclusivity isn't necessary to encourage challenge; sharing the market with other generics doesn't seem to deter them.

The real risk of discouraging challenge, then, is not for the largest drugs but for the smallest drugs, the ones for which the value of 180-day exclusivity isn't high enough to cover the anticipated costs of a challenge. But because of the smaller market for those drugs, the social value of generic entry into those markets is correspondingly smaller. That isn't to say the

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Andrew Parece, Do Authorized Generic Drugs Deter Paragraph IV Certifications? Recent Evidence 1 (working paper 2007).

[122] In the case of new chemical entities (drugs that contain no active ingredient previously approved by the FDA), generic challengers must wait to submit an ANDA with a Paragraph IV certification until four years after the brand-name approval. 21 U.S.C. § 355(j)(5)(F)(ii) (2006). That delay increases the probability that multiple generic firms will be ready to file on the first day possible.

social cost of discouraging challenges to these smaller drugs is zero, but the absence of real risk of lost challenges to big drugs reduces the possible social cost overall.

The second factor is the quality of the challenge that is likely to be deterred. Strong challenges benefit society directly when they lead to early generic entry, and indirectly by discouraging brand-name drug makers from applying for patents that are unlikely to be judged valid and infringed. Challenges that are unlikely to be successful, by contrast, just cost money and create uncertainty. So if a challenge is unlikely to succeed, we worry less about deterring it. If a challenge was likely to result in settlement that delayed entry, often until just before the patent was to expire, we worry less about deterring that challenge, because the social benefit of that delayed entry is less. And it is those generic challengers who expect to settle who are most likely to be deterred by an earned exclusivity rule. Even more dramatic, our study finds that 23 out of 49 (47%) instances of 180-day exclusivity occurred because the patentee chose not to file a suit against the ANDA at all. In each of those cases, the generic did very little to justify the exclusivity. Had we not granted exclusivity, the mere act of filing an ANDA in those cases would have opened the market. We concluded above that generics should still get exclusivity in those circumstances, but the fact that they have a decent chance at getting that exclusivity without having to litigate means that they are unlikely to forgo challenges that have even a moderate chance of success.

Third, the timing of challenges also matters. Only the first ANDA filer is entitled to 180-day exclusivity; a generic that files one day later gets no such exclusivity, even if they are the

ones to invalidate a patent. Because there is a significant advantage to being the first generic challenger, we also need to think about whether the discouraged challenge would have displaced a higher-quality challenge. For new chemical entities (NCEs), patentees get four years of data exclusivity before generic challengers may file an ANDA with a Paragraph IV certification.[123] As a result, several generics commonly file an ANDA on the same day – the first day that data exclusivity expires. But for non-NCE drugs, the desirability of being first results in a race to file the first ANDA with a Paragraph IV certification on an Orange Book-listed patent.

A generic that rushes to file an ANDA without doing its research may actually have a weaker case than one that waits. For example, an early generic entrant may rush onto the market by copying the patentee's product exactly, relying only on the possibility of invalidating the patent or on long-shot claims like inequitable conduct. By contrast, a generic firm that spends the time to design around the patentee's drug, coming up with a bioequivalent drug that may not infringe the patent, may take longer to do so, but may also bring a stronger challenge. If earned exclusivity discourages the long-shot challenge because the challenger was simply hoping for a settlement, the result may be to give the second challenger – the one with a stronger case – more incentive to bring its challenge.

We believe the relationship between speed and quality is generally inverse. But the relationship is not perfect. As a result, earned exclusivity is not a perfect solution to the race

[123] Id. Data exclusivity provides a measure of protection to drug innovators with little or no patent coverage. For analyses, see, e.g., Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 **Tex. L. Rev.** 503, 565-67 (2009); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 **Mich. Telecomm. & Tech. L. Rev.** 345, 359-64 (2007); Hemphill, *Paying for Delay*, *supra* note xx, at 1607-10.

problem. But even if earned exclusivity is deterring some challenges, if it deters weaker, long-shot challenges it may actually make it easier to bring stronger challenges.

Finally, some generic firms may file challenges as a sort of fishing expedition, hoping to find information in the course of discovery that suggests the patent was invalid (or fraudulently obtained). Settlement could conceivably encourage these fishing expedition challenges, by giving the generic challenger an "out" if the fishing for invalidity doesn't pan out.[124] As a result, an earned exclusivity rule might discourage some fishing expedition challenges, because it reduces the ex ante expected value of those challenges.

It's not clear whether we should think of this as a good thing or a bad thing. Fishing expeditions are probably weaker than other sorts of challenges. So it is not clear that we should be much bothered by a rule that discourages them. But precisely because the likely outcome of these sorts of challenges is uncertain, some of the discouraged fishing expeditions would have panned out, resulting in invalidation of the patent. And for certain types of challenges – invalidity based on incorrect inventorship, say, or unenforceability based on the concealment of prior art from the PTO – a fishing expedition may be the only way to uncover problems with the patent.

There is, then, some risk that generic firms will be less likely to bring some sorts of ANDA challenges. But the risk is surprisingly modest. Most of the challenges that will be discouraged are weak or speculative ones, and there is even some reason to believe that an

[124] While the generic challenge in that case would by definition be weak, there is always some uncertainty associated with litigation, and so the generic firm might expect to get paid some (small) amount to drop its challenge.

earned exclusivity rule may encourage stronger rather than weaker challenges. We think that while there is some potential social loss here, it is outweighed by the benefits we discussed in the previous three sections.

D. Competing for Exclusivity as an Alternative

Finally, we return to one of the alternative reforms described in Part III: giving 180-day exclusivity not to the first ANDA filer, but to the first generic to successfully enter the market. One possible variant of this approach is largely consistent with ours; it would award 180-day exclusivity only to those who actually defeat the patentee in litigation. It differs from earned exclusivity only in that it would give exclusivity to the first generic to win the lawsuit, whether or not that generic was the first ANDA filer. A second variant would give 180-day exclusivity to the first generic firm to enter the market, no matter how they enter (by defeating the patent, settling with the patentee, or never getting sued).[125]

First entry exclusivity encourages a race among generic drug makers. In the first variant, the race is to bring litigation to a conclusion before other pending suits, so the generic firm can enter the market before its generic competitors. In the second variant, the race is either to win the lawsuit or to be the first to enter through settlement with the patent owner.

First entry exclusivity shares some of the benefits of earned exclusivity. The first variant is essentially a form of earned exclusivity, since any generic challenger will have to win the

[125] S. 1315 is a proposal of the second type, except that it provides for shared exclusivity rather than sole exclusivity for the later filer.

lawsuit in order to get exclusivity. The second variant is more divergent, since it can result in equilibrium in a race to settle for an earlier entry date rather than a race to invalidate the patent. That may still have some marginal desirable effects, since it may drive reverse payment settlements to smaller payments and earlier entry dates as generic firms compete to negotiate to be first on the market. And it may encourage some generic firms to choose quick litigation over delayed entry, gambling that they will be the first to market.

As noted above, racing to enter can have negative effects: it may drive generic firms toward quick but weaker challenges. But the fact that if the challenge fails, others can still step in, ameliorates that problem to some extent.[126] The race creates another area of uncertainty for the first filer, since it may lose 180-day exclusivity through no fault of its own, simply because another generic firm is in a suit that goes to judgment faster. First entry exclusivity can also create difficult problems when defendants are sued in the same case, or when the cases are consolidated.[127] And we can imagine circumstances in which generic companies do side deals to try to influence who gets first generic exclusivity. Similarly, the risk of gaming a first-entry system (by having the patentee authorize a particular generic's entry in order to deny 180-day exclusivity to another, for instance) is one reason to prefer our earned exclusivity proposal.

[126] Not entirely, however, because a first loss by a generic will make it harder as a practical matter for a second generic to win its challenge, even if that challenge is objectively better.

[127] The logical solution would be to share exclusivity in such a case, as current law does when applicants file ANDAs on the same day. But shared exclusivity is less valuable a carrot than a unique entitlement.

A final difference between the proposals is in the ease of implementation. Legislative change is not an easy task. Statutory surgery, particularly in a field as complicated as drug regulation, carries a significant risk of unintended consequences. Indeed, when the Hatch-Waxman amendments were negotiated in 1984, the 180-day bounty was seen as a relatively unimportant provision, the future effects of which were unanticipated.[128] More important, there is some risk that any legislative proposal in this area might be hijacked by drug makers. For example, when the statute was amended in 2003, the FTC's proposals to address the pay-for-delay settlement problem were watered down and altered. In some respects, the 2003 statutory changes actually worsened the problem of delayed generic entry.[129] Thus, a proposal that can be accomplished through agency action, such as ours, has practical advantages over an alternative that requires a statutory change. Nonetheless, first entry exclusivity – particularly the successful litigation variant – is broadly consistent with earned exclusivity, and is certainly an improvement on the present system.

IV. Conclusion

The point of giving generic firms 180-day exclusivity is to encourage them to challenge weak patents and enter the market earlier, lowering prices and benefiting consumers. But 180-day exclusivity has been hijacked. Today, it is a tool that encourages weak challenges to patents

[128] See, e.g., James C. Morrison, *Update on the Hatch-Waxman Amendment Implementation*, 43 **Food Drug & Cosmetic L.J.** 553, 554 (1988) (article by FDA official describing an early controversy involving the exclusivity period, and noting that "[t]his section has not been highlighted in any speeches or guidance letters because the agency did not expect it to be of much significance").

[129] See note xx supra (explaining that forfeiture does not occur until after an appeal).

in the hopes of prompting settlement, and leads generic firms to settle even strong challenges for delayed entry in exchange for keeping their exclusivity. Consumers are arguably worse off than they would be with no 180-day exclusivity at all. Regardless, the system can be dramatically improved by a simple rule: Want to get paid a bounty? Earn it.