

# Life Sciences

## Generics: Hot Issues as Hatch-Waxman Approaches Its 25th Year

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With billions of pharmaceutical investment and sales dollars at stake,<sup>1</sup> it is little wonder generics have triggered so many disputes, investigations, litigation, and legislative initiatives. Approaching its twenty-fifth year, the Drug Price Competition and Patent Term Restoration Act of 1984 (better known as the Hatch-Waxman Act)<sup>2</sup> has precipitated vigorous debate over the rise in patent litigation settlements between brand-name and generic pharmaceutical companies (especially those involving “reverse payments”<sup>3</sup>), action by the Federal Trade Commission (FTC) and Congress intended to curb or ban reverse payments, and the rise of authorized generics. Also drawing growing attention are the expected increase in generic drugs produced by Chinese drug manufacturers and the mounting issues relating to generic biologics.

### The Hatch-Waxman Act

In 1984, given the high cost to commercialize new drugs and to accelerate the approval process and meet the demand for lower-cost generic drugs, Congress passed the Hatch-Waxman Act, which amended the Federal Food, Drug, and Cosmetic Act (FFDCA).<sup>4</sup> Intended to balance the interests of brand-name drug manufacturers with generic drug companies, the Hatch-Waxman Act established a framework to allow less expensive generics to enter the market while not disturbing incentives for innovative, research-based pharmaceutical companies to pursue new drugs.<sup>5</sup>

The Hatch-Waxman Act allows generic drug companies to seek approval from the United States Food and Drug Administration (FDA) before expiration of the brand-name company's patent(s) identified in the FDA's Orange Book<sup>6</sup> by filing an Abbreviated New Drug Application (ANDA)<sup>7</sup> and to do so by relying on the brand-name drug's safety and efficacy studies once bioequivalence of the active ingredient in the generic is shown.<sup>8</sup> The Hatch-Waxman Act requires the ANDA filer to certify for the



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—from a declaration of the American Bar Association



bioequivalent drug that no patent was filed for the listed drug (a "Paragraph I certification"), the patent has expired (a "Paragraph II certification"), the patent will expire on a specific date and the ANDA filer will not market the drug until that date (a "Paragraph III certification"), or the patent is invalid or not infringed upon by the manufacture, use, or sale of the generic drug (a "Paragraph IV certification").<sup>9</sup>

As amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),<sup>10</sup> the Hatch-Waxman Act also requires the ANDA filer making a Paragraph IV certification to notify the New Drug Application (NDA) holder and each patent holder for patents identified in the Orange Book of the ANDA submission within twenty days of the ANDA applicant's receipt of notice from the FDA of filing of the ANDA.<sup>11</sup> Upon receiving notice of the ANDA submission, the patent holder (typically the brand-name company holding the NDA approval) has forty-five days to file a patent infringement lawsuit against the ANDA applicant.<sup>12</sup> If the brand-name company files such a suit, the FDA approval of the generic drug is automatically stayed for thirty months or until a district court returns a decision on the invalidity or infringement of the patent if such a decision is reached before expiration of the thirty-month period.<sup>13</sup>

If successful, the first ANDA applicant (or first ANDA applicants when multiple generic companies simultaneously file) is awarded 180 days of market exclusivity, commencing on the first day the ANDA applicant sells the generic drug after the FDA has granted approval.<sup>14</sup> This 180-day period was intended as a reward to the ANDA applicant to allow the applicant to recoup the costs of litigation.<sup>15</sup> If, under the MMA, the successful ANDA applicant does not market a generic within seventy-five days of receiving approval from the FDA or the ANDA is withdrawn or deemed withdrawn (e.g., because of a change in the Paragraph IV certification, expiration of the patent[s] listed in the Orange Book, or two or more first-filing ANDA applicants entering into an agreement that violates the antitrust laws), the ANDA applicant or applicants forfeit(s) market exclusivity.<sup>16</sup>

To balance the patent-holder's rights and compensate the brand-name drug company's investment in safety and efficacy studies upon which the ANDA applicant relies, the Hatch-Waxman Act also provided a means by which patent holders can obtain a patent term extension for the applicable patent(s) to restore the portion of the patent term lost during the process of obtaining FDA approval of the NDA ("patent term restoration").<sup>17</sup> The patent holder can seek an extension up to an additional five years, or a total effective patent term up to fourteen years, for the FDA-approved use of the product at issue.<sup>18</sup>

## Settling Patent Disputes; Reverse Payments

Increasingly, in the event of patent litigation between the NDA holder and ANDA applicant(s), many NDA holders and ANDA applicants choose to settle such lawsuits on terms that validate the brand-name drug patent(s) in return for payments to generic drug companies, (called "reverse payments," as they are the reverse of the ordinary course of payment in settling a patent dispute).<sup>19</sup> Under the MMA, NDA holders and ANDA applicants must file certain agreements, including patent litigation settlement agreements or agreements concerning authorized generics (addressed below), with the FTC and the U.S. Department of Justice (DOJ) within ten days of execution.<sup>20</sup>

As a result, the FTC, purchasers of drugs, and rival generic drug manufacturers increasingly have brought antitrust suits against both NDA holders and ANDA applicants in several such cases alleging that such settlement agreements involving reverse payments are anticompetitive. The FTC achieved some early successes in these suits<sup>21</sup> and, for a while, the increased antitrust scrutiny chilled settlements involving brand-name drug manufacturer payments to generic companies.<sup>22</sup>

The FTC met with two severe setbacks in 2005 and 2006, however, when two appellate courts issued opinions offering a more lenient policy in reverse payment cases (essentially permitting such settlements unless they exceed the scope of the patents at issue) and the U.S. Supreme Court denied certiorari in each case. In *Schering-Plough Corp. v. FTC*, the Eleventh Circuit vacated an FTC decision holding that reverse-payment settle-

ment agreements between Schering-Plough (the brand-name company) and Upsher-Smith Laboratories and ESI Lederle (the generic companies) relating to the drug K-Dur 20<sup>®</sup> had unreasonably restrained competition and violated the antitrust laws because they delayed entry of generic versions of K-Dur 20<sup>®</sup>.<sup>23</sup> The appellate court held that the settlement agreements did not involve concessions by the generic companies that exceeded the exclusionary scope of the patent, and the agreements therefore were not anticompetitive in violation of the antitrust laws.<sup>24</sup> In the second case, *In re Tamoxifen Citrate Antitrust Litigation*, involving AstraZeneca PLC (the brand-name company) and Barr Laboratories (the generic company), although applying a different analysis to a similar reverse-payment settlement relating to a breast cancer drug, the Second Circuit dealt the FTC another blow.<sup>25</sup> The Second Circuit reached the same conclusion in determining that the agreement at issue did not exceed the scope of the patent's protection and did not violate the antitrust laws.<sup>26</sup>

Following these cases, the FTC reported receiving forty-five brand-generic and generic-generic agreements filed under the MMA for the 2006 fiscal year, more than double the number



compared to those received in each of the prior two years.<sup>27</sup> More recently, on May 21, 2008, the FTC reported receiving another forty-five such agreements for the 2007 fiscal year.<sup>28</sup> Among the forty-five agreements filed during the 2007 fiscal year, forty-two were between brand-name and generic manufacturers, one was between generic manufacturers, and two were between other manufacturers. Of the generic manufacturers involved, 79% were first-filing ANDA applicants under the Hatch-Waxman Act.<sup>29</sup> Of the forty-two agreements filed between brand-name and generic manufacturers, thirty-three were final settlements and nine were interim agreements; of these thirty-three final settlements, twenty-five contained a restriction on generic entry. Among these restricted settlements, fourteen included a reverse payment to the generic manufacturer. These payments either took the form of a side deal not directly related to the resolution of the patent litigation or an agreement by the brand-name manufacturer not to launch or sponsor an authorized generic (explained further below) for a certain period of time. The remaining eleven restricted settlements provided no compensation to the generic manufacturer. Eight of the thirty-three settlements filed between brand-name and generic manufacturers did not contain a restriction on generic entry; however, two required compensation to the brand-name manufacturer.<sup>30</sup> Overall, there is a trend to compensate generic companies in the form of a brand-name manufacturer's agreement not to sponsor or compete by introducing an authorized generic for some period of time.

The DOJ has indicated that it will not support action against such agreements.<sup>31</sup> Significant risk, however, remains in connection with such agreements, as the FTC has indicated that it will not walk away from them and legislation is pending that would restrict such agreements.

On February 13, 2008, the FTC filed suit against Cephalon Inc., attacking the company's patent suit settlement agreements with, and reverse payments totaling \$200 million to, four ANDA applicants (Teva Pharmaceuticals USA, Ranbaxy Laboratories, Mylan Pharmaceuticals, and Barr Laboratories).<sup>32</sup> The FTC did not name the generic companies and assert a Sherman Act section 1 conspiracy claim as it had in prior suits but instead sued only Cephalon—alleging that the agreements delayed generic entry for the \$800 million sleep-disorder drug Provigil® and, therefore, unlawfully monopolized the market for this drug and its generics through a course of anticompetitive, exclusionary conduct. The FTC alleges that Cephalon “bought off” the four generic companies because, during the course of the patent case it brought against all four generic companies, Cephalon realized that market entry by at least one of the four companies was inevitable in 2006 (when the thirty-month stay under the Hatch-Waxman Act would expire), given a lack of confidence in the patent at issue—which covered only the particle size patent for the active ingredient called “modafinil,” not a broader patent covering the active ingredient itself. The agreements provided that each of the generic manufacturers could introduce a generic version in April 2012—three years before Cephalon's exclusivity period (based on the term of the patent and a six-month extension obtained from the FDA) is to expire. Expressing the FTC's intent to prosecute this case fully and put pressure on companies entering

these agreements, in his statement concurring in part and dissenting in part because he believed the four generic companies also should have been named in the suit, FTC Commissioner Liebowitz stated:

Although I am confident the Commission will win this case against Cephalon, it will likely take years, as most antitrust cases do. In the meantime, Congress should pass the bipartisan legislation—now moving through both houses—that would ban these pay-for-delay deals completely (while still allowing legitimate settlements).<sup>33</sup>

Even more recently, at the same time it issued its 2007 fiscal year report, the FTC released a statement reflecting the FTC's intent to continue to scrutinize these agreements and take action when these arrangements risk harm to consumers.<sup>34</sup> On May 21, 2008, Commissioner Liebowitz commented that “pay-for-delay settlements continue to proliferate,” and FTC Chairman William E. Kovacic said that the report “confirms that settlements with potentially anticompetitive arrangements continue to be prevalent.” Chairman Kovacic also stated that the FTC “remains committed to ensuring that brand and generic companies do not use such settlements as a way to deny consumers the benefits of competition.”<sup>35</sup>

Opponents of these agreements continue to push for a legislated ban of reverse-payment agreements that delay entry of lower-cost generics. Others—including the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade association for the brand-name drug industry—support an approach in which these agreements are judged on a case-by-case basis by the FTC and the courts. Given the ongoing litigation efforts and the apparent stall in passage of the pending legislation, until the Supreme Court grants certiorari in a case involving a brand-generic or generic-generic agreement, these cases appear likely to continue to generate litigation and controversy for some time to come. Apparently, the FTC is angling to position the *Cephalon* case to elicit a split in the circuits to persuade the Supreme Court to grant certiorari following any appeal. However, because they did not bring a section 1 claim in the *Cephalon* case as it had in the *Schering-Plough* and *Tamoxifen* cases, the FTC may have undermined its chances of creating such a split and obtaining Supreme Court review. The *Cephalon* case will continue to be a closely watched case during the Hatch-Waxman Act's twenty-fifth year.

### Authorized Generics

As mentioned above, authorized generics are often a component of reverse-payment settlements. Authorized generics are drawing special scrutiny and causing division within the generics industry itself.

An authorized generic is “any drug sold, licensed, or marketed under an NDA approved by the FDA . . . and marketed, sold or distributed under a different labeler code, product code, trade name, trademark or packaging . . . than the brand drug.”<sup>36</sup> The brand-name company can offer authorized generics during the 180-day exclusivity period granted to first-filer ANDA applicants, to protect their products and revenues—typically by licensing to



a third-party manufacturer or distributor (or through a brand-name-owned subsidiary or division). The authorized generic does not require FDA approval because it relies not upon an ANDA for approval but on the original NDA filed by the brand-name drug company. Nothing in the Hatch-Waxman Act prohibits brand-name companies from selling their own generics (apparently they were the subject of discussion or debate at the time), and the courts, FDA, and FTC have agreed that marketing authorized generics during the 180-day exclusivity period is not illegal.<sup>37</sup> The issue of authorized generics, however, has fractured the generic drug community; not all generic companies oppose authorized generics.

The controversy centers around brand-name drug companies using authorized generics not only to settle Hatch-Waxman/Paragraph IV-related patent litigation but also to manage product lifecycles and protect revenue streams. By launching authorized generics, brand-name companies are able to participate in the generic market, generate royalties from generic companies to support further research and development, and keep brand-name manufacturing plants at capacity, allowing the brand-name companies to maintain productivity and margins.<sup>38</sup> Opponents argue that such practices are contrary to one of the purposes of the Hatch-Waxman Act: to encourage generic competition. Currently some opponents are pushing bipartisan legislation to amend the FFDCA to ban authorized generics during the 180-day exclusivity period for the first-filing generic(s) provided by the Hatch-Waxman Act,<sup>39</sup> and the FTC currently is studying the economic impact of authorized generics.<sup>40</sup>

Opponents of authorized generics argue that these drugs discourage generic companies from filing an ANDA and challenging invalid drug patents—by undermining the 180-day market exclusivity incentive granted to the successful patent-challenging ANDA applicant, because the 180-day exclusivity period is intended to allow the successful ANDA applicant to recoup its litigation costs in challenging the brand-name drug patent(s).<sup>41</sup> As a result, opponents of authorized generics advocate that authorized generics should be subject to the same 180-day exclusivity limit applied to a “true” generic.<sup>42</sup> Proponents reject the notion that a brand-name launch of an authorized generic undermines incentives of the Hatch-Waxman Act to allow the patent-challenging generic company to recoup litigation costs, given the profits to be gained by entering the generic drug market far outweigh the costs of patent litigation.<sup>43</sup> Proponents also point to the lack of evidence that authorized generics deter generic companies from filing ANDAs with Paragraph IV certifications.<sup>44</sup>

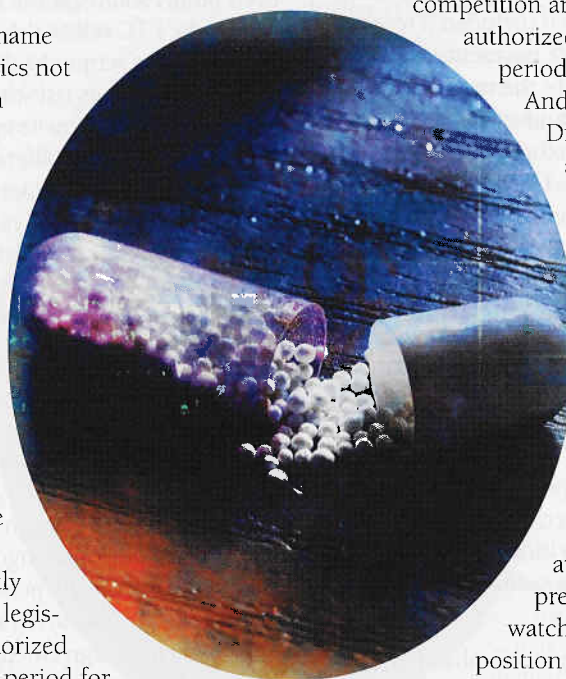
Opponents of authorized generics also argue that, because authorized generics are identical to the branded drugs, they face

fewer regulatory hurdles such as the ANDA process and securing reimbursement under Medicaid and Medicare programs.<sup>45</sup> In other words, because true generics must overcome these hurdles (unlike authorized generics), introduction of authorized generics causes harm to competition in the generic market and threatens monopolistic conduct. Authorized generic proponents, however, view authorized generics as pro-competitive, fostering competition and lower prices in both the brand-name and generic markets particularly during the 180-day market exclusivity period.<sup>46</sup>

The FDA has taken the position that authorized generics promote competition and has denied requests to stop the sale of authorized generics during the 180-day exclusivity period reserved for first-filer ANDA applicants.<sup>47</sup>

And, in *Teva Pharmaceuticals v. FDA*, the U.S. District Court for the District of Columbia and the U.S. Court of Appeals for the District of Columbia both affirmed that Pfizer could sell its authorized generic for the epilepsy drug Neurontin® during Teva’s period of exclusivity.<sup>48</sup>

The bipartisan legislation to amend the FFDCA to ban authorized generics during the 180-day exclusivity period for the first-filing generic(s) is not expected to move before the FTC completes and publishes its report in 2008. In the meantime, opponents of authorized generics likely will continue to press their case, and all stakeholders will be watching to see whether the FTC modifies its position on authorized generics.



## Chinese Generics

Layered into the reverse payment and authorized generic debates is the introduction of Chinese generics. Attempting to give India a run for its money as a producer of generic drugs, and already the world’s largest manufacturer of active pharmaceutical ingredients, China is expected to be an increasing source of finished generic drugs. Last year, the FDA granted Zhejiang Huahai Pharmaceutical Company approval of the first Chinese generic for the AIDS drug nevirapine once the Boehringer Ingelheim drug patent expires in 2012.<sup>49</sup> An additional ten Chinese companies are expected to gain approval for other generic drugs shortly, according to a recent IMS Health Inc. report.<sup>50</sup>

Assuming consumers rebound from recent safety concerns over drugs made with ingredients from China (specifically, the recent episodes concerning contaminated blood-thinning agent heparin<sup>51</sup>), the impact of approval and market entry of Chinese generic drugs is expected to increase competition and lower drug prices dramatically. One consequence may be additional reverse-payment or authorized-generic arrangements between brand-name companies and their counterpart Chinese generic competitors. An additional consequence of Chinese generics may

be to accelerate the resolution of related legislation intended to curtail such agreements and authorized generics.

## Generic Biologics

The Hatch-Waxman Act does not fully address the brewing battles between brand-name biologics and generic biologics (also referred to as “biogenerics,” “biosimilars,” “follow-on biologics,” or “FOBs”). These conflicts concern the required approval process for generic biologics, appropriate period of data exclusivity due brand-name companies, and patent-term restoration due innovative brand-name companies to compensate them and the venture capital backers for their investments. At the time Congress enacted the Hatch-Waxman Act, biologics were an infant industry.

With many biologics such as insulin, erythropoietin, human growth hormone, and filgrastim off patent or coming off patent, the debate rages over how to balance the interests of brand-name biologic companies and manufacturers of generic biologics. Biologics differ from pharmaceuticals given their genesis; while pharmaceuticals are comprised of small molecules or chemical compounds, biologics are comprised of large, more complex molecules using living organisms.

In June 2007, the Senate Health, Education, Labor, and Pensions Committee approved the Biologics Price Competition and Innovation Act of 2007,<sup>52</sup> and, in March 2008, House Representatives Anna Eshoo (D-CA) and Joe Barton (R-TX), the ranking Republican on the Energy and Commerce Committee, introduced the Pathway for Biosimilars Act in the House of Representatives.<sup>53</sup> Additional bills were introduced in the House of Representatives earlier last year.<sup>54</sup> The bills generally address a number of patent safety, interchangeability, data exclusivity, market exclusivity, and patent-related issues. Various stakeholders are now gearing up to establish the legislative and regulatory framework that will govern generic biologics in the \$90 billion biotechnology industry.<sup>55</sup> Venture capitalists, in particular, are increasingly engaging in the debate given the billions of dollars of venture capital funds invested annually in biotech companies.<sup>56</sup> Given the stakes, the pending legislation and economic impacts continue to garner close scrutiny.

## Conclusion

In its nearly twenty-five-year existence, the Hatch-Waxman Act, while attempting to balance various stakeholder interests, has triggered various stakeholders to spend hundreds of millions of dollars on judicial, administrative, and legislative activities aimed at refining its impact. The studies, debate, private and public enforcement activities, and legislative initiatives no doubt will continue. Especially with increasing global sources of competition in the pharmaceutical markets, the priority and push for more affordable medicine, and biologics garnering increasing attention as more biologics come off patent, the next twenty-five years no doubt will see new issues and corresponding additional judicial, administrative, and legislative activities.

- 1 See Janet Woodcock, M.D., Acting Deputy Comm'r for Operations, U.S. Food & Drug Administration, FDA's "Critical Path" Initiative, (July 7, 2004), [www.fda.gov/oc/initiatives/criticalpath/woodcock/woodcock.html](http://www.fda.gov/oc/initiatives/criticalpath/woodcock/woodcock.html) (estimating the cost of bringing a successful drug to market as ranging from \$800 million to \$1.7 billion). See also Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180 (2003) available at [www.cptech.org/ip/health/econ/cimasi2003.pdf](http://www.cptech.org/ip/health/econ/cimasi2003.pdf) (estimating that the total research and development cost per new drug is \$802 million in 2000 dollars). Generics, on the other hand, cost less to develop and purchase, generally entering the market priced 20–80% lower than their brand-name counterparts and capturing between 44–80% of the brand-name drug's sales within a year of launch. See CONGRESSIONAL BUDGET OFFICE, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (1998), [www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf](http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf).
- 2 21 U.S.C. § 355 (2000).
- 3 Reverse payments also are referred to as “exclusion payments” or “pay to delay.”
- 4 Hatch-Waxman Act, Pub. L. No. 980417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (1994)); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (2000).
- 5 See 21 U.S.C. § 355.
- 6 The “Orange Book” is the FDA's official listing of approved drugs and includes identification of patents covering such drugs pursuant to 21 U.S.C. § 355(j)(2)(A)(i), 355(j)(7). Formally named *Approved Drug Products with Therapeutic Equivalence Evaluations*, the Orange Book is available electronically at [www.fda.gov/cder/ob](http://www.fda.gov/cder/ob).
- 7 21 U.S.C. § 355(j).
- 8 21 U.S.C. § 355(j)(2)(A). The generic drug company may not start making the generic drug available until expiration of the brand-name drug manufacturer's patent. 21 U.S.C. § 355(j)(5)(B)(ii).
- 9 21 U.S.C. § 355(j)(2)(A)(vii).
- 10 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 26 U.S.C. and 42 U.S.C.). To comply with the MMA, brand-name and generic pharmaceutical companies must file certain brand name-generic and generic-generic agreements with the FTC and the U.S. Department of Justice within ten days of execution. See Fed. Trade Comm'n, *Medicare Prescription Drug and Improvement Act Requires Drug Companies to File Certain Agreements with the Federal Trade Commission and U.S. Department of Justice* (2004), [www.ftc.gov/os/2004/01/040106pharmules.pdf](http://www.ftc.gov/os/2004/01/040106pharmules.pdf).
- 11 21 U.S.C. § 355(j)(2)(B)(i), (i)(2)(B)(ii)(II), (j)(2)(B)(iii).
- 12 21 U.S.C. § 355(j)(5)(B)(iii).
- 13 *Id.* During this thirty-month period, the FDA cannot approve the generic drug unless the patent or patents expire, a court finds the patent(s) invalid or not infringed, or thirty months have passed since the generic ANDA filer notified the brand-name drug patent holder of the ANDA filing. 21 U.S.C. § 355(j)(5)(B)(iii).
- 14 21 U.S.C. § 355(j)(5)(B)(iv).
- 15 See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1075 (D.C. Cir. 1998).
- 16 21 U.S.C. § 355(j)(5)(D)(i).
- 17 35 U.S.C. § 156(b).
- 18 35 U.S.C. § 156(g)(6)(A), 156(c)(3).
- 19 See, e.g., *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).
- 20 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2071 (2003). See also Fed. Trade Comm'n, *supra* note 10.
- 21 See, e.g., *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 911 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004) (holding that restrictive terms exceeding the scope of a patent's monopoly in a settlement agreement involving brand-name and generic drug manufacturers were per se illegal).
- 22 Jon Leibowitz, Comm'r, Fed. Trade Comm'n, Prepared Statement Before the Subcommittee on Commerce, Trade and Consumer Protection, Committee on Energy and Commerce, United States House of Representatives on Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to Anticompetitive Patent Settlements in the Pharmaceutical Industry 14



- (May 2, 2007), available at [www.ftc.gov/os/testimony/P859910%20Protecting\\_Consume\\_%20Access\\_testimony.pdf](http://www.ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf).
- 23 402 F.3d 1056, 1058 (11th Cir. 2005).
- 24 *Id.* at 1071, 72, 76.
- 25 429 F.3d 370 (2d Cir. 2005), amended by 466 F.3d 187, 190 (2d Cir. 2006), cert. denied, 127 S. Ct. 3001 (2007).
- 26 *Id.* at 218-20.
- 27 Fed. Trade Comm'n, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2006, A Report by the Bureau of Competition 1, [www.ftc.gov/reports/mmact/MMAreport2006.pdf](http://www.ftc.gov/reports/mmact/MMAreport2006.pdf).
- 28 Fed. Trade Comm'n, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007, A Report by the Bureau of Competition 1 (2008), [www.ftc.gov/os/2008/05/mmaact.pdf](http://www.ftc.gov/os/2008/05/mmaact.pdf).
- 29 *Id.* at 1-2.
- 30 *Id.* at 3.
- 31 Brief for United States as Amicus Curiae at 11, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273) ("the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful").
- 32 Complaint for Injunctive Relief, *FTC v. Cephalon, Inc.*, No. 1:08-cv-00244 (D.D.C. Feb. 13, 2008), available at [www.ftc.gov/os/caselist/0610182/080213complaint.pdf](http://www.ftc.gov/os/caselist/0610182/080213complaint.pdf). The FTC's lawsuit came nearly two years after the generic drug company Apotex sued the same parties because the 180-day exclusivity period granted to the first ANDA filer prevented subsequent generic ANDA filers from entry. See Complaint at 25, *Apotex v. Cephalon, Inc.*, No. 02768 (W.D. Pa. June 26, 2006), available at [www.orangebookblog.com/files/7303apotex20complaint.pdf](http://www.orangebookblog.com/files/7303apotex20complaint.pdf).
- 33 Jon Leibowitz, Statement of Commissioner Jon Leibowitz Concurring in Part and Dissenting in Part in the Matter of Cephalon, Inc., Matter No. 061-0182 at 3, [www.ftc.gov/os/caselist/0610182/080213comment.pdf](http://www.ftc.gov/os/caselist/0610182/080213comment.pdf). The still-pending legislation Commissioner Leibowitz referred to is Protecting Consumer Access to Generic Drugs Act of 2007, H.R. 1902, 110th Cong. (2007), and bipartisan bills Preserve Access to Affordable Generics Act, S. 316 & H.R. 1432, 110th Cong. (2007). All bills essentially seek to ban agreements resolving or settling a patent infringement suits in which an ANDA filer receives anything of value and the ANDA filer agrees not to research, develop, manufacture, market, or sell, for any period of time, the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim.
- 34 News Release, Fed. Trade Comm'n, FTC's Bureau of Competition Issues FY 2007 Summary of Pharmaceutical Company Settlement Agreements: Nearly Half Involved Payment to Generic Firms, Restricted Generics' Ability to Enter the Market (May 21, 2008), [www.ftc.gov/opa/2008/05/drug.shtm](http://www.ftc.gov/opa/2008/05/drug.shtm).
- 35 *Id.*
- 36 42 C.F.R. § 447.506(a) (2007).
- 37 *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 53-54 (D.C. Cir. 2005) *aff'd*, 410 F.3d 51 (D.C. Cir. 2005); *Mylan Pharm., Inc. v. FDA*, 454 F.3d 270 (4th Cir. 2006); Prohibit the marketing and distribution of Authorized Generics until the expiration of the first generic applicant's exclusivity period, No. 2004P-0075/CP1 (Feb. 18, 2004) [hereinafter Prohibit Marketing] (petition denied July 2, 2004); Prevent Pfizer Inc. from marketing a generic version of Accupril until after the expiration of Teva's 180-day exclusivity period, No. 2004P-0261/CP1 (June 10, 2004) [hereinafter Prevent Pfizer] (petition denied July 2, 2004); see Jon Leibowitz, Comm'r, Fed. Trade Comm'n, Health Care and the FTC: The Agency as Prosecutor and Policy Wonk 8-10 (May 12, 2005), [www.ftc.gov/speeches/leibowitz/050512healthcare.pdf](http://www.ftc.gov/speeches/leibowitz/050512healthcare.pdf).
- 38 See Food & Drug Admin., You Know That Question That Goes Through Your Mind When You Take Your Generic Drug? Here's the Answer (2005), [www.fda.gov/cder/consumerinfo/generic\\_info/genericsquestion\\_brochure.htm](http://www.fda.gov/cder/consumerinfo/generic_info/genericsquestion_brochure.htm) (brand-name firms manufacture an estimated 50% of generics).
- 39 Fair Prescription Drug Competition Act of 2007, S. 438, 110th Cong. § 2 (2007); Fair Prescription Drug Competition Act of 2007, H.R. 806, 110th Cong. § 1 (2007).
- 40 See Notice of FTC Information Collection Activities, 71 Fed. Reg. 16,779, 16,779-80 (Apr. 4, 2006), available at [www.ftc.gov/os/2006/03/PO62105\\_AuthorizedGenericDrugStudyFRNotice.pdf](http://www.ftc.gov/os/2006/03/PO62105_AuthorizedGenericDrugStudyFRNotice.pdf).
- 41 See John R. Thomas, Congressional Research Service Report for Congress, Authorized Generic Pharmaceuticals: Effects on Innovation 9-10 (2008), [http://digital.library.unt.edu/govdocs/crs/data/2006/upl-meta-crs-9508/RL33605\\_2006Aug08.pdf](http://digital.library.unt.edu/govdocs/crs/data/2006/upl-meta-crs-9508/RL33605_2006Aug08.pdf) (hereinafter CRS Report). Mylan reportedly lost tens of millions in revenues when Procter & Gamble licensed Watson Pharmaceuticals to sell an authorized generic of nitrofurantoin for the treatment of urinary tract infection just before Mylan was to introduce its generic. See *id.* at 14-15; Mylan, 454 F.3d at 273.
- 42 Anna D. Kraus & Stefanie D. Doebler, *A Crippling Blow? CMS' Price Reporting Rule May Chill Authorized Generics*, LIFE SCI. NEWSLETTER (Am. Health Lawyers Ass'n), Mar. 2008, at 2.
- 43 The average cost of a Paragraph IV challenge, inclusive of ANDA and litigation costs, is \$10 million, while the return on investment during the 180-day period is over 1100% without competition from an authorized generic and nearly 500% with competition from an authorized generic. M. Howard Morse, Address at the 2007 Annual Pharmaceutical Care Management Association Annual Meeting: Authorized Generics (Oct. 2007), [http://pcmanet.org/assets/2008-03-24\\_Morse%20-%2010.30.pdf](http://pcmanet.org/assets/2008-03-24_Morse%20-%2010.30.pdf) (summarizing various economic studies).
- 44 See Kevin A. Hassett & Robert J. Shapiro, The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals 3 (May 2007), [www.sonecon.com/docs/studies/050207\\_authorizedgenerics.pdf](http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf).
- 45 Kraus & Doebler, *supra* note 42.
- 46 *Id.*; see CRS Report, *supra* note 41, at 10; Pharm. Research and Mfrs. Am. (PhRMA), Statement on Authorized Generics (July 31, 2006), [www.phrma.org/newsroom/press\\_releases/phrma\\_statement\\_on\\_authorized\\_generics/](http://www.phrma.org/newsroom/press_releases/phrma_statement_on_authorized_generics/) (referencing PhRMA-supported 2006 study by IMS Consulting, a division of IMS Health, finding a 15.8% discount in retail prices); see also Hassett & Shapiro, *supra* note 44 (reporting that generics launching without competition from authorized generics enjoyed a higher margin compared with generics launched with such competition). But see Aidan Hollis & Bryan A. Liang, *An Assessment of the Effect of Authorized Generics on Consumer Prices* 18 (2006), [www.gphaonline.org/AM/Template.cfm?Section=Home&section=2006&template=/CM/ContentDisplay.cfm&ContentFileID=329](http://www.gphaonline.org/AM/Template.cfm?Section=Home&section=2006&template=/CM/ContentDisplay.cfm&ContentFileID=329) (finding discounts with competition from authorized generics was "almost indistinguishable" from discounts without competition from authorized generics).
- 47 U.S. Food & Drug Admin., FDA Supports Broader Access to Lower Priced Drugs, FDA Talk Paper (July 2, 2004), [www.fda.gov/bbs/topics/answers/2004/ANS01296.html](http://www.fda.gov/bbs/topics/answers/2004/ANS01296.html); see Prohibit Marketing, *supra* note 37; Prevent Pfizer, *supra* note 37.
- 48 355 F. Supp. 2d 111 (D.D.C. 2004).
- 49 Boehringer Ingelheim offers nevirapine under the trade name Viramune® and also in the United States by Pfizer under the brand-name Viracept®.
- 50 Ben Hirschler, *Chinese Drugs Seen Driving Down Generic Prices*, REUTERS, May 13, 2008.
- 51 E. g., Gardiner Harris, *U.S. Identifies Tainted Heparin in 11 Countries*, N.Y. TIMES, Apr. 22, 2008.
- 52 Biologics Price Competition and Innovation Act, S. 1695, 110th Cong. (2007).
- 53 Pathway for Biosimilars Act, H.R. 5629, 110th Cong. (2008).
- 54 Patient Protection and Innovative Biologics Medicine Act of 2007, H.R. 1956, 110th Cong. (2007); Access to Life-Saving Medicine Act, H.R. 1038, 110th Cong. (2007).
- 55 See Stephen Langel, *Lawmakers Ponder Fix for the FDA*, ROLL CALL, May 22, 2008, at 19, 32.
- 56 PriceWaterhouseCoopers & Nat'l Venture Capital Ass'n, *Venture Capital Investing Hits \$25.5 Billion in 2006* 2 (2006), [www.nvca.org/pdf/06Q4MTPRnewsFINAL.pdf](http://www.nvca.org/pdf/06Q4MTPRnewsFINAL.pdf) (estimating venture capital groups invested \$25.5 billion in 2006, 28% of which was invested in life science companies).