Authorized Generics: Consumer Friend or Foe?

By Michelle H. Seagull[*]

I. INTRODUCTION

The Drug Price Competition and Patent Term Restoration Act of 1984[1] (the "Hatch-Waxman Act" or "Act") aims to "strike a balance between two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."[2]

The Hatch-Waxman Act's efforts to promote these two competing goals has resulted in unintended consequences—many of which force courts and regulators to confront conduct that is at the intersection of antitrust and intellectual property law. One such example is the growing prevalence of "authorized generics."

Under the Hatch-Waxman Act, the first generic firm that challenges the brand-firm's patent is rewarded with a 180-day period of marketing exclusivity as against other generic products.[3] Today, brand firms are increasingly authorizing a generic version of the branded product to be marketed at the beginning of, or just prior to, that 180-day period.[4] By doing this, "the pioneer drug maker prevents [the first generic firm] from winning all of the customers who want to switch from the branded drug to a cheaper generic form."[5] Whether this ultimately helps or harms consumers, however, is an open question.

In the short-run, authorized generics arguably benefit consumers by providing greater competition during the 180-day period of generic market exclusivity—there are two generic products instead of one. In the long-run, however, authorized generics have the potential to harm consumers because the incentive for generic firms to challenge patents covering brand products is arguably reduced. Thus, the increased marketing of authorized generics raises three important issues. One, do consumers benefit during the 180-day exclusivity period when there is an additional generic product on the market? Two, if so, do authorized generics sufficiently devalue the benefit of the 180-day exclusivity period to lead to long-term consumer harm? And, three, if authorized generics have short-term benefits, but long-term costs, do the benefits outweigh the costs?

The pharmaceutical industry is a multi-billion dollar business that impacts almost every consumer at some point in his or her life.[6] Properly answering these questions and, if appropriate, amending the Hatch-Waxman Act to address authorized generics is, therefore, a worthy goal. To better understand the impact of authorized generics, the Federal Trade Commission ("FTC" or "Commission") is conducting a comprehensive industry-wide study.[7]

This article discusses some of the conflicting research on the impact of authorized generics, legislative proposals that have been considered by Congress and the status of the FTC study.

II. BACKGROUND

A. The Hatch-Waxman Act

Before a pharmaceutical drug can come to market, it must be approved by the Food and Drug Administration ("FDA"). FDA ordinarily approves a brand drug pursuant to a New Drug Application ("NDA"). Obtaining approval of a brand drug can be a time consuming and expensive process because the brand firm must demonstrate, through a series of clinical trials, that its product is safe and efficacious.[8] The average new drug that obtained FDA approval in the 1990s has been estimated to have cost the producer more than $800 million.[9] The costs involved included development, clinical and other testing plus the expense associated with products that were ultimately unsuccessful.[10]

[*] Ms. Seagull is an associate at the law firm of Axinn, Veltrop & Harkrider LLP in Hartford, Connecticut.

And, "the clinical trial process took upwards of 8 years."[11]

Prior to the passage of the Hatch-Waxman Act in 1984, generic firms were required to undertake a similar NDA approval process.[12] The Hatch-Waxman Act sought to encourage generic entry by, among other things, simplifying the generic approval process. Under the Hatch-Waxman Act, the FDA may approve a generic product pursuant to an Abbreviated New Drug Application ("ANDA").[13] An ANDA applicant does not need to undertake the same safety and efficacy studies as the NDA applicant. Rather, the ANDA applicant need only demonstrate that its product is bioequivalent to the brand product and that it satisfies other safety criteria such as sufficient shelf stability.[14]

In addition to simplifying the process for obtaining generic approval, the Hatch-Waxman Act sought to encourage early generic entry by rewarding the first generic firm that challenges or designs around patents covering the brand firm's product. At the same time, however, the Act sought to increase the protections for brand firms. To accomplish these goals, Congress created an intricate process.

First, the brand firm must list in the FDA's "Orange Book"[15] the "patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."[16] To protect the patent rights of the brand company, the Act requires that each generic firm include with its ANDA a certification as to each listed patent. There are four certifications available to the generic firm: (i) no patents cover the brand product, (ii) the relevant patent(s) have expired; (iii) the relevant patent(s) will have expired before the generic product is marketed; or (iv) the patent(s) covering the brand product are invalid or will not be infringed.[17]

The last certification, typically referred to as a "Paragraph IV certification," is essential for understanding the controversy surrounding authorized generics. A generic firm making a Paragraph IV certification is indicating that it believes its product can lawfully enter the market prior to the expiration of the brand firm's patent(s).

The filing of a Paragraph IV certification constitutes an act of infringement and, as such, permits the NDA holder to immediately file suit for patent infringement.[18] Moreover, the Hatch-Waxman Act encourages the brand firm to file such a suit expeditiously. Specifically, if the NDA holder files a patent suit against the ANDA applicant within 45 days of being notified of the Paragraph IV filing, approval of the ANDA is automatically stayed for 30 months unless, before that time, a court holds that the patent is invalid or not infringed.[19]

Because the 30-month stay is triggered automatically, the NDA holder does not have to meet the criteria, such as irreparable harm or likelihood of success on the merits, that would ordinarily be required of a firm seeking a preliminary injunction. Thus, there is a significant incentive for the brand firm to file suit within the 45-day window provided by the Act.

The result is that a generic firm that makes a Paragraph IV certification opens itself up to a high risk of patent litigation. To encourage generic firms to take this risk, and thereby potentially enter the market prior to patent expiration, a 180-day period of marketing exclusivity is awarded to the first ANDA applicant to make a Paragraph IV certification (the "first-filer").[20] This incentive has served its purpose; for many products, particularly heavily prescribed drugs, generic firms race to become the first-filer. Moreover, since the passage of the Hatch-Waxman Act, generic's share of prescriptions increased from 19% in 1984 to 63% in 2006.[21]

This incentive, however, is designed in a way that makes it possible for the brand firm to sell its own generic product during the 180-day

exclusivity period. Specifically, the Act provides that no other ANDA may be approved until the 180-day exclusivity period expires.[22] Thus, the exclusivity period prevents the marketing of other ANDA products, not products sold pursuant to the NDA.[23] As a result, the brand firm can either sell a generic version of its NDA product or license a third-party to do so during the 180-day exclusivity period. A generic drug sold under the brand firm's NDA is commonly referred to as an "authorized generic."

B. The Increased Marketing of Authorized Generics

Offering an authorized generic can provide several benefits to the brand-firm. One, it enables the brand-firm to recoup some of the sales that would be lost to the generic product once generic competition began.[24] Two, by entering early as a generic, the brand firm is at an advantage when true generic competition begins because some studies have contended that "generic drug markets are characterized by substantial first mover advantage."[25] Third, and most troubling to critics of the practice, by consistently marketing an authorized generic at the beginning of the 180-day exclusivity period, brand firms may dilute the incentive of generic firms to make Paragraph IV filings and to aggressively litigate the follow-on patent lawsuit.[26]

Given the benefits to the brand firm of selling an authorized generic, it is not surprising that, as FTC observed in its Notice, "[i]n recent years and with increasing frequency, brand-name drug manufacturers have begun to market authorized generic drugs at precisely the same time that a paragraph IV generic is beginning its period of 180-day marketing exclusivity."[27]

The increased marketing of authorized generics during the 180-day exclusivity period has raised concerns in Congress and at the FTC. For example, Representative Waxman, one of the authors of the Hatch-Waxman Act, has stated: "Of course, the practice of using authorized generics substantially reduces the value of the 180-day exclusivity to the generic drug manufacturer who challenged the patent. The practice raises the serious possibility that generic drug manufacturers may stop challenging patents—at least in the substantial numbers they have up until now."[28] FTC Commissioner Leibowitz has similarly suggested that "[a]lthough there are likely to be short-term benefits to consumers from an authorized generic, the growth of the practice generally seems designed to send a signal (and a disturbing one) to [the generic] industry—something along the lines of, 'If you thought you were going to make big profits like you used to, you should forget about it.'"[29]

Generic pharmaceutical products confer significant benefits to consumers, and the Hatch-Waxman Act has played an important role in hastening the introduction of these drugs.[30] Because authorized generics have both pro- and anti-competitive potential, a comprehensive study, such as the one FTC is conducting, has the potential to be a valuable tool for Congress as it considers whether and how to amend the Hatch-Waxman Act.

III. ANALYSIS OF THE IMPACT OF AUTHORIZED GENERICS ON CONSUMERS

There is a general belief that authorized generics likely benefit consumers during the 180-day exclusivity period, but potentially deter generic entry more generally, thereby harming consumers in the long-run. The research on this topic, however, is conflicting. Furthermore, studies that have been done to date lack the full range of data necessary to balance the benefits and costs of authorized generics to conclusively determine if consumers come out ahead at the end of the day.[31] Two studies that illustrate these limitations are ones commissioned by PhRMA, the brand-firm trade association, and GPhA, the generic-firm trade association.

Not surprisingly, these studies, although using the same data sets, reached very different conclusions. The PhRMA study found that the benefits to consumers from authorized generic entry during the 180-day exclusivity period are significant and that, in markets with fewer than 6

generic products, some of the benefits of an authorized generic persist beyond the exclusivity period.[32] Conversely, the GPhA study concluded that the short-term benefits are illusory whereas the potential for long-term harm is significant.[33] Neither study engaged in the sort of balancing that would be necessary if authorized generics have both benefits and harms. Rather, they found the existence of one and the absence of the other.

A. PhRMA Study

The objective of the PhRMA study was to analyze the impact of authorized generics "on short and long-term generic pricing" and, if there were any pricing impacts, whether they "have led to a financial benefit for patients."[34] Significantly, the study did not even consider the impact of authorized generics on the incentives of generic firms to race to be the first-filer of a Paragraph IV certification.

With regard to short-term pricing, the PhRMA study found a significant discount off outlet-level[35] brand prices in markets with an authorized generic as compared to markets without an authorized generic. In month 1, in markets with an authorized generic, the study found an average discount off brand price of 36.9%. The discount in month 6 averaged 41.2%. And, the six-month average was 38.8%.[36] By comparison, in markets without an authorized generic, the discount in month 1 averaged 22.8%, the discount in month 6 averaged 23.4%, and the six-month average was 23.0%.[37] Based on this, the authors concluded that "the presence of an authorized generic led to generic discounts that were 15.8 percentage points lower on average . . . than the average for comparable examples in which there was no authorized generic."[38]

Next, the authors considered whether the presence of an authorized generic resulted in any savings to the healthcare system. To make this assessment, they looked to the: (i) "number of generic units sold;" (ii) "brand unit average price;" (iii) "outlet price differential;" and (iv) "generic unit price differential due to the presence of an authorized generic."[39] Considering these variables, the authors found that the savings during the six month exclusivity period totaled $212.8 million across the nine cases studies that were used for the analysis.[40]

Looking to the long-term impact, the authors found that, in markets with 2-5 generics, the greater discount associated with an authorized generic persisted beyond the exclusivity period. The long-term benefits, however, disappeared in markets with 6 or more generics.[41]

Although the PhRMA study did not assess the impact of authorized generics on the incentives of generic firms to make Paragraph IV filings, a later study, also funded by PhRMA, did.[42]

Specifically, the authors in this later study considered whether the increased marketing of authorized generics during the 180-day exclusivity period had resulted in either: (i) fewer drugs facing a Paragraph IV certified generic; or (ii) delayed generic entry because the first filer's submission was made at a later date than would have occurred had the generic firm not anticipated an authorized generic.[43]

As to the first point, the authors considered whether there was a reduction in the number of drugs facing a Paragraph IV certification over time, concluding that there was not a downward trend. Rather, based on FDA data "the number of distinct drugs facing their first paragraph IV certification increased from 41 in 2004 to 48 in 2005."[44] In contrast, the number of drugs for which a Paragraph IV filing could be made decreased slightly, from 268 in 2004 to 263 in 2005.[45]

With regard to the second possibility—delayed generic entry—the authors again found an absence of harm. To test whether generic entry was delayed, the authors looked to the number of firms filing a Paragraph IV certification within six months of the first filer. They found that the number of such subsequent Paragraph IV filers increased from an average of approximately one and a half to almost two.[46] From this they concluded that "for many drugs experiencing paragraph IV certifications there is not just one, but there are multiple generic

manufacturers ready to challenge that drug's patents in a timely manner."[47]

In addition, the authors attempted to quantify more directly whether the first-filer's Paragraph IV certification was later than it may have been absent an expected authorized generic. Again, they found no delay. First, the authors explained that four years following new chemical entity ("NCE") approval is the earliest that a Paragraph IV filing could be made. They then looked to the number of drugs facing a Paragraph IV certification within 6 years following NCE approval and observed that the number had "increased substantially in recent years."[48] Thus, they concluded that "not only are more drugs facing paragraph IV certifications in recent years, but they are facing paragraph IV certifications at a very early stage."[49]

Ultimately, the authors concluded that consumers benefit from authorized generics because generic drugs are sold at a greater discount during the 180-day exclusivity period and there is no long-term impact either in terms of a meaningful reduction in generic entry or delayed generic entry. Because the authors found that consumers benefited in the short-run and were not harmed in the long-run, there was no need for them to engage in a balancing of benefits and harms.

B. GPhA Study

In response to the PhRMA study, GPhA conducted a study of the impact of authorized generics on consumers using the same data as the PhRMA study. It reached the exact opposite conclusion, finding that authorized generics do not benefit consumers in the short-run, but have the potential to harm consumers in the long-run.[50]

To explain the different results between the studies, the GPhA study offered several critiques of the PhRMA study. First, the PhRMA study's conclusion that authorized generics lead to greater discounts off the brand price was based on a comparison of markets with an authorized generic and markets where no authorized generic entered. The GPhA study observed that the entry of an authorized generic was not a random event. Thus, the differences in pricing in markets with and without an authorized generic could be correlated with other market attributes and did not necessarily stem from the entry of the authorized generic. For example the two markets could differ in terms of "sales volume, number of anticipated entrants, [and] potential for licensing."[51] Also, the GPhA study noted that the sample authorized generic markets in the PhRMA study were later than the sample of markets without authorized generics. [52]

Second, the GPhA study criticized the PhRMA study's use of wholesale prices rather than retail prices since retail prices are indicative of what consumers are actually paying.[53]

Finally, the GPhA study observed that brand prices tended to increase more in markets with an authorized generic. Hence the apparently greater generic discount between brand price and generic price in markets with an authorized generic could be the result of higher brand prices and not lower generic prices.[54]

Using the same data set as the PhRMA study, the GPhA study found only a 5% greater discount in markets with an authorized generic as compared to those without an authorized generic. Moreover, when the GPhA study made adjustments to account for differences in the significance of products (e.g. weighing more heavily products that were commercially important), it found that the discounts off brand price were within 1% in markets with an authorized generic and markets without. Also, the slightly higher discounts were available in markets without the authorized generic.[55]

This study thus suggests that, rather than benefiting from authorized generics during the 180-day exclusivity period, consumers could actually be harmed. The harm stems from the fact that the generic products are not sold at a meaningfully discount, if at all, in the face of an authorized generic. But, the brand drugs are sold at a higher price.

After concluding that consumers do not benefit during the 180-day exclusivity period, the

authors considered whether they could be harmed in the long-run.

Specifically, the authors focused on the intended incentives of the Hatch-Waxman Act and concluded that because authorized generics dilute those benefits, consumer harm is likely. "If the incentive to challenge patents and develop non-infringing products is severely reduced, then generic companies will respond by investing less in those areas . . . . This could easily result in delays of several months or even longer in the arrival of generic competition."[56] As with the PhRMA study, the GPhA study's results did not necessitate a balancing of benefits and costs.

C. Congress' Response

Due to the importance of pharmaceutical products to consumers and the benefits derived from generic drugs, it is not surprising that Congress has shown a willingness to refine the Hatch-Waxman Act so as to maintain the Act's intended balance between rewarding innovation and encouraging early generic entry. Already, the Act has been amended twice to address perceived abuses of the incentive structure.[57]

Because the marketing of an authorized generic is widely perceived as a strategy that brand-firms are employing to delay or otherwise discourage generic entry, it is not surprising that Congress has weighed in on this issue as well.

One step taken by Congress is the recent enactment of Section 6003 of the Deficit Reduction Act of 2005. This law amends the definition of "best price" for purposes of Medicaid rebates so that the "best price" now includes prices charged for authorized generics.[58] This legislation, which went into effect in 2007, could result in increased Medicaid rebates for drugs where there is an authorized generic.[59] Such a change could be significant for brand firms because Medicaid is a significant purchaser of pharmaceuticals and, for many drugs, its purchases constitute the largest percentage of sales of any single purchaser.[60] Thus, it has been argued that "this change in the law will create a powerful disincentive for branded manufacturers to compete on price through the use authorized generics."[61]

Also, some members of Congress have proposed legislation to further amend the Hatch-Waxman Act to directly outlaw the marketing of an authorized generic during the 180-day exclusivity period. Specifically, legislation has been proposed to amend the Federal Food, Drug and Cosmetic Act, to provide that "no holder of a new drug application approved under subsection (c) shall manufacture, market, sell, or distribute an authorized generic drug, direct or indirectly, or authorize any other person to manufacture, market, sell, or distribute an authorized generic drug."[62] This limitation would not apply to an arrangement where the authorized generic would be marketed by the first-filer or subsequent to the termination of the 180-day exclusivity period.[63] Neither the Senate nor House version of this bill has passed.

In addition to reducing the benefits of offering an authorized generic and proposing legislation that would outlaw them altogether, several members of Congress have encouraged the FTC to study the issue. "Given the importance of generic drugs in lowering health care costs, Senators Grassley, Leahy, and Rockefeller have requested that the Commission conduct a study of 'the short term and long term effects on competition of the practice of 'authorized generics.'"[64]

D. FTC Study

The FTC has been at the forefront in challenging conduct that it perceives as undoing or lessening the benefits of generic entry and has been an advocate for legislative changes when it views portions of the Hatch-Waxman Act as being susceptible to abuse. For example, the FTC has challenged patent settlements involving reverse payments from brands to generics, prohibited the improper listing of patents in the FDA Orange Book, among other measures.[65] Because authorized generics have both pro-competitive and anticompetitive potential, the FTC has taken a cautious approach in addressing this strategy. Specifically, the FTC has accepted the

recommendation of the members of Congress that requested a study of this practice.[66]

The FTC study has the potential to shed further light on the impact of authorized generics on the pharmaceutical industry and, particularly, the incentive structure of the Hatch-Waxman Act. As compared to earlier studies, the FTC has the ability to use its compulsory process authority to subpoena detailed, internal financial and other information from industry participants. The FTC has exercised this authority; possibly subpoenaing almost 200 pharmaceutical companies.[67]

The FTC subpoenaed brand and generic firms, including firms that have licensed NDA products to be marketed as authorized generics.[68] The subpoenas primarily seek a broad range of data, which will enable the Commission to conduct an economic analysis of the impact of authorized generics in various pharmaceutical markets that is more thorough than what others have been able to do with publicly available data.[69]

The subpoenas also include document requests that will provide a qualitative component to the study. For example, the proposed subpoena to generic drug companies seeks, among other things, documents analyzing "AGs or the possibility of AGs with regard to whether to file an ANDA and/or make a paragraph III or IV certification . . ."[70] This could help answer the question of whether the incentives and behavior of generic drug firms are negatively impacted by the expected entry of an authorized generic. In particular it could address the hypothesis of some, including FTC Commissioner Leibowitz, that "for blockbuster drugs, the pot of gold for generics will still be large enough so that they will fight to be first to file and first to market. But we could very well see fewer generic applications for smaller drugs—the ones that won't earn several hundred million dollars a year in revenues."[71]

This possibility was previously addressed in a study of the impact of authorized generics in Canada where at least one generic firm executive indicated that authorized generics "have their primary anticompetitive effect on the decision . . . to enter a drug market."[72] The executive went on to explain that under current reimbursement regulations and with authorized generics present, "he will not bother challenging a drug market with less than $10 million in annual sales."[73]

Also, the FTC study includes a request to brand firms and authorized generic drug companies for "planning, decisional, or strategy documents . . . that discuss the effect(s) or possible effect(s) of the enactment of Section 6003 of the Deficit Reduction Act of 2005, P.L. 109-171."[74] These documents could provide insight into whether Congress has already taken steps that will reduce or eliminate authorized generics.

As a result, once complete, the FTC study will likely serve as an important tool for the FTC in its consumer protection role and for policy makers considering whether further amendments to the Hatch-Waxman Act are appropriate.

IV. CONCLUSION

The Hatch-Waxman Act's encouragement of early generic entry has benefited consumers significantly. It has been estimated, for example, that consumers have saved billions of dollars due to the increased production and use of generic drugs.[75] These benefits, however, have come at the expense of brand-firms, which lose substantial sales upon entry of a generic product.[76] It is not surprising, therefore, that brand firms have taken steps to capture some of the sales that otherwise would go to a generic competitor.

Protecting brand firm profits is important as it provides an incentive for continued innovation. Congress, through the Hatch-Waxman Act, recognized this competing objective and designed the Act with the protection of brand firm intellectual property rights as an important goal.

Authorized generics raise complex issues regarding how to properly balance the rights of brand firms to profit from their NDA products without overly diluting the benefits of the 180-

day exclusivity period that is the cornerstone of the Hatch-Waxman Act's effort to encourage generic entry.

The studies that have been done to date have tended to rely on incomplete data and have not reached a consensus on the impact of authorized generics on consumers. Because hundreds of billions of dollars are spent on prescription drugs each year, FTC and Congress are appropriately concerned with ensuring that a proper balance is struck. The FTC study, which will be based on comprehensive, internal industry data and documents, will likely be an important resource for policy makers as they consider how to best treat authorized generics.

---

[1] Pub. L. No. 98-417, 98 Stat. 1585.

[2] Mylan Pharms., Inc. v. United States FDA, 454 F.3d 270, 272 (4th Cir. 2006) (quoting aaiPharma Inc. v. Thompson, 296 F.3d 227, 230 (4th Cir. 2002).

[3] 21 U.S.C. § 355(j)(5)(B)(iv).

[4] Jon Leibowitz, FTC Commissioner, Oral Statement at the Hearing of the Senate Special Committee on Aging (July 20, 2006).

[5] *Mylan Pharms.*, 454 F.3d at 273.

[6] "Research indicates that 87 percent of persons aged 65 and older take at least one prescription drug on a regular basis." Jon Leibowitz, FTC Commissioner, Oral Statement at the Hearing of the Senate Special Committee on Aging (July 20, 2006).

[7] Notice, 72 Fed. Reg. 25,304 (May 4, 2007).

[8] 21 U.S.C. § 355(b)(1)(A).

[9] DAVID REIFFEN & MICHAEL R. WARD, "BRANDED GENERICS" AS A STRATEGY TO LIMIT CANNIBALIZATION OF PHARMACEUTICAL MARKETS 7 (May 2005), *available at* http://www.ftc.gov/be/healthcare/wp/12_Reiffen_BrandedGenericsAsAStrategy.pdf.

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] *Id.* at 7-8.

[14] *Id.* at 8.

[15] FDA publishes information regarding the patents that claim to cover the brand firm's product in a publication entitled "Approved Drug Product with Therapeutic Equivalence Evaluations," which is commonly referred to as the Orange Book. Saami Zain, *Sword or Shield? An Overview and Competitive Analysis of the Marketing of 'Authorized Generics,'* 62 FOOD DRUG L.J. 739, 741 (2007).

[16] 21 U.S.C. § 355(b)(1)(G).

[17] 21 U.S.C. § 355(j)(2)(A)(vii).

[18] 35 U.S.C. § 271(e)(2); *see also* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990) (explaining that "a highly artificial act of infringement" was created so that an NDA holder could file suit upon receiving notice of a Paragraph IV certification).

[19] 21 U.S.C. § 355(j)(5)(B)(iii).

[20] 21 U.S.C. § 355(j)(5)(B)(iv).

[21] KEVIN A. HASSETT & ROBERT J. SHAPIRO, THE IMPACT OF AUTHORIZED GENERIC PHARMACEUTICALS ON THE INTRODUCTION OF OTHER GENERIC PHARMACEUTICALS 2-3 (April 2007), *available at* http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf.

[22] 21 U.S.C. § 355(j)(5)(B)(iv).

[23] *See Mylan Pharms.*, 454 F.3d 270; Teva Pharm. Indus. v. Crawford, 410 F.3d 51 (D.C. Cir. 2005).

[24] REIFFEN & WARD, *supra* note 9, at 13; *see also* Paul Grootendorst, *Effects of 'Authorized Generics' on Canadian Drug Prices*, SEDAP Research Paper No. 201, at 5 (June 2007) (observing that "launching an AG might be profitable . . . the brand firm faces low fixed market entry costs. Because the AG is the brand drug, the brand firm does not face the costs of conducting bioequivalence studies, nor does it face the costs of challenging the validity of any outstanding patents.").

[25] Zain, *supra* note 15, at 757.

[26] Grootendorst, *supra* note 24, at 6 ("The second reason that the brand firm might find it in their interest to launch an AG is to establish a reputation among [independent generics] that it will launch an AG in 'marginally profitable' markets—markets in which the presence of the AG can tip the balance between economic profitability and loss.").

[27] Notice, 72 Fed. Reg. 25,304, 25,305 (May 4, 2007).

[28] Rep. Henry Waxman, Statement at the Generic Pharmaceutical Association's First Annual Policy Conference: Securing the Future of Affordable Medicine (Sept. 20, 2005).

[29] Jon Leibowitz, FTC Commissioner, How Settlements Make Strange Bedfellows: Or How the Federal Trade Commission Has Managed to Unite the Entire Pharmaceutical Industry, Speech Before the Generic Pharmaceutical Association's Annual Policy Conference (Sept. 29, 2006).

[30] Leibowitz, *supra* note 4 (observing that "generic competition following successful patent challenges to just four products—Prozac, Zantac, Taxol, and Platinol—is estimated to have saved consumers more than $9 billion dollars alone").

[31] Zain, *supra* note 15, at 753 (observing that none of the studies to date employed extensive data sets and that "current economic analysis on the competitive effects of authorized generics is limited in both design and focus").

[32] IMS Consulting, *Assessment of Authorized Generics in the U.S.: Prepared for PhRMA* (Spring 2006) [hereinafter PhRMA study].

[33] Aidan Hollis & Bryan A Liang, *An Assessment of the Effect of Authorized Generics on Consumer Prices* (July 31, 2006), available at http://www.gphaonline.org/AM/Template.cfm?Section=Home&Template=/CM/ContentDisplay.cfm&ContentID=2647 [hereinafter GPhA study].

[34] PhRMA study, *supra* note 32, at 5.

[35] Outlet-level prices were described as "the cost to outlets (either retail such as pharmacies, or non-retail such as hospitals) for products, whether purchased directly from a manufacturer or indirectly through a wholesaler." *Id.* at 7 n.5.

[36] *Id.* at 9.

[37] *Id.* at 10.

[38] *Id.* at 11.

[39] *Id.* at 12.

[40] *Id.* at 13.

[41] *Id.* at 14-15.

[42] Ernst R. Berndt et al., *Do Authorized Generic Drugs Deter Paragraph IV Certifications? Recent Evidence*, Working Paper (April 17, 2007), *available at* http://www.analysisgroup.com/analysisgroup/uploadedFiles/Publishing/Articles/PhRMA_Authorized_Generic_Entry.pdf.

[43] *Id.*

[44] *Id.* at 11.

[45] *Id.* Moreover, is has been posited that even if authorized generics discourage generic firms from making Paragraph IV filings, this would not necessarily result in fewer generic entrants. Rather, authorized generics would most likely deter those firms that are most uncertain about the likely success of their Paragraph IV certification. Ernst Berndt, Richard Mortimer, Ashoke Bhattacharjya, Andrew Parece, & Edward Tuttle, *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, HEALTH AFFAIRS (May/June 2007).

[46] Berndt et al., *supra* note 42, at 12.

[47] *Id* at 12-13.

[48] *Id.* at 13.

[49] *Id.*

[50] GPhA study, *supra* note 33.

[51] *Id.* at 5

[52] *Id.*

[53] *Id.*

[54] *Id.* at 18. The study also criticized other aspects of the PhRMA study including inconsistent data and the fact that the study averaged prices across dosage forms. *Id.* at 6-7.

[55] *Id.* at 14-15.

[56] *Id.* at 20.

[57] Zain, *supra* note 15, at 742-43.

[58] Pub. L. No. 109-171, 120 Stat. 4 (2006).

[59] Zain, *supra* note 15, at 775.

[60] *Id.* at 763.

[61] Comments of Ronald W. Davis to FTC's Proposed Study on Authorized Generics, *available at* http://www.ftc.gov/os/comments/genericdrugstudy3/060604davis.pdf.

[62] S. 438, 110th Cong. (2007); H.R. 806, 110th Cong. (2007).

[63] *Id.*

[64] Notice, 72 Fed. Reg. 25,304, 25,305 (May 4, 2007).

[65] Jon Leibowitz, FTC Commissioner, Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!, Remarks at the Second Annual

In-House Counsel's Forum on Pharmaceutical Antitrust (April 24, 2006).

[66] Notice, 72 Fed. Reg. 25,304, (May 4, 2007).

[67] Erin Marie Daly, Branded Drug Cos. Paying Off Generics: FTC Report, IPLaw 360 (April 25, 2006).

[68] Details on the scope of the FTC study and the comments provided in response to the FTC's Notice are available at http://www.ftc.gov/os/comments/genericdrugstudy3/index.shtm.

[69] *Id.*

[70] Proposed Generic Drug Company Special Order, Request 18, *available at* http://www.ftc.gov/os/comments/genericdrugstudy3/otherdocuments/GenericSpecialOrders4-30-FINAL.pdf.

[71] Jon Leibowitz, FTC Commissioner, Health Care and the FTC: The Agency as Prosecutor and Policy Wonk, Remarks at the Antitrust in Health Care Conference (May 12, 2005).

[72] Grootendorst, *supra* note 24, at 16.

[73] By comparison, "if he was certain that there would be no AG entry, he would challenge drug markets with $5+ million in annual sales." *Id.*

[74] Proposed Brand-Name Drug Company Special Order, Request 30; Proposed Authorized Generic Drug Company Special Order, Request 12, *available at* http://www.ftc.gov/os/comments/genericdrugstudy3/index.shtm.

[75] Zain, *supra* note 15, at 739.

[76] It has been estimated that a generic drug sometimes captures as much as 80-90% of a brand drug's sales in a matter of weeks. *Id.*