

HATCH-WAXMAN REFORM AND ACCELERATED MARKET ENTRY OF GENERIC DRUGS: IS FASTER NECESSARILY BETTER?

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Recently there has been a considerable amount of pressure to accelerate consumer access to generic drugs, which are significantly less expensive than their brand-name counterparts. One way to bring generic drugs on to the market sooner is through revision of the existing law relating to pharmaceutical patents. This iBrief describes recent regulatory changes to the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act), which governs the patenting process for new drug products, as well as current legislative efforts to speed generic access through Hatch-Waxman reform. This iBrief also assesses whether these changes will be beneficial to consumers on a long-term basis.

The Hatch-Waxman Act and the Current Landscape of Pharmaceutical Patent Law

¶1 While the debate over access to generic drugs has peaked in recent years, the topic has long been of concern to pharmaceutical companies, consumers, and legislators. Innovating pharmaceutical companies have historically sought rigid patent protection due to the unique circumstances surrounding drug development. Unlike other products, new pharmaceuticals must undergo rigorous testing and several phases of clinical trials before they reach the market, which creates significant research and development costs. In fact, recent studies estimate that the cost of bringing a new drug to market is nearly \$800 million.² Furthermore, while the full patent term in the United States is 20 years, patents on drug products are usually conferred very early in the development process, many years before the company completes the clinical trials necessary to obtain approval from the Food and Drug Administration (“FDA”). Thus, the period of market exclusivity that the company enjoys following FDA approval may be significantly less than 20 years. This period, known as the “effective patent life,” averaged only between 11 to 12 years for new medicines introduced in the early to mid-1990s.³ In order to compensate for reduced effective patent life, and the substantial costs incurred in research and development and clinical trials, pharmaceutical companies charge high prices for their patented drugs, often placing them out of the affordable reach of many consumers. In

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² *The Ballooning Price Tag*. TUFTS UNIVERSITY E-NEWS, Dec. 4, 2001, at <http://www.tufts.edu/communications/stories/120401BallooningCosts.htm>

³ Robin J. Strongin, *Hatch-Waxman, Generics, and Patents: Balancing Prescription Drug Innovation, Competition, and Affordability*, NATIONAL HEALTH POLICY FORUM Background Paper, Jun. 21, 2002.

1990, the average cost per prescription for brand-name medications was \$27.16, and by 2000 it had nearly tripled to \$65.29.⁴

¶2 Due to the skyrocketing costs of prescription drugs, consumers have long argued that they should be allowed greater access to generic alternatives, which can be obtained at more reasonable prices. The average cost per prescription for generic drugs in 2000 was only \$19.33, nearly \$50 less than the average for brand-name medications.⁵ However, until the early 1980s, manufacturers wishing to develop generic counterparts to patented drugs had no choice but to wait for the original patents to expire before they could begin the application process to obtain FDA approval, which significantly delayed the market entry of generic drugs.⁶ In response to these concerns, Congress enacted the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), in 1984.⁷ The Hatch-Waxman Act, which amended the Food, Drug, and Cosmetic Act⁸, established a "regulatory framework designed to balance incentives for continued innovation among research-based pharmaceutical companies with opportunities for market entry by generic drug manufacturers."⁹ Under Hatch-Waxman, generic manufacturers may now seek FDA approval to market the generic drug before the expiration of the patent of the branded product, via the Abbreviated New Drug Application (ANDA) Process.¹⁰

¶3 Under the ANDA provisions, generic manufacturers are not required to repeat clinical trials performed by the innovator or conduct research on ingredients or dosage forms that have already been approved for safety and effectiveness. Instead, the generic manufacturer need only establish that the generic drug is the bioequivalent of the brand name drug. In other words, it must meet the same standards for strength, quality, purity, and identity as the branded product.¹¹ Thus, if a generic manufacturer establishes bioequivalence and obtains FDA approval, the generic product may be made available to patients the day the innovator's patent expires.¹²

¶4 However, the Hatch-Waxman Act allows pioneer manufacturers a way to delay FDA approval of the generic alternative. To begin the FDA approval process as specified under the ANDA provisions, a generic applicant must do two things: (1) certify in its ANDA that the patent in question is invalid or is not infringed by the generic product (known as "paragraph IV certification") and (2) notify the patent holder of the

⁴ Press Release, Congressman Rahm Emanuel, Emanuel Seeks to Reduce Prescription Drug Costs Through Market Reforms, Co-Sponsors Bills to Foster Competition and Lower Prices (Jun. 20, 2003).

⁵ *Id.*

⁶ Strongin, *supra* note 3, at 9.

⁷ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. §355 (1994)).

⁸ 21 U.S.C. §301 *et seq.*

⁹ Prepared Statement of the Federal Trade Commission Before the Committee on Judiciary, United States Senate (Jun. 17, 2003).

¹⁰ Strongin, *supra* note 3, at 10.

¹¹ *Id.* at 9.

¹² *Id.* at 13.

submission of the ANDA.¹³ Once the patent holder receives the ANDA notification, they have 45 days to file a patent infringement suit against the generic applicant.¹⁴ If an infringement suit is filed within the 45-day period, FDA approval to market the generic version is automatically postponed for 30 months.¹⁵ The 30-month stay is intended to allow time for the patent holder to litigate the infringement suit.¹⁶ These stays are extremely advantageous to innovating companies, because they provide over 2 years of additional market exclusivity, during which the derived profits from the patented drug far outweigh any incurred litigation costs.¹⁷

Extending the Extensions: Alleged Abuse of the 30-month Stay Provision

¶5 Once pharmaceutical companies began to realize the advantageous nature of the 30-month stays, they also began looking for ways to extend them beyond the intended 30-month period. According to a recent study conducted by the Federal Trade Commission, one of the most common ways that patent-holding companies are able to further delay the market entry of generic drugs is through multiple patent listings in the Orange Book, which is the FDA's official listing of all approved products.¹⁸ The FTC study identified several instances in which brand-name companies listed related patents in the Orange Book *after* an ANDA had already been filed by a generic manufacturer.¹⁹ The effect of these "later-listings" is that the generic applicant is then required to re-certify that the later-listed patent is also invalid or not infringed and notify the patent holder of the re-certification.²⁰ In essence, the generic applicant is required to repeat the ANDA process for the later-listed patent. Furthermore, if upon notice of the generic manufacturer's re-certification, the brand-name company sues for infringement within 45 days, then a *new* 30-month stay will begin to run, during which the FDA is prohibited from approving the original ANDA.²¹ According to the FTC, between 1992 and 2000 there were 8 instances in which brand-name companies listed patents in the Orange Book after an ANDA was filed; for these 8 drug products, the additional delay of FDA approval caused by the additional 30-month stay (beyond the original 30-month stay) ranged from 4 to 40 months.²² The following list shows the total length of stays issued for each of the 8 drug products, and the net sales gained from the drug during the extended period of market exclusivity:²³

¹³ *Id.* at 10.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July 2002, at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

¹⁹ *Id.* at 40.

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *Id.* at 49.

- *Platinol*: number of stays: 1; length of stays (total): 30 months; net sales in year second stay was issued: between \$100 and \$250 million.
- *Hytrin (tablets)*: number of stays: 3; length of stays (total): 70 months; net sales in year second stay was issued: between \$500 and \$750 million.
- *Paxil*: number of stays: 5; length of stays (total): 65 months; net sales in year second stay was issued: over \$1 billion.
- *Taxol*: number of stays: 2; length of stays (total): up to 60 months (the actual length of the stays was shortened due to court actions);²⁴ net sales in year second stay was issued: between \$0.75 and \$1 billion.
- *BuSpar*: number of stays: 2; length of stays (total): up to 30 months (the actual length of the stays was shortened due to court actions);²⁵ net sales in year second stay was issued: between \$500 and \$750 million.
- *Neurontin (capsules)*: number of stays: 2; length of stays (total): 53 months; net sales in year second stay was issued: between \$250 and \$500 million.
- *Neurontin (tablets)*: number of stays: 2; length of stays (total): 37 months; net sales in year second stay was issued: between \$250 and \$500 million.
- *Tiazac*: number of stays: 2; length of stays (total): up to 60 months (the actual length of the stays was shortened due to court actions);²⁶ net sales in year second stay was issued: between \$100 and \$250 million.

¶6 One reason that these “later-listings” have been attacked is because it is unclear whether many of these patents meet the FDA’s requirements for listing in the Orange Book. The FDA’s listing regulation requires that additional patents listed in the Orange Book must either “claim the approved drug product” or claim a new use of the approved product.²⁷ The specific categories of patents that may be listed in the Orange Book include drug substance patents, drug formulation patents, and method of use patents. Thus, almost all changes to a drug’s formulation or labeling (which indicates all approved uses of the product) require additional FDA approval and are properly listed in the Orange Book.²⁸ However, it is unclear whether certain types of patents meet the FDA criteria, specifically metabolite patents, polymorph patents, drug intermediate patents, product-by-process patents, and patents for unapproved uses.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ 21 C.F.R. §314.53(b).

- *Metabolite Patents.* According to the FTC, there are at least two instances in which brand-name companies have listed and sued generic companies for infringement of metabolite patents.²⁹ A metabolite is a chemical compound created when the patient's body metabolizes the active ingredient of a drug product.³⁰ Thus, a generic applicant cannot directly infringe upon a metabolite patent, but patent holders contend that the generic applicant will contribute to infringement by selling the drug to patients who will metabolize it.³¹ At least one district court has held that a brand-name company may not list a metabolite patent in the Orange Book, because it does not "claim the approved product" as required by the FDA listing regulations.³²
- *Polymorph Patents.* Polymorph patents claim a chemical compound that differs from the active ingredient by water-of-hydration or that forms a crystalline structure different from the active ingredient already approved by the FDA.³³ Typically, the FDA grants approval for a brand-name company to sell only one polymorph of an active ingredient in a single application.³⁴ Given this fact, many argue that polymorphs are not part of the approved drug product, and therefore additional patents for polymorphs do not claim the approved product and thus may not be listed in the Orange Book.³⁵ However, the FDA will approve polymorphic generic formulations as bioequivalents of the patented drug, and thus it can be argued that polymorphs do claim the same active ingredient and should be listed.³⁶ In one such instance, a district court upheld the listing of a polymorph for the hypertension medication, Hytrin.³⁷
- *Drug Intermediate Patents.* An intermediate patent claims a chemical compound that is used during the production of an active ingredient, but is not present in the final, marketed form of the drug product.³⁸ It is argued that patents for such intermediates also do not "claim the approved drug product" as required by the listing regulations. However, a district court did hold that an intermediate of the cancer drug, Aredia, could

²⁸ FTC, *supra* note 18, at A-39.

²⁹ *Id.* at A-40.

³⁰ *Id.*

³¹ *Id.*

³² Mylan Pharmaceuticals, Inc. v. Thompson, 139 F. Supp. 2d 1, 19-21 (D.D.C. 2001), *rev'd on other grounds*, 268 F.3d 1323 (Fed. Cir. 2001).

³³ FTC, *supra* note 18, at A-40.

³⁴ *Id.*

³⁵ *Id.* at A-41.

³⁶ *Id.*

³⁷ Zenith Labs. v. Abbott Labs., 1996 WL 33344963, at *10 (D.N.J. Aug. 7, 1996).

³⁸ FTC, *supra* note 18, at A-42.

be listed in the Orange Book, but the court based its decision on a finding that the claimed compound was a “component” of Aredia and did not address whether the intermediate compound “claimed the approved drug product.”³⁹

- *Product-by-Process Patents.* Product-by-process patents are essentially a hybrid of a product patent and a process patent; they claim a drug product that is produced by a specified process.⁴⁰ There are two main arguments supporting a prohibition on the listing of these patents in the Orange Book. First, product-by-process patents do not comprise a category of listable patents under the FDA’s listing regulations (only drug substance, formulation, and method of use patents are included).⁴¹ Second, the listing regulations explicitly prohibit the listing of process patents, and product-by-process patents are arguably more similar to process patents than product patents due to the fact that the scope of coverage afforded by a product-by-process patent is almost identical to that afforded by a process patent.⁴²
- *Patents for Unapproved Uses.* While the above types of patents concern drug substance and formulation, there are also some uncertainties regarding which types of patents may be listed which claim a method of use. It is unclear whether patents which claim only unapproved uses of the drug can be listed in the Orange Book. For example, a patent listed for Neurontin claims the use of the drug to treat neurodegenerative diseases, although the FDA has only approved Neurontin for treating epilepsy, which is not a neurodegenerative disease.⁴³ Many argue that allowing the listing of only approved uses is the only way to stop patent holder from claiming broad uses or indications not in the approved labeling.⁴⁴ Several courts have held that an ANDA applicant does not need to re-certify to a patent claiming a use not approved in the original drug application.⁴⁵

Tightening the Loopholes: How the New FDA Regulations Affect Orange Book Listings and the 30-Month Stay Provision

¶7 Under the current system, there is no official mechanism to remove an improperly listed patent from the Orange Book. The FDA itself does not have the resources to review the patents listed in the Orange

³⁹ Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 10 F. Supp. 2d 446, 454 (D.N.J. 1998).

⁴⁰ FTC, *supra* note 18, at A-43.

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.* at A-39.

⁴⁴ *Id.*

Book, and courts have ruled that generic applicants have no private right of action to challenge the listings. These arguments have historically been made in the course of infringement litigation, and the courts' decisions in these cases have provided little guidance as to the types of patents (i.e. polymorph, metabolite, etc.) that may be listed.⁴⁶ As a result, the FDA announced new regulations on June 12, 2003 which aim to resolve much of the uncertainty regarding the type of patents that may be listed and prevent unwarranted extensions of the 30-month stay.⁴⁷ The new regulations, which go into effect on August 19, 2003 clarify the types of patents that may and may not be listed in the Orange Book:

1. Any patents claiming metabolites, intermediates, or packaging features may not be submitted for listing in the Orange Book.⁴⁸
2. Polymorph patents may be submitted if they claim the same active ingredient as the approved product. However, the applicant must now certify that they have test data demonstrating that a drug product containing the polymorph will perform the same as the original drug product, including demonstration of bioequivalence and comparative in vitro dissolution testing on the polymorph and the original drug product.⁴⁹
3. Product-by-process patents are listable in the Orange Book; however, new declaration forms require the applicant to certify that the patent being submitted is a product-by-process patent in which the product claimed is novel, as opposed to the process being novel. This certification is intended to eliminate the submission of patents that are actually process patents, which cannot be submitted for listing.⁵⁰
4. Patents on unapproved methods of use cannot be submitted. Furthermore, patent information submitted claiming approved methods of use must identify each individual claim and the corresponding use or indication in the approved drug labeling. The applicant must also publish this information under the "use code description" in the Orange Book.⁵¹

⁴⁵ See *Purepac Pharm Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002); see also *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003); see also *Allergan, Inc. v. Alcon Labs. Inc.*, 324 F.3d 1322 (Fed. Cir. 2003).

⁴⁶ FTC, *supra* note 18, at v.

⁴⁷ Press Release, United States Department of Health and Human Services, HHS Revises Regulations and Procedures to Speed Access to Generic Drugs (Jun. 12, 2003).

⁴⁸ 21 C.F.R. §314.53 (b)(1), as revised by Food and Drug Administration Final Rule 02N-0417, *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*.

⁴⁹ Revised 21 C.F.R. §514.53(b)(2).

⁵⁰ Comments to Final Rule 02N-0417 at 18.

⁵¹ *Id.* at 28-29.

¶8 While the new regulations clarify which types of patents may or may not be listed, there remain many circumstances in which a patent holder may validly list a patent after a generic applicant has filed an ANDA, such as patents related to improved purity of the active ingredient, safer dosing regime, or new indications for which a drug was approved but the patent was not issued until after application approval.⁵² However, even if a patent holder does validly list a patent after the filing of a generic ANDA, the new regulations specify that no additional notice has to be provided by the applicant following re-certification to the later-listed patent. Thus, the patent holder has no opportunity to file a subsequent infringement suit, thereby invoking an additional 30-month stay. The regulations, therefore, effectively limit the patent holder to one 30-month stay per ANDA.⁵³

¶9 The FDA estimates that the elimination of multiple 30-month stays per ANDA and earlier market entry by generic drugs will reduce consumer expenditures on pharmaceuticals by \$2.040 billion per year.⁵⁴ The savings to generic manufacturers will also be substantial, since the number of litigations will be reduced due to the new regulations limiting each ANDA to one patent infringement suit. Furthermore, clarification of the types of later-issued patents that may be submitted will increase the predictability of the generic drug entry process and reduce product introduction costs faced by generic drug firms.⁵⁵

Closing the Loopholes Even More: Pending Legislation Regarding Access to Generics

¶10 While the FDA regulations fix many of the existing problems with the Hatch-Waxman Act, many feel that the new rules are not an adequate solution, and that Congress should take further action regarding Hatch-Waxman reform. According to Kathleen Jaeger, President and CEO of the Generic Pharmaceutical Association, “more measures outside of the FDA’s authority are necessary to ensure timely access.”⁵⁶ In fact, the Senate has been addressing the issue of access to generic drugs since early 2002, when Senator John McCain introduced the Greater Access to Affordable Pharmaceuticals Act (“GAAP”), which proposed additional reforms to the Hatch-Waxman Act. While the GAAP passed in the Senate by an overwhelming margin, the House of Representatives did not act on the bill.⁵⁷ The issue was revived in 2003, when Senators Judd Gregg and Charles Schumer each introduced a new version of the GAAP, and a bipartisan compromise

⁵² U.S. Food and Drug Administration, *FDA Generic Drugs Final Rule: Questions and Answers*, at <http://www.fda.gov/oc/initiatives/generics/qna.html>.

⁵³ *Id.*

⁵⁴ Comments to Final Rule 02N-0417 at 100.

⁵⁵ *Id.* at 102.

⁵⁶ Joel B. Finkelstein, *Feds Fire on Patent Law That Delays Generics*. AMERICAN MEDICAL NEWS, June 30, 2003, available at http://www.ama-assn.org/sci-pubs/amnews/pick_03/gvsc0630.htm.

⁵⁷ Testimony of Senator Howard M. Metzenbaum (Ret.), Chairman of the Consumer Federation of America, before the Senate Judiciary Committee, regarding Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace (Jun. 17, 2003).

was recently passed by the Senate (94-1) on June 19, 2003.⁵⁸ The GAAP was also added as an amendment to the Prescription Drug & Medicare Improvement Act of 2003, which was passed by the Senate on June 26.⁵⁹

¶11 The GAAP⁶⁰ includes several provisions which aim to further tighten loopholes in the Hatch-Waxman Act and speed consumer access to generic drugs:

Provisions Regarding the 30-Month Stay

¶12 The GAAP, like the FDA regulations, is clear in its intent to allow only one 30-month stay will be allowed per ANDA. However, one criticism of the regulations is that they allow brand name companies to seek stays on patents listed right up until the day before the generic drug is to enter the market, provided that the company did not already exhaust its opportunity for a 30-month stay by filing an infringement suit on the original patent certified by the generic ANDA. Thus, by merely declining to file an infringement suit on its original patent, the patent-holding company can leave the door open for a later-listing, and an initiate a 30-month stay which would delay market entry of the generic drug at the last possible moment.⁶¹

¶13 By comparison, the GAAP would only allow a 30-month stay to be triggered when a brand-name company sues a generic applicant for infringement of a patent that was listed in the Orange Book *before* the ANDA was submitted to the FDA.⁶² As such, the 30-month stay would not be likely to cause a significant delay in the generic's introduction to the marketplace, because the stay would run concurrent to the FDA's consideration of the application, which usually takes 18-25 months.⁶³ While this provision does significantly limit the number of patents that can trigger the 30-month stay, it is more permissive than the provision in last year's GAAP, which only allowed a stay for patents that were already listed by a brand-name company at the time the drug product was approved by the FDA. This year's bill allows for stays on patents which are listed in the Orange Book following FDA approval, as long as they are listed prior to the generic applicant's filing of the ANDA.⁶⁴

¶14 As an extra assurance to generic applicants, the GAAP also provides that if a brand-name company does not bring an infringement suit within 45 days of the generic applicant's initial certification and notice, the generic applicant may seek a declaratory judgment stating that *no* patents are being violated.⁶⁵ Thus the GAAP would provide generic drug companies with additional protection from potential abuses by pioneer manufacturers of the 30-month stay.

⁵⁸ USA Today, *available at* <http://capwiz.com/usatoday/issuesaction/votelist>.

⁵⁹ *Id.*

⁶⁰ S. 1225, 108th Cong. (2003).

⁶¹ Metzenbaum, *supra* note 57, at 4.

⁶² Press Release, Senator Judd Gregg, Breakthrough, Bipartisan Legislation to Make More Prescription Drugs Affordable, Available Gets Boost, (Jun. 11, 2003) (on file with author).

⁶³ *Id.*

⁶⁴ Metzenbaum, *supra* note 57, at 2.

⁶⁵ *Id.*

Provisions Regarding Orange Book Listings

¶15 Unlike the FDA regulations, the GAAP does not specify which patents may or may not be listed in the Orange Book. However, it does create a new mechanism for challenging improper Orange Book listings. If a name-brand company lists a questionable patent and sues a generic applicant for violating that patent in order to trigger the 30-month stay, the GAAP allows the generic company to file a counterclaim, arguing that the patent should not have been listed. Subsequently, an order may be entered requiring the patent owner to correct or delete the patent information from the Orange Book.⁶⁶ This provides an official mechanism for unlisting improper patents from the Orange Book, one which previously did not exist under current law or FDA regulations.

Provisions Regarding Generic Exclusivity

¶16 Another provision of the Hatch-Waxman Act that has historically been subject to abuse by pharmaceutical companies but which was ignored by the FDA regulations is the 180-day exclusivity period granted to generic applicants. Under Hatch-Waxman, the first generic company to submit a paragraph IV certified ANDA to the FDA has an exclusive right to market the generic drug for 180 days, during which the FDA may not approve a subsequent generic applicant's ANDA.⁶⁷ The 180-day exclusivity period was included in the Hatch-Waxman Act for the purpose of encouraging generic companies to invest in the required product testing and to submit to the expensive patent infringement suits that are filed against them.⁶⁸ However, this provision has been criticized because it creates incentive for name brand and generic companies to enter into anticompetitive agreements, under which a generic manufacturer may accept payment from a brand name company not to market the generic product, thereby blocking other generic manufacturers from entering the market.⁶⁹ If the 180-day period of market exclusivity does not begin to run, then the FDA is prohibited from approving any subsequent eligible generic applicants indefinitely.⁷⁰

¶17 The FTC has identified three instances in which the Commission alleged that a brand-name drug company paid the first generic applicant not to enter the market, thereby precluding the FDA from approving subsequent applicants.⁷¹ Under the GAAP, if it were found that a generic drug company entered into an anticompetitive agreement with a brand company or otherwise failed to come to market in a timely manner, then the generic company would be required to forfeit its rights to exclusivity, and the 180-day period would be awarded to any other generic company ready to come to market.⁷²

Provisions Regarding Bioequivalence Testing

⁶⁶ S. 1225, 108th Congress, § 2(a)(2)(C)(iii)(II).

⁶⁷ FTC, *supra* note 18, at vi.

⁶⁸ Strongin, *supra* note 3, at 11.

⁶⁹ *Id.*

⁷⁰ FTC, *supra* note 18, at vii.

⁷¹ *Id.*

⁷² Press Release, Senator Judd Gregg, *supra* note 62.

¶18 Generic drugs will not receive FDA approval unless they can show that they are the bioequivalent of the previously approved brand-name drug. Typically, bioequivalence is determined by measuring the rate and absorption of the drug into the bloodstream. However, for certain drugs which are not absorbed into the bloodstream, such as topical medications, the FDA uses different tests to determine bioequivalence. In certain instances, brand-name companies have challenged these tests, and these challenges have led to the delay of approval of generic versions of these drugs.⁷³ The GAAP clarifies that the FDA has the authority to establish separate tests for determining the bioequivalence of drugs which are not absorbed into the bloodstream, so long as those tests are scientifically valid.⁷⁴ Thus the GAAP includes a number of safeguards against abusive tactics that are employed by pioneer manufacturers in order to skew the pharmaceutical market in their favor.

Is Legislation Really Necessary?

¶19 American consumers have a substantial economic interest in increased access to prescription medications at affordable prices. According to the Congressional Budget Office ("CBO"), the original version of the GAAP was estimated to save consumers \$60 billion over the next ten years.⁷⁵ It is also not surprising that prescription drugs prices have been under attack in Medicare reform legislation; the CBO predicts a 10% per year increase in Medicare beneficiaries' drug costs during the next decade; expanded drug coverage for senior citizens will further increase spending.⁷⁶

¶20 However, it is probable that dollar figures alone will not determine what is ultimately in the best interest of consumers. While consumers may realize economic benefits in the short term by gaining greater access to generic versions of drugs that are currently available, they may not realize the health benefits that would otherwise arise from the discovery of new drugs by research-based pharmaceutical companies. By lessening patent protection and decreasing the period of exclusivity during which pharmaceutical companies may market drugs, profits decrease, and accordingly, so do companies' incentives for further innovation. While many criticize pharmaceutical companies for setting a too-high profit margin, it is important to recognize that research and development costs are extremely high, notably in comparison to other industries. Recent studies estimate that the cost of bringing a new drug to market is nearly \$800 million.⁷⁷ This high cost is mostly due to the fact that for every 5,000 chemicals tested in animals, only five go on to human clinical

⁷³ *Id.*

⁷⁴ S. 1225, 108th Cong. § 4(a) (2003).

⁷⁵ Press Release, Generic Pharmaceutical Association, CBO Report Confirms that the Bi-partisan GAAP Bill Will Save at Least \$60 Billion in Next Decade (Jul. 18, 2002).

⁷⁶ Jill Wechsler, *Pharmaceutical Pricing and Innovation Key Issues for 2003*, PHARMACEUTICAL TECHNOLOGY, Jan. 2003, 22-30.

⁷⁷ *The Ballooning Price Tag*. Tufts University E-News, December 4, 2001, at <http://www.tufts.edu/communications/stories/120401BallooningCosts.htm>

testing, and of this five, only one makes it to market.⁷⁸ Thus, a pharmaceutical company must have the financial resources to develop and test thousands of compounds, knowing that very few of them will ever reach consumers or potentially reap a profit. Due to this lottery-like effect, when a company latches on to a “winner,” they must gain enough profit from that drug to fuel the continuing research and development cycle.

¶21 To what extent will the proposed changes in pharmaceutical patent protection affect research-based companies’ investment in research and development? One fact is clear: The number of new drug applications submitted by research-based firms is already declining. In the mid-1990s, the FDA was approving approximately 120 new applications per year.⁷⁹ In 2001, the FDA approved only 66 new drug applications.⁸⁰ Industry analysts say that much of the decline is due to expanded pre-market test requirements imposed by the FDA, which often require companies to run more preclinical screening tests and clinical trials in order to obtain additional safety data.⁸¹ While most will agree that drug safety is an important concern, it is arguable whether changes in patent protection are called for at a time when the number of new drugs being made available to patients is already decreasing.

¶22 At least one study has attempted to measure the cost to consumers of eliminating patent protection and accelerating generic entry in terms of the lost health benefits which would otherwise be gained from the development of new drugs. The study made the following findings:⁸²

1. The long run effect of such generic entry on total revenues to branded pharmaceutical companies is a decline in revenues of 65%;
2. A 65% decline in revenues leads to a 65% decline in research and development spending;
3. A 65% decline in research and development spending leads to a 65% decline in new chemical entities;
4. A 65% decline in new chemical entities leads to a reduced longevity of 1.6 million life years per year;
5. The value of this longevity decline is \$240 billion dollars per year.

¶23 Using this analysis, the study concludes that consumers would lose roughly \$3 in health benefits due to future innovation for every \$1 gained due to easier access to generic drugs in the short-term.⁸³ While the

⁷⁸ *Id.*

⁷⁹ Wechsler, *supra* note 76, at 26.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² J. Hughes, M. Moore, and E. Snyder, *Napsterizing Pharmaceuticals: Access, Innovation, and Consumer Welfare*, National Bureau of Economic Research Working Paper No. 9229 (Cambridge, MA: NBER, June 2002).

⁸³ *Id.* at 39.

study assumes the elimination of patent protection entirely, a similar analysis could be performed using the decline in revenues that would result from the proposed legislation, which would be less than 65%, but substantial nonetheless.

¶24 Thus, if patent protection is decreased, there will be at least *some* losses to consumers resulting from lessened incentives for innovation among research-based pharmaceutical companies. Consumers must decide if they are willing to exchange the potential for future development of new life-saving drugs for smaller bills at the pharmacy in the short-term. Perhaps the FDA regulations and the GAAP strike the proper balance: both attempt to clarify the existing law and prevent abuse of the current system, without radically weakening the patent protection afforded to brand-name pharmaceutical companies. However, they will both have the effect of decreasing an already-shortened effective patent life for a product that is extremely costly to develop. In order to compensate, pharmaceutical companies may raise prices even more for a drug that is first introduced, knowing that there is little they can do to delay generic entry on to the market.

¶25 Clearly the debate will continue, and consumer groups and pharmaceutical companies will likely be tracking the GAAP very closely in the upcoming months. Undoubtedly, much of the attention will be focused on consumer savings. Hopefully, consumers will be able to look beyond the numbers and see the larger picture: that waiting a little bit longer for a generic cholesterol medication may give a pharmaceutical company the resources it needs to discover a cure for heart disease ten years down the road.