GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY

Executive Summary and Legislative Recommendations

Pharmaceutical drug products have become increasingly important to providing consumers with a myriad of treatments and cures that increase life expectancy and enhance lives. It is critical to maintain appropriate incentives for the development of new drug products, because the necessary research and development is risky and costly. Innovation in the pharmaceutical industry, spurred in part by competitive market forces, continues to bring enormous benefits to Americans.

At the same time, expenditures on pharmaceutical products continue to grow and often outpace expenditures for other consumer products. Pharmaceutical expenditures concern not only consumers, but government payers, private health plans, and employers as well. Generic drugs offer opportunities for significant cost savings over brand-name drug products.

The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act have shaped substantially the current legal environment governing Food and Drug Administration (FDA) approval of generic drug products. Hatch-Waxman established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers. The Amendments compensate brand-name companies, in certain circumstances, for a lengthy drug approval process, which can shorten the effective life of patent protection for drug products. The Amendments also streamline the procedures for bringing generic drug products to the market.

Beyond any doubt, Hatch-Waxman has increased generic drug entry. Generic drugs now comprise more than 47 percent of the prescriptions filled for pharmaceutical products – up from 19 percent in 1984, when Hatch-Waxman was enacted.

In spite of this record of success, two of the provisions governing generic drug approval prior to patent expiration (the 180-day exclusivity and the 30-month stay provisions) are susceptible to strategies that, in some cases, may have prevented the availability of more generic drugs. These provisions continue to have the potential for abuse.

The Commission has taken antitrust law enforcement actions against certain brand-name and generic drug companies whose allegedly anticompetitive agreements took advantage of one or the other of these provisions. Through vigorous enforcement of the antitrust laws, the FTC has taken an active role in ensuring that consumers benefit from competition in the pharmaceutical industry.

This study examines whether the conduct that the FTC challenged represented isolated instances or is more typical, and whether the 180-day exclusivity and the 30-month stay provisions of the Hatch-Waxman Amendments are susceptible to strategies to

delay or deter consumer access to generic alternatives to brand-name drug products. The study focuses solely on the procedures used to facilitate generic drug market entry *prior to* expiration of the patent(s) that protect the brand-name drug product. The study does not address other procedures for generic entry, and it does not address the patent restoration features of Hatch-Waxman.

To accomplish the study, the Commission subpoenaed documents and information from brand-name and generic drug manufacturers, and examined instances since 1992 in which generic applicants filed an application with FDA seeking to enter the market with a generic version of a drug product prior to expiration of the brand-name drug products' patents.[1] An increasing number of generic applicants have sought entry prior to patent expiration. During the 1980s, only 2 percent of generic applications sought entry this way, but from 1998 to 2000, approximately 20 percent of the generic applications sought entry prior to patent expiration.

The brand-name drug products included in the study represent some of the largest drug products as measured by annual sales. They include "blockbuster" drugs[2] such as Capoten, Cardizem CD, Cipro, Claritin, Lupron, Neurontin, Paxil, Pepcid, Pravachol, Prilosec, Procardia XL, Prozac, Vasotec, Xanax, Zantac, Zocor, Zoloft, and Zyprexa.

Based on the data obtained through the study, we make two primary recommendations concerning the 30-month stay provision and the 180-day exclusivity to mitigate the possibility of abuse that deters more generic drugs from becoming available.[3]

Recommendation 1: Permit only one automatic 30-month stay per drug product per ANDA to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA.

The Current 30-Month Stay Provision: A 30-month stay of FDA approval of a generic applicant[4] is invoked if a brand-name company receives notice of a generic applicant's paragraph IV certification and files suit for patent infringement within 45 days of that notice. Filing of the lawsuit stays FDA's approval of the ANDA until the earliest of: (1) the date the patents expire; (2) a determination of non-infringement or patent invalidity by a court in the patent litigation; or (3) the expiration of 30 months from the receipt of notice of the paragraph IV certification.

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[1] These applications are technically referred to as Abbreviated New Drug Applications (ANDAs) containing a paragraph IV certification.

[2] As used herein, "blockbuster" is defined as a drug product that appears in the top 20 drug products (as ranked publicly by annual gross sales) during one of the years covered by this study.

[3] The study did not provide data on whether, or how, the suggested recommendations might affect brand-name companies' and generic applicant's incentives to enter the market with new brand-name or generic drug products.

[4] For ease of discussion purposes, the term "generic applicant" means those applicants who have filed an ANDA containing a paragraph IV certification. *See* Appendix A for a glossary of frequently used terms.

Key Facts From the Study:

To What Extent Does 30 Months Approximate the Time Typically Required for FDA Review of a Generic's ANDA or for Resolution of the Contemplated Patent Infringement Litigation?

Thirty months historically has approximated the time required for FDA review and approval of the paragraph IV ANDAs of generic applicants that were not sued, and for district and appellate court resolutions of ANDA-related patent infringement litigation. On average, the time required for FDA review and approval was 25 months and 15 days from the application filing date in those cases where generic applicants filing a paragraph IV certification were not sued (and thus could begin commercial marketing once they had FDA approval). On average, the time between the filing of a patent infringement lawsuit and a district court decision in the case was 25 months and 13 days. On average, the time between the filing of a patent infringement lawsuit and a court of appeals decision in the case was 37 months and 20 days.

In the future, patent infringement litigation brought by brand-name companies against generic applicants that have filed ANDAs with paragraph IV certifications may take longer to resolve. The data suggest that cases involving multiple patents take longer than those involving fewer patents. As of June 1, 2002, for 6 out of the 7 cases that have been pending for more than 30 months before a decision from a district court, the brand-name company has alleged infringement of 3 or more patents.

Prior to 1998, for only 1 out of the 9 "blockbuster" drug products in which the brand-name company sued the first generic applicant did the brand-name company allege infringement of 3 patents. Since 1998, for 5 of the 8 "blockbuster" drug products where the brand-name company filed suit against the first generic applicant, the brand-name company alleged infringement of 3 or more patents. Thus, future 30-month stays may expire more frequently *before* the parties obtain a decision of a court in the patent infringement litigation.

Has the Study Identified Any Circumstances That Can Prevent FDA Approval of Generic ANDAs Beyond 30 Months?

Yes. If a brand-name company lists an additional patent in the Orange Book *after* the generic applicant has filed its ANDA, more than one 30-month stay may be generated. The generic applicant is required to re-certify to this later-listed patent, and if, upon notice of the generic's re-certification, the brand-name company sues within 45 days, then FDA approval of the generic's previously filed ANDA is stayed for *an additional* 30-months from the notice date or until a court decision in the newly instituted patent litigation.

From 1992 through 2000, brand-name companies have listed patents in the Orange Book after an ANDA has been filed for the drug product in 8 instances; 6 of these 8 instances occurred since 1998. For the 8 drug products, the additional delay of FDA approval caused by the additional 30-month stay (beyond the first 30-month stay) ranged from 4 to 40 months. In all 4 of the

cases so far with a court decision on the validity or infringement of a later-issued patent, the patent has been found either invalid or not infringed by the ANDA.

Arguments exist that the later-issued patents, which have provided the basis for additional 30-month stays, do not meet FDA's requirements for listing patents in the Orange Book. (These arguments are discussed in detail in Appendix H to the Report.) Under current court rulings and FDA procedures, however, it is very difficult for generic applicants to test these arguments. Recent court opinions have held that Hatch-Waxman does not provide a private right of action through which generic applicants may challenge a patent listing in the Orange Book. The FDA has stated that it lacks the resources and the expertise to review patents to determine whether they are properly listed.

Reasons for the Recommendation:

One 30-month period historically has approximated the time necessary for FDA review and approval of the generic's ANDA. Thus, it does not appear that the 30-month stay provision, as applied once to each ANDA for patents listed in the Orange Book prior to the ANDA's filing date, has a significant potential to delay generic entry beyond the time already necessary for FDA approval of the generic's ANDA. The data also do not indicate that court decisions in ANDA-related patent litigation typically are reached much earlier than 30 months from notice of the generic's ANDA.

The expiration of the 30-month stay may have more significance in the future, if ANDA-related patent litigation begins to last longer than was the case from 1992-2000. Generic applicants may rely on expiration of the 30-month stay more frequently as the first point at which they may decide whether to enter the market, rather than to wait for a court decision on ANDA-related patent litigation that may take longer than 30 months.

The history thus far of multiple 30-month stays caused by the filing of later-issued patents appears problematic, however. The 4 courts that have ruled so far on the patents causing more than one 30-month stay each have found the relevant patent to be invalid or not infringed. The other 4 drug products with multiple 30-month stays involved patents whose listing in the Orange Book could have been the subject of non-frivolous challenges by the generic applicant, had either FDA review of listability or a private right of action to challenge listability under Hatch-Waxman been available.

Multiple 30-month stays prevented FDA approval of the generic applicants' ANDAs for 4 to 40 months *beyond* the initial 30-month period. FDA approval may have occurred more quickly in the absence of the multiple 30-month stays, because the data indicate that FDA approval has occurred, on average, within 25 months and 15 days for generic applicants with paragraph IV certifications that were not sued.

Even without an additional 30-month stay, later-listed patents still receive the usual protections of patent infringement litigation. The brand-name company may sue for patent infringement with respect to any of its patents that it believes may be

infringed by a generic applicant's ANDA, and may seek a preliminary injunction, just as other patent holders do against alleged infringers.[5]

One minor change to the patent statute, which would clarify when brand-name companies can sue generic applicants for patent infringement, would ensure that brand-name companies have recourse to the courts to protect their rights under later-issued patents. Congress may wish to overrule a recent district court decision, *Allergan, Inc. v. Alcon Labs, Inc.*, 200 F. Supp. 2d 1219 (C.D. Cal. 2002), which questions the rights of brand-name companies to sue for patent infringement regarding patents obtained or listed after an ANDA with a paragraph IV has been filed. Under the plain language of 35 U.S.C. § 271(e)(2), however, *all* ANDAs constitute acts of infringement sufficient to establish the existence of a case or controversy with respect to *all* patents that claim any drug or any method of using the drug that may be infringed by generic marketing under an ANDA – regardless of whether the patent has been listed in the Orange Book or has been the subject of a paragraph IV ANDA (as opposed to a different kind of ANDA).

To permit only one 30-month stay per drug product per ANDA[6] should eliminate most of the potential for improper Orange Book listings to generate unwarranted 30-month stays. However, it should be noted that, currently, the FDA does not review the propriety of patents listed in the Orange Book, and courts have ruled that generic applicants have no private right of action to challenge those listings. As a result, there is no mechanism to delist an improperly listed patent from the Orange Book. The lack of such a mechanism may have real world consequences in that the Commission is aware of at least a few instances in which a 30-month stay was generated solely by a patent that raised legitimate listability questions.

There have been various suggestions to address this situation, each with its own pros and cons. One proposal has been to establish an administrative procedure through which generic applicants could obtain substantive FDA review of listability. The FDA, however, has taken the position that it lacks the expertise and resources necessary to perform such a review, and its solely ministerial review of Orange Book listings has been upheld by the courts. At a minimum, it appears useful for the FDA to clarify its listing requirements (*see* Appendix H).

Another remedy that may warrant consideration would permit a generic applicant to raise listability issues as a counterclaim in the context of patent infringement litigation already initiated by the brand-name company in response to a paragraph IV notice from the generic applicant. This would permit resolution of the issue in the same district court proceeding in which other aspects of the relevant patents were at issue. It remains unclear how frequently such a provision

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[5] Thus, the usual patent protections would remain for brand-name companies whose patents may be listed in the Orange Book after the filing of a generic applicant's ANDA solely because it took a long time for the Patent Office to issue the patent.

[6] This would be applied only to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA.

would be used.

Recommendation 2: Pass legislation to require brand-name companies and first generic applicants to provide copies of certain agreements to the Federal Trade Commission.

The Current 180-Day Marketing Exclusivity Provision: The first generic applicant to file an ANDA containing a paragraph IV certification is awarded 180 days of marketing exclusivity, during which the FDA may not approve a subsequent generic applicant's ANDA for the same drug product. The 180-day exclusivity period is calculated from either the date of the first commercial marketing of the generic drug product or the date of a court decision declaring the patent invalid or not infringed, whichever is sooner. Through this 180-day provision, Hatch-Waxman provides an incentive for companies to challenge patent validity and to "design around" patents to find alternative, non-infringing forms of patented drugs. The 180-day marketing exclusivity provision was intended to increase the economic incentives for a generic company to be the first to file an ANDA containing a paragraph IV certification and get to market.

Key Facts From the Study:

How Frequently Has FDA Granted 180-Day Exclusivity?

The regulatory landscape implementing 180-day exclusivity has shifted over the last several years. Before 1992 (a time period not included in this study), the FDA granted 180-day exclusivity to 3 generic applicants. From 1992 until 1998, the FDA did not grant 180-day exclusivity to any generic applicant. Since 1998, when the FDA changed its regulations in response to a court ruling, and more ANDAs containing paragraph IV certifications have been filed, the FDA has granted 180-day exclusivity to the first generic applicant for 31 drug products. Thus, the 180-day exclusivity has been granted for 31 out of the 104 drug products for which a first generic applicant filed an ANDA containing a paragraph IV certification from 1992 through 2000.

Has the 180-Days Exclusivity Been Triggered Most Often by a Court Decision or by the First Generic's Commercial Marketing?

For 19 of the 31 drug products, commercial marketing triggered the running of the first generic applicant's 180-day exclusivity.[7] For the other 12 drug products, a court decision favorable to the generic applicant triggered the 180-day exclusivity.

How Have Generic Applicants Fared in Patent Infringement Litigation?

Generic applicants have prevailed in 73 percent of the cases in which a court has resolved the patent dispute.[8] The rate at

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[7] The data further indicate that, when not sued, first generic applicants begin commercial marketing, after receiving FDA approval, in a timely manner that triggers the running of the 180 days and thus would allow FDA approval of subsequent eligible generic applicants once the 180 days has run.

[8] These statistics include other cases in addition to those involving the 12 drug products where a court decision triggered the 180-day exclusivity. For example, during a time when FDA did not consider a *district court* decision sufficient to trigger the 180-day exclusivity, some generic applicants began commercial marketing following

which the U.S. Court of Appeals for the Federal Circuit reversed district court decisions of patent invalidity and non-infringement for drug products in this study was 8 percent.

When Did Generic Applicants Enter the Market?

In most instances, generic applicants have waited to enter the market until at least a district court has held that the patent covering the brand-name company's drug product was invalid or not infringed by the generic applicant's ANDA.

Are There Circumstances in which the 180-Day Exclusivity Has Been "Parked" For Some Period of Time, So That the First Generic Applicant Does Not Trigger It, and FDA Approval of Any Subsequent Eligible Generic Applicant Would Be Precluded?

Yes. During the time period of the study, there were 20 final settlements of ANDA-related patent litigation. Fourteen of the 20,[9] at the time they were executed, had the potential to delay the start of the first generic applicant's 180-day exclusivity.[10] If the 180-day exclusivity for the first generic applicant does not run, then the FDA may not approve any subsequent eligible generic applicants. Once the 180-day exclusivity runs, the FDA may approve any additional generic ANDAs that have been filed and meet regulatory requirements.

Under 2 of these 14 settlement agreements, the first generic applicant did begin commercial marketing, but each generic was marketing the brand-name company's product as a generic – neither was marketing under its own ANDA. As discussed in more detail below, it is unclear whether this type of "commercial marketing" is sufficient to trigger the running of the 180-day exclusivity.

In addition to the 20 final settlement agreements, there were 4 interim settlement agreements pursuant to which the patent litigation continued, but the parties agreed upon certain conditions in the meantime. The Commission has challenged interim settlements for 3 drug products.[11] In those agreements, the Commission alleged that the brand-name drug company paid the first generic applicant not to enter the market, thereby retaining its (unused) 180-day marketing exclusivity and precluding FDA from approving any eligible subsequent generic applicants.

Have Such Agreements Continued Following FTC Enforcement Action in this Area?

Between April 1999 (shortly after FTC investigations in this area became

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expiration of the 30-month stay and a favorable decision of a district court. In each of these instances, the generic applicant ultimately prevailed in the appellate court, but commercial marketing, not the district court decision, triggered the 180-day exclusivity.

[9] Ten brand-name companies and 10 generic companies used these types of agreements with respect to14 drug products.

[10] In some cases, this delay did not occur due to subsequent events.

[11] *See Abbott Laboratories*, No. C-3945 (May 22, 2000) (consent order), *available at* <http://www.ftc.gov/os/2000/03/abbott.do.htm> (this consent order related to 2 drug products: Hytrin tablets and Hytrin capsules). *Hoechst Marion Roussel, Inc.*, No. 9293 (May 8, 2001) (consent order), *available at* <http://www.ftc.gov/os/2001/05/hoechstdo.pdf>.

public) and the end of the period covered by this study, brand-name companies and first generic applicants have not entered agreements similar to the interim agreements challenged by the FTC.

Reasons for the Recommendation:

The data in the study suggest that the generic applicants have brought appropriate patent challenges: generic applicants prevailed in nearly 75% of the patent litigation ultimately resolved by a court decision.[12] Moreover, most generic applicants have waited to enter the market until at least a district court has held that the patent covering the brand-name company's drug product was invalid or not infringed by the ANDA. This may reflect the fact that a generic applicant's potential liability for lost profits on the brand-name drug usually will vastly exceed its own potential profits after market entry.

The data also indicate that, when not sued, first generic applicants, upon receiving FDA approval, begin commercial marketing in a timely manner that triggers the running of the 180 days and allows FDA approval of any subsequent eligible generic applicant once the 180 days has run. Thus, the data suggest that, in and of itself, the 180-day exclusivity provision generally has not created a bottleneck to prevent FDA approval of subsequent eligible generic applicants.

[12] The data do not establish, however, whether even more appropriate patent challenges might have been brought if the period of generic market exclusivity was longer than 180 days.

Require Brand-Name Companies and First Generic Applicants to Provide Copies of Certain Agreements to the Federal Trade Commission

Issues that merit antitrust scrutiny, however, may arise when brand-name companies and first generic applicants reach agreements that have the potential to "park" the first generic applicant's 180-day exclusivity for some period of time. Fourteen of the 20 final settlement agreements obtained through the study had this potential as of the time they were executed. Such agreements may be procompetitive or competitively neutral. But they also may raise antitrust issues, as was alleged to be the case in the interim settlement agreements the FTC challenged.

Given this history, we believe that notification of such agreements to the Federal Trade Commission and the U.S. Department of Justice is warranted. We support the Drug Competition Act of 2001 (S. 754) introduced by Senator Leahy, as reported by the Committee on the Judiciary, which would require that if a brand-name company and a generic applicant enter into an agreement that relates in any way to the 180-day exclusivity or which concerns the manufacture, marketing, or sale of either the brand name drug or its generic equivalent, then both companies must file a copy of the agreement (or a complete written summary of any oral agreement), along with copies of any other related agreements, with the Commission and the Department of Justice.

Minor Recommendations to the 180-Day Exclusivity Provision:

It is unclear whether a few types of

factual circumstances trigger the running the 180-day exclusivity. Three minor changes would clarify that these circumstances should trigger the 180-day exclusivity and thus reduce any potential for the 180-day marketing exclusivity provision to function as a bottleneck to subsequent generic entry.

Minor Recommendation 1: Clarify that "commercial marketing" includes the first generic applicant's marketing of the brand-name product.

The data revealed 2 instances when the brand-name company and the first generic applicant settled the patent infringement lawsuit with a supply agreement, and 3 other instances in which an optional supply agreement was one part of a patent settlement. In all instances, the agreements contemplated that the brand-name company would supply the generic applicant with the brand-name drug product, so that the generic applicant could market it as a generic version. Currently, it is somewhat unclear whether marketing of the brand-name product by the first generic applicant constitutes "commercial marketing" sufficient to trigger the 180-day exclusivity.[13]

To avoid situations in which the running of the 180 days is not triggered because of this uncertainty, it would be desirable to clarify that "commercial marketing" includes *any* marketing by the first generic applicant, even under a supply agreement with the brand-name company. In some circumstances, such commercial marketing may be the only event that can trigger the running of the 180-day exclusivity. For example, if there is a second generic applicant, but it is not sued by the brand-name company, then there will not be a court decision to trigger the 180 days, and only the first generic applicant's commercial marketing under the supply agreement could start the running of the 180 days and thus, after 180 days, free the FDA to approve any eligible subsequent generic applicants.

Minor Recommendation 2: Codify that the decision of any court on the same patent being litigated by the first generic applicant constitutes a "court decision" sufficient to start the running of the 180-day exclusivity.

There is some question as to *which* court's decision is sufficient to activate the "court decision" trigger of the 180-day exclusivity. Two courts of appeal have held,[14] and the FDA has issued guidance, [15] that *any* court's decision on whether the

[13] In response to a citizen petition involving the 30 mg strength of Procardia XL, the FDA determined that the first generic applicant was ineligible for 180-day exclusivity, because the generic applicant and the brand-name company had settled their patent litigation and effectively changed the generic applicant's certification from a paragraph IV to a paragraph III. In addition, and under alternative reasoning, the FDA determined that even if the first generic applicant was eligible for the 180-day exclusivity, that exclusivity already had been triggered by the generic applicant's marketing under a supply agreement with the brand-name company. *See* FDA Letter to Deborah A. Jaskot, Docket No. OPP-1446/CP1 (Feb. 6, 2001). This letter leaves somewhat unclear whether a supply agreement alone would be sufficient to satisfy the commercial marketing trigger for the 180-day exclusivity. *See, also, Mylan Pharmaceuticals, Inc. v. Tommy G. Thompson*, 2001 U.S. Dist. LEXIS 24234 (N.D. WV Apr. 18, 2001).

[14] *See Teva Pharmaceuticals, USA, Inc. v. FDA*, 182 F.3d 1003 (D. C. Cir 1999), *Granutec, Inc. v. Shalala*, 139 F.3d 889 (4th Cir. 1998).

[15] *See* FDA Guidance for Industry: 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act (Jun. 1998). *See also Teva Pharmaceuticals, USA, Inv. v. FDA*, 182 F.3d 1003, 1005 (D.C. Cir. 1999).

patent at issue is invalid or not infringed is sufficient to trigger the running of the first generic applicant's 180-day exclusivity.

On balance, we believe this is the correct result, but there are pros and cons. On the one hand, the rule would make it less likely that agreements between brand-name and generic companies that had the effect of "parking" the 180-day exclusivity for some period of time could forestall FDA approval of a subsequent eligible generic applicant. This is because, if the brand-name company sues the second (or later) generic applicant, and that generic applicant won its patent litigation, then the 180-day exclusivity of the first generic applicant would begin to run from the date of the later generic applicant's favorable court decision. Such circumstances may arise; the data showed that brand-name companies sued later generic applicants in nearly 85% of the cases. The rule would be consistent with the mandate in the legislative history of Hatch-Waxman to "make available more low-cost drugs,"[16] because the rule would assist in eliminating potential bottlenecks to FDA approval of subsequent eligible generic applicants.

Such a rule also could speed generic entry when the second generic applicant's lawsuit is resolved prior to that of the first applicant. This appears to be appropriate given the low reversal rate of district court opinions of patent invalidity and non-infringement. For example, under this rule, if both the first and second generic applicants are sued, but the court hearing the second generic applicant's case is the first to arrive at a decision, then that court's decision would trigger the running of the first generic applicant's 180-day exclusivity, regardless of whether the first generic applicant had received FDA approval. The data revealed 1 such case.

On the other hand, as illustrated in the preceding paragraph, the operation of this rule could deprive the first generic applicant of its ability to market under the 180-days exclusivity, even though the first generic applicant had been diligently pursuing resolution of its patent litigation. This result could dampen the incentive to become the first generic applicant.[17] Moreover, if the later court issues a non-infringement decision, the reasoning underlying the holding may not apply to the first generic applicant's ANDA, depending upon the facts of the case.

Minor Recommendation 3: Clarify that a court decision dismissing a declaratory judgment action for lack of subject matter jurisdiction constitutes a "court decision" sufficient to trigger the 180-day exclusivity.

One court of appeals has held that a dismissal of a declaratory judgment action for lack of a case or controversy is a "court decision" of non-infringement sufficient to trigger the 180-day exclusivity.[18] We believe that the court's reasoning is persuasive and should be adopted.

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[16] H.R.Rep. No. 98-857, pt. 1, 98th Cong., 2d Sess., at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

[17] By contrast, the absence of such a rule also could dampen the incentive for later generic applicants to develop eligible ANDAs containing paragraph IV certifications.

[18] *Teva Pharmaceuticals, USA, Inc. v. FDA*, 182 F.3d 1003 (D. C. Cir 1999).

The U.S. Court of Appeals for the District of Columbia confronted a situation in which the brand-name company did not sue any of the generic applicants for patent infringement, presumably because the brand-name company's patents were not infringed by the ANDA. To trigger the first generic applicant's 180-day exclusivity (because it had not yet been approved by the FDA), the second generic applicant sought a declaratory judgment that its ANDA did not infringe the brand-name product's patents. The district court hearing the case dismissed the lawsuit for lack of subject matter jurisdiction, because the brand-name company indicated that it would not sue the second generic applicant for patent infringement, thus eliminating its reasonable apprehension of a patent infringement suit and the existence of a case or controversy. This dismissal also estopped the brand-name company from suing the generic applicant in the future.

The Court of Appeals determined that the dismissal for lack of case or controversy was, in fact, a court decision, because the brand-name company indicated that the second generic applicant's ANDA did not infringe the relevant patent. As a result, the dismissal activated the court decision trigger. Such a rule eliminates the potential for a bottleneck created by a first generic applicant that does not exercise its commercial marketing rights.

Chapter 1 Introduction and Background

Introduction

In April 2001, the Commission began an industry-wide study focused on certain aspects of generic drug competition under the Hatch-Waxman Amendments.[1] The Amendments provide certain methods by which generic drug manufacturers can obtain approval to market a generic version of a brand-name product. The study's purpose was to provide a more complete picture of how generic drug competition has developed under one method the Amendments established: generic entry *prior to* expiration of the brand-name company's patents on the relevant drug product.[2] This report sets forth the results of the study.[3]

The study was prompted, in part, by the Commission's enforcement actions against alleged anticompetitive agreements that relied on certain Hatch-Waxman provisions.[4] The study was designed to determine whether such agreements are isolated instances or more typical, and whether particular provisions of the Hatch-Waxman Amendments are susceptible to strategies to delay or deter consumer access to low-cost generic alternatives to brand-name drug products.

The study also was requested by Representative Henry Waxman, one of the co-sponsors of Hatch-Waxman, who asked the FTC to "investigate and produce a study on the use of agreements between and among pharmaceutical companies and potential generic competitors and any other strategies that may delay generic drug competition throughout the U.S." Other members of Congress have proposed legislation to amend various portions of Hatch-Waxman, including the sections that

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

[2] The study did not examine how generic competition has developed under the other methods the Amendments established. Nor did the study examine whether Hatch-Waxman provisions have achieved another purpose of the Amendments: to compensate brand-name companies for lost patent life due to the time needed for FDA's safety and efficacy review process.

[3] Appendix A contains a glossary of frequently used terms and their meanings under Hatch-Waxman.

[4] *See, e.g., Abbott Laboratories*, No. C-3945 (May 22, 2000) (consent order), *available at* <http://www.ftc.gov/os/2000/03/abbott.do.htm>. *Hoechst Marion Roussel, Inc.*, No. 9293 (May 8, 2001) (consent order), *available* <http://www.ftc.gov/os/2001/05/hoechstdo.pdf>. The same issues are raised by another case in which the Commission settled similar allegations, *see* American Home Products, Docket No. 9297 (Feb. 19, 2002) (decision and order) *available at* <http://www.ftc.gov/os/2002/02/ahpdo.pdf>. *See also Schering-Plough Corp., et al.*, Docket No. 9297, Initial Decision (Jul. 2, 2002), *available at* <http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf>. The Commission also has accepted for public comment a consent order settling charges that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent pursuant to another provision of the FDA's regulations implementing Hatch-Waxman. *Biovail Corp.*, File No. 011-0094, Agreement Containing Consent Order, (Apr. 19, 2002), *available at* <http://www.ftc.gov/os/2002/04/biovaildecision.htm>. Moreover, the Commission has accepted for public comment a consent order settling charges that Elan and Biovail entered into a supply and distribution agreement for a generic drug product that may have unreasonably restrained their incentives to compete against each other. *See* FTC, *Biovail Corp. and Elan Corp.*, File No. 011 0132, Agreement Containing Consent Order (Jun. 27, 2002), *available at* <http://www.ftc.gov/os/2002/06/biovailelanagreement.pdf>

are the subject of the Commission's study.[5]

Finally, the study was motivated, in part, by the prospect of a substantial sales volume of brand-name drug products coming off patent in the next several years.[6] This represents an enormous opportunity for the generic drug industry and, conceivably, a commensurate threat to the brand-name pharmaceutical industry. Brand-name pharmaceutical drug manufacturers seeking to protect the sales of brand-name drugs may have an incentive and ability to enter into agreements with would-be generic competitors, or engage in other types of activities, that would slow or thwart the entry of competing generic drug products.

The Commission has developed significant expertise regarding competition in the pharmaceutical industry. The Commission has, for example, brought antitrust enforcement actions affecting both brand-name and generic drug manufacturers.[7] Commission staff have conducted empirical analyses of competition in the pharmaceutical industry, including in-depth studies by the staff of the Bureau of Economics.[8] The Commission has provided testimony before Congress,[9] and Commission staff have filed comments with the Food and Drug Administration ("FDA") regarding competitive aspects of Hatch-Waxman implementation.[10] In addition, individual Commissioners have addressed the subject of pharmaceutical competition before a variety of audiences, both to solicit input from affected parties and to promote dialogue regarding practical solutions.[11]

[5] *See, e.g.*, S. 812, 107th Cong. (2001) (introduced by Sens. Schumer and McCain); S. 2677, 107th Cong. (2002) (introduced by Sen. Rockefeller); S. 754, 107th Cong. (2001) (introduced by Sen. Leahy).

[6] National Institute for Health Care Management, "Prescription Drugs and Intellectual Property Protection" (Aug. 2000) at 3.

[7] *See, e.g., FTC v. Mylan Laboratories, Inc. et al.*, 62 F. Supp. 2d 25 (D.D.C. 1999); *Roche Holding Ltd.*, 125 F.T.C. 919 (1998) (consent order); *Ciba-Geigy Ltd.*, 123 F.T.C. 842 (1997) (consent order).

[8] Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999) *available at* <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>; David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002) ("Reiffen and Ward"), *available at* <http://www.ftc.gov/be/econwork.htm>

[9] Testimony of Federal Trade Commission before the Committee on Commerce, Science and Transportation, United States Senate (April 23, 2002) *available at* <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>; Testimony of the Federal Trade Commission before the Committee on the Judiciary, United States Senate, *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements* (May 24, 2001) *available at* <http://www.ftc.gov/os/2001/05/pharmtstmy.htm>.

[10] *FDA: Citizen Petition*, Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Mar. 2, 2000) *available at* <http://www.ftc.gov/be/v000005.pdf> (recommending modifications to the FDA's Proposed Rule on citizen petitions intended to discourage anticompetitive abuses of the FDA's regulatory processes); *FDA: 180-Day Marketing Exclusivity for Generic Drugs*, Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Nov. 4, 1999) (AMarketing Exclusivity Comment@) *available at* <http://www.ftc.gov/be/v990016.htm> (recommending that the FDA's Proposed Rule on 180-day marketing exclusivity be modified to limit exclusivity to the first ANDA filer and to require filing of patent litigation settlement agreements).

[11] *See, e.g.*, Sheila F. Anthony, *Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property* (June 1, 2000) *available at* <http://www.ftc.gov/speeches/anthony/sfip000601.htm>; Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes* (Nov. 3, 2000) *available at* <http://www.ftc.gov/speeches/leary/learypharma.htm>; Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II* (May 17, 2001) *available at* <http://www.ftc.gov/speeches/leary/learypharmaceutical settlement.htm>; Timothy J. Muris, *Competition and*

In October 2000, the Commission began the formal process of obtaining authorization to conduct this study. As required by the Paperwork Reduction Act and implementing regulations of the Office of Management and Budget,[12] the Commission published a Federal Register notice[13] that included, among other things, the special orders under Section 6(b) of the Federal Trade Commission Act[14] that the Commission planned to serve on brand-name pharmaceutical companies and generic drug manufacturers.

In response to the public comments received following this Federal Register notice, the Commission clarified the proposed information requests as suggested by several parties and published in March 2001 a second notice requesting public comments.[15] On April 6, 2001, the Commission obtained OMB approval to conduct the study, and on April 25, 2001, the Commission began service of the special orders on 28 brand-name companies and over 50 generic drug companies.[16] By December 31, 2001, the Commission had received substantial compliance with the special orders.

Overview of the Hatch-Waxman Act and the FDA's Implementing Regulations

Before describing the scope of the study, it is important to understand the historical context in which Hatch-Waxman arose. Moreover, the generic approval process Hatch-Waxman implemented demands an understanding of the interaction of the patent system and the regulatory structure governing the approval of brand-name drugs.

Pre-Hatch-Waxman Regulatory Environment

In 1962, amendments to the Federal Food, Drug, and Cosmetic Act added a proof-of-efficacy requirement to new drug approvals; before that time, the FDA approved drugs for safety only. As a result of the amendments, brand-name companies are required to prove that new drugs are safe and effective prior to FDA approval. To prove safety and efficacy, brand-name companies are required to conduct tests on humans ("clinical trials") and to submit those results to the FDA with their new drug application (NDA).

Those seeking to market a generic version of an existing post-1962 brand-name drug also had to perform their own safety and efficacy studies, much like the brand-name companies had to demonstrate the safety and efficacy of the brand-name drug.[17] The FDA did not have a streamlined

Intellectual Property Policy: The Way Ahead, at 5-6 (Nov. 15, 2001) *available at* <http://www.ftc.gov/speeches/muris/intellectual.htm>.

[12] The Commission was required to obtain OMB clearance before it could begin the study because the number of special orders to be sent triggered the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. Ch. 35, as amended.

[13] *See* 65 Fed. Reg. 61334 (Oct. 17, 2000).

[14] 15 U.S.C. § 46(b).

[15] *See* 66 Fed. Reg. 12512 (Feb. 27, 2001).

[16] Several brand-name drug companies have equity interests in generic subsidiaries and, thus, were requested to answer questions relating to both brand-name products and generic products.

[17] The FDA considered "such retesting to be unnecessary and wasteful because the drug [had] already been determined to be safe and effective. Moreover, such

procedure by which to approve generic versions of brand-name drug products whose patents had expired.[18] By 1984, the FDA estimated that there were approximately 150 brand-name drugs whose patents had expired for which there was no generic equivalent.[19]

Another factor complicating generic drug approval concerned the timing of when generic companies could perform their clinical tests. Before Hatch-Waxman was enacted, a generic company could not begin the required FDA approval process until *after* patents on the relevant brand-name product had expired; to begin earlier would typically have infringed the brand-name company's patents.[20] Thus, at that time, patent law coupled with the FDA generic approval process, in effect, extended the term of the brand-name company's patent protection and delayed market entry by generic versions of brand-name pharmaceutical drug products.

Brand-name pharmaceutical companies also confronted problems. The discovery and development of new drug products are expensive and time-consuming.[21] To spur this investment, as well as to recoup investments made, brand-name companies obtain patent protection to exclude others from making, using, or selling an invention for a number of years. Often, however, the brand-name companies obtained patents prior to FDA approval of the drug product. Thus, the effective terms of many patents were shortened due to the time required for the FDA to ensure the safety and efficacy of the brand-name company's drug product.

The Hatch-Waxman Amendments

Congress passed the Hatch-Waxman Amendments to address both issues.[22] To enable earlier generic entry, the Amendments provided that certain conduct related to obtaining FDA approval that would otherwise constitute patent infringement would be exempt from infringement liability under the patent laws. In addition, generic applicants were permitted to rely on the brand-name company's trade secret data demonstrating the safety and efficacy of the brand-name drug product. To restore patent protection to brand-name companies to compensate them for the time used to obtain FDA approval, the Amendments contained provisions to extend patent terms in certain circumstances.

Thus, Hatch-Waxman balanced an expedited FDA approval process to speed generic entry with patent term restoration to

retesting is unethical because it requires that some sick patients take placebos and be denied treatment known to be effective." *See* H.R. Rep. No. 98-857, Part I at 16 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649.

[18] The FDA did establish, however, a procedure to determine the effectiveness of all drugs approved prior to 1962, and it established a policy of permitting the approval of a generic equivalent to a safe and effective pre-1962 brand-name drug. This generic approval procedure, however, did not apply to drugs approved after 1962. *Id.*

[19] *Id.* at 17.

[20] *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984).

[21] *See* Pharmaceutical Research and Manufacturers of America, "Delivering on the Promise of Pharmaceutical Innovation: The Need to Maintain Strong and Predictable Intellectual Property Rights, White Paper," *submitted to* Federal Trade Commission and the Department of Justice – Antitrust Division (Apr. 22, 2002) at 7-10, *available at* <http://www.ftc.gov/os/comments/intelpropertycomments/phrma020422.pdf>.

[22] Appendix B contains the Hatch-Waxman Amendments, as codified at 21 U.S.C. 355 et seq.

ensure continuing innovation. As one federal appellate judge explained, the Amendments "emerged from Congress's efforts to balance two conflicting policy objectives: to induce brand-name 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."[23]

Pursuant to the Federal Food, Drug, and Cosmetic Act, a brand-name company seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application (NDA). The NDA ultimately must include a variety of information that is extremely expensive and time-consuming to develop, including clinical trial data.

When the NDA is filed, the NDA filer also must provide the FDA with certain categories of information regarding the patents that cover the drug that is the subject of its NDA.[24] Upon approval of the NDA, the FDA lists the patents in an agency publication entitled "Approved Drug Products with Therapeutic Equivalence," commonly known as the "Orange Book."[25] In addition to patents on the active ingredient in a drug product, patents on specific formulations (*i.e.*, a tablet form) or methods of use (*i.e.*, used to treat heartburn in mammals) of the drug product are also listed in the Orange Book.

Rather than requiring a generic manufacturer to repeat the costly and time-consuming NDA process, the Amendments permit the company to file an Abbreviated New Drug Application ("ANDA"). The object of the ANDA process is to demonstrate that the generic drug product has the same active ingredient, route of administration, dosage form and strength, and proposed labeling as the brand-name drug. The ANDA also must contain sufficient information to demonstrate that the generic drug is "bioequivalent" to the relevant brand-name product.[26] As a result of providing this information, the generic applicant is allowed to rely on the FDA's previous findings of safety and effectiveness for the referenced brand-name drug, and thus the applicant does not have to provide its own clinical studies to demonstrate the generic drug product's safety and effectiveness. This reliance on the innovator's safety and efficacy data allows generic applicants to save very substantial amounts of money in development costs.

An ANDA also must contain a certification regarding each patent listed in the Orange Book that relates to the relevant NDA for which the generic applicant is seeking to make a generic version. The statute provides ANDA applicants with four certification options: they may certify (I) that the required patent information has not been filed; (II) that the patent has expired; (III) that the patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (IV) that the patent is invalid or will not be infringed by the generic drug for which the ANDA

[23] *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds) (citations omitted).

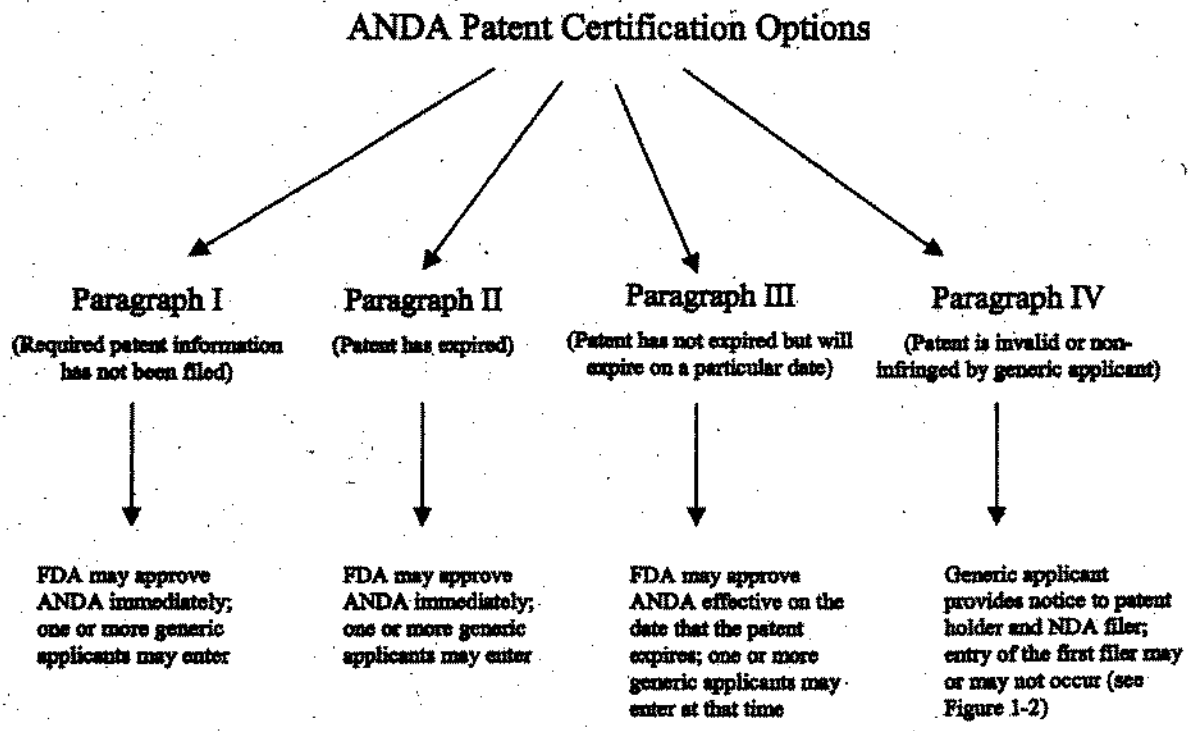
[24] 21 U.S.C. § 355(b)(1).

[25] *Id.* at § 355(j)(7)(A).

[26] *Id.* at § 355(j)(2)(A)(iv). Bioequivalence means that the rate and extent of absorption of the generic drug is not significantly different from the rate and extent of absorption of the listed drug when administered at the same dosage.

applicant seeks approval. For ease of discussion throughout this study, these certifications will be referred to as paragraph I, II, III and IV certifications, respectively. Figure 1-1 depicts graphically the FDA approval process depending upon which certifications the generic applicant makes.

Figure 1-1 ANDA Patent Certifications



If the applicant makes a certification under paragraphs I or II, the FDA may approve the ANDA immediately, provided other requirements are met.[27] If the applicant makes a paragraph III certification, the FDA may approve the ANDA effective on the date that the patent expires.[28]

Paragraph IV Certifications

When an applicant makes a paragraph IV certification, two additional provisions of Hatch-Waxman are implicated. These two provisions are at the heart of the FTC's study.

The first is the automatic "30-month stay" protection afforded brand-name companies. An ANDA filer that makes a paragraph IV certification must provide a notice to both the patent holder and the

[27] *Id.* at § 355(j)(5)(B)(ii).

[28] *Id.*

NDA filer[29] with a detailed statement of the factual and legal basis for the ANDA filer's assertion that the patent is invalid or not infringed. Once the ANDA filer has provided such notice, a patent holder (usually the brand-name company) must bring an infringement suit within 45 days to take advantage of the statutory stay provision.[30] If the patent holder does not bring suit within 45 days, the FDA approval process may proceed, and the FDA may approve an ANDA as soon as regulatory requirements are fulfilled.[31] A 30-month stay of FDA approval of an ANDA applicant is invoked when a brand-name company receives notice of a generic applicant's paragraph IV certification and files suit for patent infringement within 45 days of that notice.[32] Filing of the lawsuit stays the FDA's approval of the ANDA until the earliest of: (1) the date the patent(s) expire; (2) a final determination of non-infringement or patent invalidity by a court in the patent litigation; or (3) the expiration of 30 months from the receipt of notice of the paragraph IV certification.

The second provision is the "180-day period of exclusivity." The first generic applicant to file an ANDA containing a paragraph IV certification is eligible for 180 days of marketing exclusivity, during which the FDA may not approve subsequent ANDAs for the same drug product.[33] The 180-day exclusivity period thus increases the economic incentives for a generic company to be the first to file an ANDA containing a paragraph IV certification. Through this 180-day provision, the Amendments also provide an incentive for generic companies to litigate patents that may be invalid and to "design around" patents to find alternative, non-infringing forms of patented drugs.[34] The 180-day exclusivity period is calculated from either the date of the first commercial marketing of the generic drug product or the date of a court decision declaring the patent invalid or not infringed, whichever is sooner.[35] After the 180 days, other generic products can enter the market, provided they obtain the FDA regulatory approval. Subsequent eligible generic applicants must wait until the first generic applicant's 180 days have run before the FDA can approve the subsequent ANDA.

Figure 1-2 describes graphically how the 30-month stay and 180-day exclusivity provisions affect FDA approval of a generic applicant's ANDA.

[29] *Id.* at § 355(j)(2)(B). Although the patent holder and the NDA filer are often the same person, this is not always the case. The Hatch-Waxman Amendments require that all patents that claim the drug described in an NDA must be listed in the Orange Book. Occasionally, this requires an NDA filer to list a patent that it does not own.

[30] *Id.* at § 355(j)(5)(B)(iii).

[31] *Id.* For example, the statute requires the ANDA applicant to establish bioequivalence.

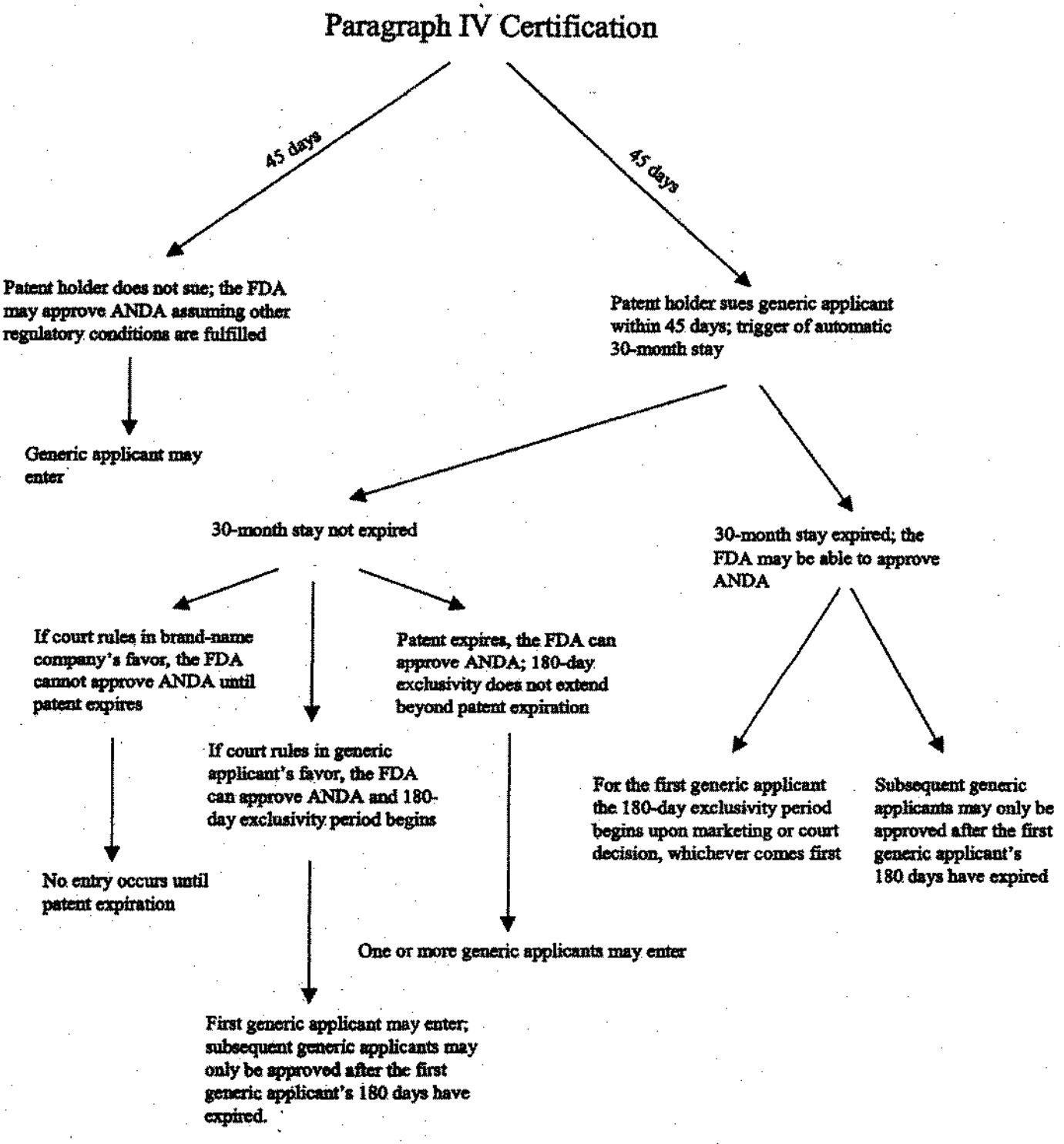
[32] 21 U.S.C. at § 355(j)(5)(B)(iii).

[33] *Id.* at § 355(j)(5)(B)(iv).

[34] *See Granutec, Inc. v. Shalala*, 139 F.3d 889, 891 (4th Cir. 1998).

[35] 21 U.S.C. § 355(j)(5)(B)(iv).

Figure 1-2 Paragraph IV Certifications



Price Effect of Generic Entry

Because generic drugs are typically far less expensive than their corresponding brand-name versions, competition from generic drugs can deliver large savings to consumers. A Congressional Budget Office (CBO) study attempted to quantify the magnitude of this effect by analyzing retail pharmacy data from 1993 and 1994. The study found that, for drugs that are available in both generic and brand-name versions, the average price of a generic prescription was approximately half of the average price of a brand-name prescription.[36] The CBO estimated that, in 1994, the availability of generic drugs saved purchasers between $8 billion and $10 billion.[37]

The broader empirical economics literature also points to a number of competitive effects associated with the introduction of generic drugs. Early research using small data samples with information on brand name and generic prescription drug prices and sales found that (1) brand name drug prices rose slightly, but that average drug prices declined some 20 percent within approximately two years of generic entry,[38] and (2) generic entry produces slight reductions in brand name drug prices and declines in generic prices as the number of generic rivals increases.[39]

A more recent study of 32 drugs that lost patent protection around the time of the passage of the Hatch-Waxman Amendments found that generic entry results in somewhat higher prices for brand-name prescription drugs (in light of factors such as inelastic demand among users of brand-name products), but large decreases in the prices of corresponding generic drugs.[40] Another recent study of 32 drugs that lost patent protection after passage of the Hatch-Waxman found that generic drug prices fell until at least the fifth generic firm enters, and that falling prices from increased competition can continue with the entry of additional generic competitors.[41] It is also noteworthy that elements of this literature indicate that generic entrants gain significant market share at the expense of their rival brand name drug companies after their entry. Overall, this literature points to significant short-run competitive impacts of generic entry that can lead to substantial benefits for consumers of prescription drugs.

Scope of the Study

This study focuses solely on the competitive circumstances surrounding

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[36] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) ("CBO Study") at 28, *available at* <http://www.cbo.gov/showdoc.cfm?index'655&sequence'0>.

[37] *Id.* at 31.

[38] Henry Grabowski & John M. Vernon, "Brand Loyalty, Entry and Price Competition In Pharmaceuticals After the 1984 Drug Act," 35 J. of Law & Econ. 331-50 (Oct. 1992).

[39] Richard E. Caves, et al., "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry" (Brookings Papers on Economic Activity, Microeconomics, Martin Neil Baily & Clifford Winston, eds., Brookings Institution, Washington, DC 1991).

[40] Richard G. Frank & David S. Salkever, "Generic Entry and the Pricing of Pharmaceuticals," 6 J. of Econ. & Mgmt Strategy, 75-90 (Spring 1997) (Generic entry will induce those buyers who are highly sensitive to price to switch to low-price generics; price-insensitive buyers continue to purchase branded products. This segmentation of the market means that the branded drug often will face a less elastic demand curve, which can induce the profit-maximizing branded producer to raise its price.).

[41] Reiffen and Ward, *supra* n. 8.

generic competition for those brand-name drug products (1) subject to an ANDA notice containing a paragraph IV certification (2) that brand-name companies received after January 1, 1992 and prior to January 1, 2001. By focusing on these brand-name drug products, the study could examine how the 180-day marketing exclusivity and the 30-month stay provisions have influenced the development of generic drug competition.

The study does not address how generic competition has developed under paragraph I, II, or III certifications. The study also does not address the patent restoration features of Hatch-Waxman.

ANDAs Under Hatch-Waxman

According to the FDA, from the time Hatch-Waxman became effective in 1984 through December 31, 2000, 8,019 ANDAs were filed with the FDA.[42] Of these applications, 7,536 (94 percent) raised no patent issues (*i.e.*, the ANDAs did not contain a paragraph IV certification). A substantial portion of the total number of ANDAs, however, relate to the same brand-name product or NDA. Thus, the total number of ANDAs does not represent 8,019 unique brand-name drug products, and it is unclear as to how many unique brand-name drug products the total 8,019 ANDAs related.

Four hundred eighty-three (483) (or six percent of the total number of ANDAs filed) contained Paragraph IV certifications. The 483 ANDAs relate to 130 unique brand-name drug products as measured by unique NDAs. The share of ANDAs with paragraph IV certifications – compared to all ANDAs filed (those with paragraph I-IV certifications) -- has increased significantly since Hatch-Waxman was enacted. According to the data provided by the FDA, during the 1980s (1984-89), only 2 percent of ANDAs contained paragraph IV certifications. This share increased to approximately 12 percent for the 1990s, and it has increased substantially in the last few years: from 1998-2000, approximately 20 percent of ANDAs contained paragraph IV certifications.

The brand-name drug products this study covered include any drug product for which the brand-name company received notification of an ANDA containing a paragraph IV certification after January 1, 1992 and prior to January 1, 2001.[43] This selection criteria resulted in 104 drug products, as represented by New Drug Applications (NDAs) filed with the FDA, within the scope of the study. As noted previously, from 1984 to January 2001, 130 unique NDAs were subject to at least one ANDA with a paragraph IV certification. The most recent 104 brand-name drug products (of the 130 total) are included within the scope of the study.

Appendix C contains a list of the NDAs within the scope of the study. The drug products included in the study represent some of the largest drug products as measured by annual sales, including so-called "blockbuster" drugs such as Capoten, Cardizem CD, Cipro, Claritin, Lupron Depot, Neurontin, Paxil, Pepcid, Pravachol,

[42] FDA staff provided this information to the FTC staff.

[43] If any later-filed generic applicant filed its ANDA with the requisite certification after January 1, 1992, even if the first generic applicant for a particular drug product filed its application prior to January 1, 1992, the drug product was included within the scope of the study.

Prilosec, Procardia XL, Prozac, Vasotec, Xanax, Zantac, Zocor, Zoloft, and Zyprexa.

The FDA provided the Commission with the identity of the generic companies that have filed ANDAs containing paragraph IV certifications since enactment of Hatch-Waxman in 1984. Using this information, FTC staff identified which brand-name companies had received notice of the filing of an ANDA containing a paragraph IV certification. The list of brand-name companies and generic companies are attached as Appendix D. Special orders were served on all identified brand-name companies who received notice of, and on the first three generic drug companies who had filed, the ANDA.[44]

The FTC's special orders required the brand-name companies to produce agreements with generic applicants that relate to the ANDA filing, results of ANDA patent infringement litigation with generic applicants, listing of patents in the FDA's Orange Book, sales information, and the use of citizen petitions. Generic applicants were required to produce agreements relating to the innovator's drug products for which they had filed an ANDA containing a paragraph IV certification, and to respond to questions about the results of patent infringement litigation with the brand-name company, sharing of litigation expenses with other generic applicants, allegations of improper Orange Book listings, and sales information.

Organization of the Report

Chapter 2 of the Report reviews the frequency and outcome of patent infringement lawsuits in connection with paragraph IV certifications. Chapter 3 discusses the agreements that litigants have used to settle patent infringement litigation under Hatch-Waxman. Chapters 4 and 5 examine in more detail how certain Hatch-Waxman provisions, the 30-month stay and the 180-day exclusivity provisions respectively, affect generic entry. Chapter 6 discusses the use of citizen petitions by brand-name companies for drug products included in the study.

Appendix A contains a glossary of terms used most frequently. Appendix B contains the text of Hatch-Waxman. Appendix C lists the NDAs within the scope of the study. Appendix D lists the brand-name companies and generic companies that received special orders. Copies of the questions in the special orders are contained in Appendix E. Appendix F contains a copy of the FTC Staff's Citizen Petition on the listability of certain patents in the Orange Book. Appendix G describes the drug products where the brand-name company has filed a patent in the Orange Book after being notified of the ANDA, which, in turn, generated an additional 30-month stay upon suit. Appendix H analyzes certain categories of patents that raise Orange Book listability issues.

[44] In many instances, only one generic applicant had filed an ANDA containing a paragraph IV certification for a particular drug product. In these cases, special orders were served only on the first generic applicant.

Chapter 2 Outcomes of Patent Infringement Lawsuits Under the Hatch-Waxman Amendments

Introduction

The application of both the 180-day exclusivity and 30-month stay provisions depends, at least in part, upon whether the brand-name company initiates patent infringement litigation against a generic applicant.[1] As noted earlier, the 180-day exclusivity provision grants, under certain circumstances, 180 days of exclusive marketing to the first generic applicant that files an ANDA containing a paragraph IV certification. A 30-month stay of FDA approval of a potential generic competitor is invoked if a brand-name company receives notice of a generic applicant's paragraph IV certification and files suit for patent infringement within 45 days of that notice.

Filing of the lawsuit stays the FDA's approval of the ANDA until the earliest of: (1) the date the patents expire; (2) a final determination of non-infringement or patent invalidity by a court in the patent litigation; or (3) the expiration of 30 months from the receipt of notice of the paragraph IV certification. This chapter reviews the frequency and outcome of these patent infringement lawsuits.

For nearly 75 percent of drug products this study covered, brand-name companies initiated patent infringement litigation against the *first* generic applicant. In the other 25 percent, there was no suit, and the FDA has approved most of the generic products, thus allowing generic entry to occur. FDA approval of ANDAs submitted by first generic applicants who were not sued by the brand-name company took, on average, 24 months and 2 weeks from the ANDA filing date.

In 70 percent of the cases in which the brand-name company sued the *first* generic applicant, there has been either a court decision, or the parties have agreed to a final settlement. Of these lawsuits, involving 53 drug products, 20 settled without a court decision on the merits of the patent infringement lawsuit. These settlement agreements are discussed in detail in Chapter 3. In the other 30 percent of the cases, a district court had not yet ruled as of June 1, 2002.

Of all the patent infringement cases (including first and subsequent generic applicants) in which there has been a decision of a court as of June 1, 2002, generic applicants prevailed in 73 percent of the cases, and brand-name companies prevailed in 27 percent. Of the decisions favoring the generic applicant, there were slightly more non-infringement decisions (14) than patent invalidity decisions (11). The rate at which the U.S. Court of Appeals for the Federal Circuit overturned district court decisions of patent invalidity for drug products in this study was 8 percent.

In most instances when the 30-month

[1] For ease of discussion purposes, the term "generic applicant" means those applicants who have filed an ANDA containing a paragraph IV certification. *See* Appendix A for a glossary of frequently used terms.

stay has expired without a decision of a district court and the FDA approved the generic applicant's ANDA, the generic applicant did not enter the market until it secured a district court decision of patent invalidity or non-infringement.

How Frequently Have Brand-Name Companies Sued the First Generic Applicant?

The study sought to determine the frequency with which brand-name companies have initiated patent infringement lawsuits against generic applicants within the required 45-day period, thus triggering the 30-month stay provision. The data revealed 75 drug products, out of a total of 104 NDAs (72 percent), in which the brand-name company sued the *first* generic applicant. For all but 5 of the 104, the first generic applicant for one dosage strength of the drug product (*e.g.*, 10, 20, and 40 mg tablets) was the first applicant for all strengths of the drug product. In light of this fact, unless otherwise noted, all of the drug products with multiple strengths (with the same 5 exceptions) involved one NDA, and therefore were counted as one brand-name drug product with one first generic applicant. The 5 exceptions are presented in footnotes 4, 7, and 8 to ensure completeness. Table 2-1 summarizes this result.

Table 2-1 Patent Litigation Frequency

[illegible]	[illegible]
Brand-Name Company Sued the First Generic Applicant	75
Brand-Name Company Did Not Sue the First Generic Applicant	29[2]
Total	**104**

For the 75 drug products where patent litigation was brought, the median net sales in the year the first generic applicant filed its ANDA were $190 million per year. By contrast, the majority of the 29 NDAs for which no suit was filed had net sales of less than $100 million in the year the generic applicant filed its application.[3]

For 15 of the 29 drug products where the brand-name company did not sue the first generic applicant, the generic applicant began commercial marketing soon after FDA approval and prior to patent expiration. In 6 cases, the FDA has not approved the generic applicant's ANDA as of June 1, 2002, and the patents have not yet expired. In 6 cases the FDA has approved the ANDA, but commercial marketing has not yet begun. And in the remaining 2 cases, the

[2] For 1 of the 29 drug products, 2 different generic applicants were the first to file for each of the 3 different strengths of this drug product. In each strength, the brand-name company did not sue the generic applicant. As noted above, this brand-name drug product is only counted once in the total of 29.

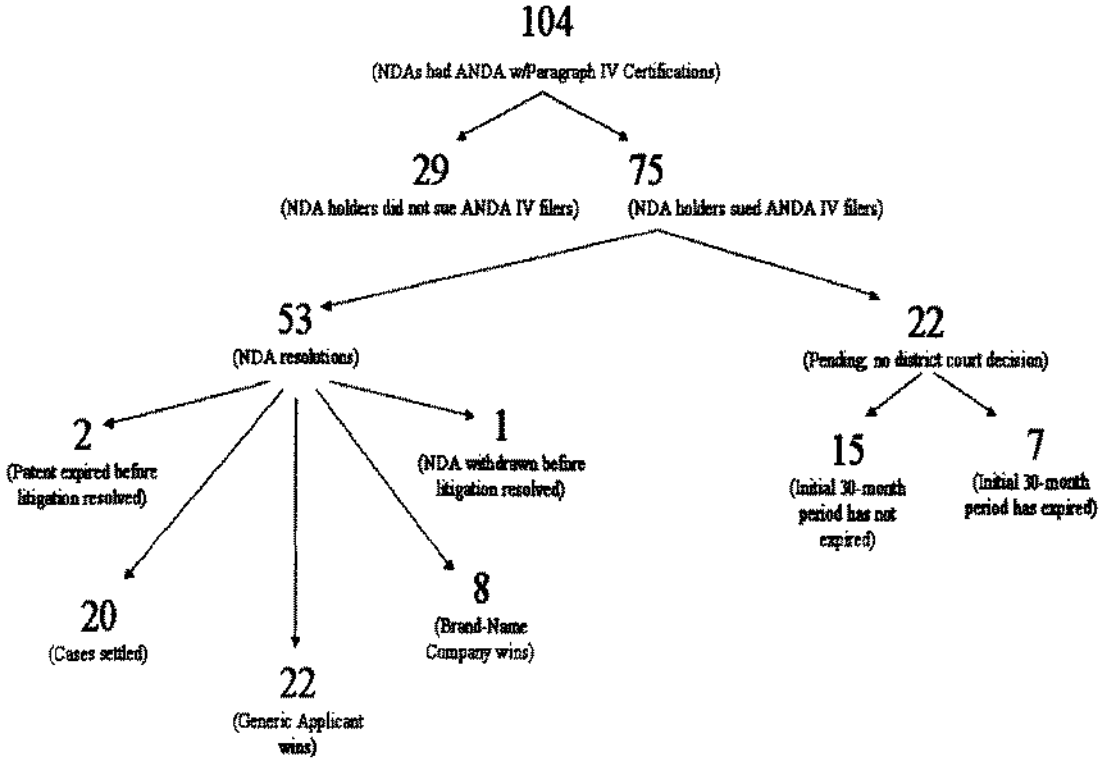
[3] For 2 of the 29 drug products in which no suit was filed, the brand-name company's patents would have expired during the first several months of the 30-month stay. Because patent expiration terminates the 30-month stay, it may not have made sense in those cases to initiate patent infringement litigation, which takes, on average, 25 months to resolve.

patents expired before FDA approved the generic applicant's ANDA.

What Were the Results of Patent Infringement Litigation with the First Generic Applicant?

The brand-name company sued the first generic applicant for patent infringement involving 75 NDAs. Figure 2-1 shows a graphical depiction of the resolution (*i.e.*, a decision of a court, a final settlement, or miscellaneous resolutions) of each case as of June 1, 2002. For 4 drug products, different generic applicants were the first to file on different dosage strengths of the drug product, thus contributing to multiple suits on the same drug product (and the same patent) with different generic applicants. For clarity, the results of more than one suit involving the same drug product are not included in the totals reported, but are described in footnotes 4, 7, and 8. Only results from the first applicant for a drug product are included in the totals discussed below.

Figure 2-1 Summary of Brand Company and 1st ANDA IV Filer Activity



Pending Patent Infringement Litigation

As of June 1, 2002, for 22 of the 75 drug products,[4] the district court hearing the lawsuit has not yet ruled on the merits of the patent infringement allegations.[5] For 7 of these 22 drug products, the 30-month stay has expired. For 3 of these 7 drug products, the brand-name company also sued for infringement of a patent that was listed in the Orange Book *after* the first generic applicant had filed its ANDA.[6] In these cases, it has been possible for a brand-name company to obtain more than one 30-month stay. The first 30-month stay has expired in these 3 cases, but the second (or even later) one has not. In none of these cases has the generic applicant entered the market.

Resolution of Patent Infringement Suits

There has been a court decision for 53 drug products (75 in total less 22 pending). The resolution of each is classified in Table 2-2 and also is described in Figure 2-1. Settlements were used in 38 percent of the instances (20 drug products out of 53 settled).[7] A court decision resolved the patent infringement claims for 30 drug products. Generic applicants prevailed 73 percent of the time (22 out of 30),[8] and brand-name companies prevailed 27 percent of the time (8 out of 30). In 3 miscellaneous instances, either the patents expired before the 30-month stay expired, or the brand-name company withdrew the NDA due to safety reasons.

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[4] In addition to these 22 cases, there are 2 more pending cases on a dosage strength of a drug product for which the patent litigation on another strength has been resolved. The resolution of these cases is discussed in the following section.

[5] In one pending case, the FDA determined that the brand-name company failed to submit the required information for a particular patent in a timely manner. Therefore, the generic applicant was not required to submit a patent certification to address that patent, the 30-month stay was dissolved, and the FDA subsequently approved the ANDA. Commercial patent litigation was still pending as of June 1, 2002, however, and the generic applicant has not yet entered the market.

[6] As discussed further in Chapter 4, if a brand-name company lists in the Orange Book later-issued patents (*i.e.*, patents obtained from the U.S. Patent and Trademark Office after obtaining NDA approval) after receiving notification from a generic applicant, the generic applicant must re-certify that its ANDA does not infringe the later-issued patent. If the brand-name company initiates a patent infringement suit within 45 days of notice of the generic applicant's re-certification, then FDA approval of the ANDA is stayed automatically for an *additional* 30 months from the notice date or upon final determination of non-infringement or patent invalidity by a court in the patent litigation.

[7] For one of these 20 drug products, a different generic applicant was first for each of the product's 3 strengths; the brand-name company settled with 2 of these applicants, and the litigation involving the other strength is pending. This drug product is counted only once as "settled." *See supra* n. 4. For another of these 20 drug products, a different generic applicant was first for each of the product's 2 strengths; the brand-name company entered a settlement with one generic applicant, and the first applicant for the other strength prevailed on non-infringement at the Federal Circuit. This drug product is counted only as "settled."

[8] For one of these 22 drug products, a different generic applicant was first for each of the product's 2 strengths; the first generic applicant prevailed on non-infringement at the Federal Circuit on one strength, while the other case is pending. This drug product is counted only once as "generic prevails." *See supra* n. 4. For another of these 22 products, a different generic applicant was first for each of the product's 3 strengths; the first generic applicant for each strength prevailed in each patent suit, which were on the same patent. This drug product is counted only once as "generic prevails."

Table 2-2 Results of Lawsuits with the First Generic Applicant

[illegible]	[illegible]
Settlement Between Brand-Name Company and Generic Applicant	20
Generic Applicant Prevails in Patent Infringement Suit	22
Brand-Name Company Prevails in Patent Infringement Suit	8
Miscellaneous	3
Total Number of Cases Resolved	**53**

Patent Settlements with the First Generic Applicant

As shown in Table 2-2, the brand-name company and the first generic applicant settled patent infringement litigation involving 20 drug products. Most of the settlements can be classified into 3 types. Nine of these settlements contained a provision by which the brand-name company, as one part of the settlement, paid the generic applicant (settlements involving "brand payments"). Seven of the 20 settlements involved the brand-name company licensing the generic applicant to use the patents for the brand-name drug product prior to patent expiration. Two of the settlements allowed the generic applicant to market the brand-name drug product as a generic product, under the brand-name company's NDA, not the generic applicant's own ANDA. The remaining 2 settlements do not fit into any of these 3 categories. The provisions of each of these settlement agreements are discussed more fully in Chapter 3.

Generic Applicant Prevails

Table 2-3 shows that the generic applicant prevailed in litigation over 22 drug products.[9] In 18 instances, a court held that the brand-name company's patents were either invalid or not infringed. Of these 18 court decisions, 13 were appellate and 5 were district court (4 of which the brand-name companies have appealed as of June 1, 2002, but the decisions are pending). In 9 of these instances, the court held that the generic applicant's ANDA did not infringe the brand-name company's product; in the remaining 9 instances, a court held that the underlying patent was invalid for reasons such as being anticipated by prior art or double patenting.

For 2 of the 18 drug products, the parties implemented interim settlements that included brand payments to the generic applicant. For both of these drug products, the generic applicant began marketing after the interim settlement was terminated and the Federal Circuit had affirmed the district court's ruling of patent invalidity.[10]

For 3 of the 4 remaining drug

[9] This total does not include the resolution of follow-on lawsuits on 2 drug products that are counted as "settled." In the first instance, after the parties settled, the brand-name company submitted a late-issued patent for listing in the Orange Book, and a second round of litigation ensued in which the generic applicant prevailed. In the second instance, the parties settled the initial lawsuit, but the generic applicant later re-filed an ANDA for a reformulated version of the product. The brand-name company dismissed this second case with prejudice after determining that the reformulated version did not infringe its patents.

[10] One of these drug products (Hytrin tablets) was discussed in *Abbott Laboratories*, No. C-3945 (May 22, 2000) (consent order), *available at* <http://www.ftc.gov/os/2000/03/abbott.do.htm>.

products (of the 22), the brand-name company dismissed the litigation after receiving samples of the generic applicant's proposed product. In 2 of these cases, the FDA approved the generic drug soon thereafter, and generic entry occurred after the case was dismissed.[11] In the other case, the FDA had not approved the generic drug product as of June 1, 2002. For the last of the 4 drug products, the brand-name company dismissed the litigation without prejudice. Entry was delayed in light of an interim settlement on a later-listed patent for which the brand-name company failed to sue the first generic applicant within the requisite 45 days.[12]

The patents covering the 22 brand-name drug products in which the generic applicant prevailed involved formulation or method of use patents. In 3 instances (out of 6 where a drug substance patent was at issue), a drug substance patent was found invalid or not infringed.

Brand-Name Company Prevails

For 8 drug products, the brand-name company prevailed in the patent infringement litigation. For 7 drug products, a court held that the generic applicant's ANDA infringed the brand-name company's patents. Two of these decisions were appellate decisions; the other 5 were district court decisions, of which only one has been appealed by the generic applicant. As of June 1, 2002, this appeal is pending. By contrast, brand-name companies appealed nearly 90 percent of the cases in which they obtained an adverse district court opinion. In the last of the 8 cases, the generic applicant abandoned its ANDA after it was sued, and the court did not issue a final judgment.

The patent claims in 3 of these patent lawsuits involved drug substance claims, and the other 5 involved method of use and/or formulation claims.

How Frequently Have Brand-Name Companies Sued the Second Generic Applicant?

If the brand-name company sued the first generic applicant, it also sued the second generic applicant, if there was one, in nearly 85 percent of the cases. There were 43 such instances. Of the suits that have been resolved as of June 1, 2002, in no instance did different district courts reach different results in resolving infringement issues over the same brand-name drug product.

The brand-name company generally sued all generic applicants if the drug product had annual sales larger than $500 million in the year the first generic applicant filed its ANDA. Twenty such drug products are included in the study.

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[11] For the details of one of these case, *see* Hoechst Marion Roussel, Inc., No. 9293 (May 8, 2001) (consent order), *available at* <http://www.ftc.gov/os/2001/05/hoechstdo.pdf>.

[12] This drug products (Hytrin capsules) was discussed in *Abbott Laboratories*, No. C-3945 (May 22, 2000) (consent order), *available at* <http://www.ftc.gov/os/2000/03/abbott.do.htm>.

What Are the Results of Litigation with the Second Generic Applicant if the Brand-Name Company Settles with the First Generic Applicant?

Table 2-3 shows the results of litigation with the second generic applicant in those instances in which the first generic applicant settled its patent infringement litigation. Out of a total of 20 drug products with first generic settlements (*see* Figure 2-1), 9 drug products involved litigation with the second generic applicant.[13] In 1 case, litigation is still pending. Table 2-3 shows the resolution of the 8 decided cases.

Table 2-3 Resolution of Patent Litigation with Second Generic Applicant if the First Generic Applicant Settled its Litigation

[illegible]	[illegible]
Settlement with Second Generic Applicant	4
Second Generic Applicant Wins Patent Infringement Suit	3
Brand-Name Company Wins Patent Infringement Suit	1
Total	**8**

In these 8 cases, the parties settled in 4, while in 3 the generic applicant prevailed (2 non-infringement decisions and 1 invalidity decision). In 1 case, the brand-name company won a decision of infringement.

For Those Patent Litigations that Resulted in a Court Decision, How Often Did Generic Applicants Prevail for All of the Drug Products in the Study?

For many drug products, the brand-name company sued several generic applicants over the same patents. Thus, in determining how frequently generic applicants or brand-name companies prevailed in patent litigation on a drug product basis, it would be misleading simply to count the number of decisions in either party's favor, because several of the decisions may be related to the same patent. Table 2-4 shows the results of the resolution of the patent suits without counting any similar outcomes involving the same drug product. For example, if both the first and second generic applicant obtained court decisions of non-infringement, the drug product is included only once as a generic win. If the case against the first generic applicant settled or is pending, but the case against the second applicant was resolved, the resolution of the second case is included. In no instance were the outcomes of the suits against the first and second generic applicant different.

There were court decisions on 40 different drug products. Table 2-4 presents the resolution of the patent litigation derived from five sources: (1) litigation with the first generic applicant (Table 2-2), (2) litigation with the second generic applicant if the first

[13] Eleven drug products either did not have a second generic applicant, or the brand-name company did not sue the second applicant.

generic applicant settled (Table 2-3), (3) litigation with the second generic applicant was resolved, but either the first generic applicant was not sued or the case is pending (3 drug products), (4) litigation with a third generic applicant when the first two generic applicants had settled, and (5) follow-on litigation with the first generic applicants on two drug products described in footnote 9.

Generic applicants prevailed for 29 out of 40 drug products (or 73 percent). Decisions involving 14 drug products held that the generic applicant did not infringe the patent, decisions involving 11 drug products held the relevant patent(s) invalid, and in 4 cases, the brand-name company abandoned the litigation with the first generic applicant before a decision of a court.

The brand-name company prevailed against the generic applicant in litigation involving 11 drug products. In one of these 11 cases, the generic applicant abandoned the litigation and admitted infringement before the court issued a decision.

Table 2-4 Patent Litigation Results per Drug Product

[illegible]	[illegible]
Generic Applicant Wins	29
Brand-Name Company Wins	11
Total	**40**

Results of Litigation and Patent Invalidity Rates

Out of 40 drug products in Table 2-4, 11 drug products had at least one patent listed in the Orange Book that was determined to be invalid. Thus, the minimum invalidity rate of patents that the parties chose to litigate to conclusion is 28 percent (11 invalid findings / 40 total). This rate assumes that the patents underlying the non-infringement decisions and cases when the brand-name company abandoned the litigation are valid, even though the courts in these cases may not have addressed the validity question. Thus, the invalidity rate may be higher than 28 percent, although we do not have data to determine it.

The recent empirical literature on the outcome of patent litigation provides a point of comparison with these findings, and suggests that this invalidity rate, although it may be understated as noted above, is not out of line with that of patents generally. Moore compares the outcomes of patent cases decided by judges with the outcomes of patent cases in which the finder-of-fact is a jury.[14] In her data set of 1209 patent trial decisions from 1983 through 1999, she finds that patents are invalidated in 36 percent of cases with a judge as the adjudicator and in 29 percent of cases with a jury.[15]

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[14] Kimberly A. Moore, *Judges, Juries & Patent Cases: An Empirical Peek Inside the Black Box*, 98 Mich. L. Rev. 365 (2000).

[15] *Id.* at 391. *See, also*, John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA L.Q. 185 (1998). Allison and Lemley study the outcomes of patent validity cases from 1989 to 1996. They focus on those cases in which there exist final written decisions at either the district court or the Federal Circuit levels. In their study, a district court decision is "final" if a later decision by the Federal Circuit does not supersede it. In their data set of 299 patents in 239 different cases, they find that 46 percent of the final decisions hold the relevant patent invalid. In contrast to this figure which covers all patent validity decisions, they find that pharmaceutical patents are found invalid in 27 percent of cases. Allison and Lemley do not consider decisions that focus only on infringement.

How Frequently Did the Federal Circuit Reverse a District Court Decision of Non-Infringement or Patent Invalidity?

Of the 29 NDAs where the generic applicant prevailed, as noted in Table 2-4, in 14 instances, the brand-name company appealed a district court decision that the patent at issue was either invalid or not infringed in a patent suit against either the first or second generic applicant.[16] In 13 of these decisions, the U.S. Court of Appeals for the Federal Circuit affirmed district court decisions of patent invalidity or non-infringement – 8 affirmed decisions of non-infringement,[17] and 5 affirmed decisions of patent invalidity. In the remaining case, two patents were at issue. The district court had determined both patents to be valid, but the Federal Circuit reversed as to one of the patents, and affirmed the validity decision for the other. Thus, the rate at which the Federal Circuit reversed decisions of invalidity and non-infringement for drug products included in this study was 8 percent.[18]

Table 2-4 shows that the brand-name company prevailed in litigation for 11 drug products. Of the 4 cases in which the generic applicant appealed the district court's decision of infringement, the Federal Circuit affirmed all 4 of these district court decisions of infringement.

In Which District Courts Did Brand-Name Companies Initiate Patent Infringement Litigation?

In 62 percent of the cases involving litigation with the first and second generic applicants, brand-name companies initiated patent litigation in just five federal judicial districts. These were the District of New Jersey, the Southern District of New York, the Southern District of Indiana, the Northern District of Illinois, and the Southern District of Florida. Thus, these courts have more experience with ANDA patent infringement litigation than most other federal district courts.[19]

[16] To ensure no double counting, if the suits against the first and second generic applicant were consolidated into 1 district court opinion, and that decision was appealed, the appellate decision is counted only once. This also does not include one case where the district court's decision on summary judgment was vacated and remanded. Moreover, of the 29 drug products in which the generic applicant prevailed, some of the appeals are pending, or the district court decision was not appealed.

[17] In one of these decisions, the district court held the patent invalid and not infringed. The Federal Circuit upheld the non-infringement holding, but reversed on the invalidity holding. This has not been counted in the rate at which the Federal Circuit reversed decisions of invalidity and non-infringement for drug products included in this study because the non-infringement decision was affirmed and generic entry occurred prior to patent expiration.

[18] This rate does not include Federal Circuit overrules of summary judgement or collateral estoppel decisions.

[19] For those drug products in which both the first and second generic applicant were sued, approximately 50 percent of the suits were pursued in different district courts.

When Did Generic Applicants Enter the Market?

If a generic applicant was sued for patent infringement, it generally did not enter the market until there was a district court holding that the brand-name company's patent was invalid or not-infringed. In no instance has a generic applicant (either the first or second) entered the market and then a court later has found that the patent was infringed, making the generic applicant subject to damages.

In 22 cases (out of 75, Table 2-1) involving litigation between the brand-name company and the first generic applicant, as of June 1, 2002, the first 30-month stay had expired before the district court decision. In 8 of those cases, the FDA approved the generic applicant's ANDA prior to a district court ruling on the merits of the patent infringement suit.[20] In the first 2 cases, the district court case was ongoing as of June 1, 2002, and the generic applicant had not entered, although it had FDA approval to do so. In the next 2 cases, the generic applicant entered after obtaining a district court decision, but prior to the Federal Circuit's decision.[21] In the fifth case, the generic applicant waited until the Federal Circuit affirmed the district court's ruling. In the sixth case, the generic applicant reformulated its product and the brand-name company dismissed the litigation before a ruling on the merits. The generic applicant entered the market soon thereafter.

In the seventh case in which the FDA approved the generic applicant after the 30-month stay had expired but before a district court decision, there were two generic applicants for different dosage strengths (30 mg and 60 mg) of the same drug product (Drug Product A). The discussion of generic entry that follows only relates to the 60 mg product. The brand-name company sued each generic applicant over the same patent in different district courts. The first generic applicant on the 30 mg product obtained a district court decision of non-infringement and the Federal Circuit affirmed this decision. The 60 mg generic applicant entered once the Federal Circuit affirmed the district court's decision of non-infringement on the 30 mg product. This occurred, however, before the district court reached a decision on the litigation involving the 60 mg generic applicant's litigation.

In the eighth case involving a drug product that was covered by the same patent that covered Drug Product A (described above), the generic applicant also entered prior to a district court decision. Like the 60 mg generic applicant, the first applicant for this drug product also entered after the 30 mg decision of non-infringement of Drug Product A was affirmed by the Federal Circuit.

In separate instances involving the drug products Taxol and BuSpar, which are not included in the 22 described above, the generic applicants began commercial marketing without waiting for a district

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[20] In the other 14 cases (22 less 8), either the district court had not ruled as of June 1, 2002 and the FDA has not yet approved the ANDA, or the district court ruled and the FDA acted accordingly, depending upon the outcome of the litigation.

[21] In addition to these 2 instances, generic applicants for 3 other drug products entered after a district court case, but prior to the Federal Circuit's ruling. In these cases, however, the 30 month stay had not expired before the district court ruled.

court decision in their favor on the patent the brand-name companies had listed in the Orange Book after the generic applicants had filed their ANDAs.[22] In both cases the district court eventually held the patent to be invalid or not infringed.

[22] *See* Chapter 4 for a full discussion of multiple 30-month stays. Both suits on the later-issued patents raised questions whether the patents should be listed in the Orange Book.