

THE IMPACT OF RECENT REFORMS OF THE HATCH-WAXMAN SCHEME ON ORANGE BOOK STRATEGIC BEHAVIOR AND PHARMACEUTICAL INNOVATION

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I. INTRODUCTION

If one were to ask even a well-informed individual what was significant about the year 2003 for the pharmaceutical drug industry, the response likely would be the adoption of the Medicare prescription drug benefit as passed in the Medicare Reform Legislation.¹ No doubt, this is a substantial step forward in making health care more affordable by controlling pharmaceutical costs within the Medicare system.² The Medicare

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¹ *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

² Some people might question whether the Medicare Reform Legislation will actually control pharmaceutical costs. A much criticized aspect of the legislation by Democrats is that it gives little or no authority to the government to control drug prices. In practice, however, it seems that cost control over drug prices will be inevitable. Drug prices will be controlled, if not by the government, then through a private scheme, since private companies offering drug coverage “should be able to negotiate lower drug prices with drug makers because of large volumes involved.” See Edward Walsh & Bill Brubaker, *Drug Benefit’s Impact Detailed; Many Will Face Big Out-of-Pocket Costs*, Wash. Post A10 (Nov. 26, 2003).

prescription drug benefit was not the only notable event of 2003 for the pharmaceutical drug industry, however, nor was it the only notable aspect of the Medicare Reform Legislation. Unbeknownst to many, 2003 was also significant for the pharmaceutical industry because numerous reforms were made to the laws and regulations that govern the playing field between innovative pharmaceutical companies (i.e., those companies that conduct pharmaceutical research to discover new drugs (“innovators”)) and generic pharmaceutical companies (i.e., those companies that make generic copies of those drugs (“generics”)). Some of these reforms were introduced by the Medicare Reform Legislation. This article reviews and analyzes these reforms and considers their impact on the behavior of innovators and generics within the pharmaceutical industry. The article also contemplates the impact of such reforms on the future of pharmaceutical innovation.

The main legal structure that defines the relations between generics and innovators is the Drug Price Competition and Patent Term Restoration Act, better known as the “Hatch-Waxman Act,” which introduced amendments to the Federal Food, Drug and Cosmetic Act (“FDCA”) and the Patent Act in 1984.³ The Hatch-Waxman Act was the result of a compromise reached between innovators and generics. It was intended to facilitate generic drug entry on the one hand, and support and encourage drug innovation on the other. Some of the complex mechanisms by which the Hatch-Waxman Act sought to achieve these two often opposing goals will be discussed further below. These mechanisms amount to two different types of policy levers. On the one hand, such mechanisms affected the scope of exclusivity that an innovative company had both for its drug product pursuant to patent law and for its supporting safety and effectiveness data pursuant to the law of confidential information. On the other hand, such mechanisms affected the term of marketing exclusivity for an innovative drug product, particularly pursuant to patent law.

A historical perspective on the drug approval process in the United States helps explain how the Hatch-Waxman compromise arose. In 1962, Congress enacted the Drug Amendments of 1962, which introduced a pre-market drug approval process that required proof of drug effectiveness and drug safety.⁴ At the root of this process was the filing of a New Drug Application (“NDA”).⁵ Prior to the passage of the Hatch-Waxman Act, the

³ *The Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

⁴ Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosmetic L.J. 269, 272-73 (1985).

⁵ *Id.* at 273.

Supreme Court held that generic drugs also were considered “new drugs” and so generic companies also needed to demonstrate that their drugs were safe and effective.⁶ Moreover, the Food and Drug Administration took the position that the supporting safety and effectiveness data for an NDA was confidential and not usable by another applicant.⁷ Consequently, to get drug approval for a generic drug, generic companies essentially had to go through the NDA drug approval process, generating their own safety and effectiveness data,⁸ which was prohibitively costly. At the same time, innovative companies were becoming increasingly concerned about the diminishing effective term of patent exclusivity remaining on patents covering their products once such products went through the rigorous drug approval process.⁹ Hence, the pharmaceutical industry was poised to reach a compromise, now known as the Hatch-Waxman Act.

In the past few years, certain aspects of the Hatch-Waxman Act came under intense scrutiny because observers found that both innovators and generics were engaging in strategic behavior within the Hatch-Waxman scheme to better their own economic positions. As a result, the entry of certain generic drugs into the marketplace may have been delayed.¹⁰ Much of this strategic behavior occurred pursuant to what is known as the “Orange Book.” The Orange Book is an FDA-published document available in paper and electronic form that lists all FDA-approved drugs together with any patents pertaining thereto.¹¹ As will be discussed in this article, the listing of patents in the Orange Book is the step that triggers an entire cascade of events under the Hatch-Waxman Act intended to encourage rapid entry of generic drugs onto the market while safeguarding innovation incentives. One practice that observers became concerned with was innovative companies’ practice of listing numerous patents in the Orange Book with regard to an FDA-approved drug, which increased the number of automatic

⁶ *U.S. v. Generix Drug Corp.*, 460 U.S. 453, 461 (1983); see also Flannery & Hutt, *supra* n. 4, at 273.

⁷ Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law—Cases and Materials* 484 (2d ed., The Foundation Press, Inc. 1991).

⁸ The “paper NDA” process, discussed *infra* notes 31-35 and accompanying text, provided a limited exception to these stringent requirements by allowing a generic company to rely on published scientific data of an innovative company’s drug’s safety and effectiveness. However, such published data generally provided inadequate data to warrant NDA approval. Hutt & Merrill, *supra* n. 7, at 485.

⁹ *Id.*

¹⁰ See Generic Drug Entry Prior to Patent Expiration: An FTC Study, i (FTC July 2002) [hereinafter FTC Study].

¹¹ For more information, see *infra* note 18 and accompanying text.

30-month stays on generic drug entry potentially available to the company.¹² Also of concern was the practice of innovative and generic companies entering into agreements to settle patent disputes initiated pursuant to the Hatch-Waxman scheme, possibly delaying generic drug entry.¹³ This strategic, and in some instances anticompetitive, behavior provided regulators and legislators with the impetus to make changes to the Hatch-Waxman scheme.

Part II of this article provides an overview of the original Hatch-Waxman scheme, particularly as it relates to the Orange Book, laying a foundation for the analysis that follows. Part III examines the various types of strategic behavior that occurred in the context of Orange Book patent listings and litigation in detail and highlights some of the problems that existed with the original Hatch-Waxman scheme. Part IV examines the fallout resulting from this strategic behavior both in the form of further antitrust challenges and early—but unsuccessful—reform attempts. Part V scrutinizes regulatory and legislative reforms that have now become law and considers whether these reforms are likely to be successful in curtailing the observed strategic behavior and in facilitating generic drug entry. Finally, Part VI evaluates the impact that the Hatch-Waxman reforms may have on the future of pharmaceutical innovation. This is an important consideration given that the original intent of the Hatch-Waxman Act was to balance two interests—pharmaceutical innovation and the availability of affordable pharmaceuticals. While the Hatch-Waxman reforms will accelerate generic drug entry, which should lead to cheaper drugs that will provide immediate benefits to consumers, this article proposes that these reforms may have a negative effect on pharmaceutical innovation in the long run.

II. AN OVERVIEW OF THE ORIGINAL HATCH-WAXMAN SCHEME AND THE ORANGE BOOK

Prior to analyzing the recent reforms to the Hatch-Waxman scheme, it is necessary to understand the structure and features of the original Hatch-Waxman scheme, particularly with respect to Orange Book patent listings. Although some of the details of the scheme described below have changed recently, as will be discussed in Part V, the basic outline of the scheme described in this part remains the same in the post-reform Hatch-Waxman universe.

A pharmaceutical company seeking to manufacture and sell a new

¹² *Infra* nn. 105-09 and accompanying text; *see also* FTC Study, *supra* n. 10, at i.

¹³ FTC Study, *supra* n. 10, at i.

drug must file a lengthy document with the Food and Drug Administration called a New Drug Application (“NDA”),¹⁴ which must include detailed information pertaining to laboratory and clinical studies demonstrating a drug’s safety and efficacy¹⁵ and must also include a list of patents that claim the drug.¹⁶ The statutory language pertaining to patent listings provides that:

The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.¹⁷

As directed by this statutory language, once the FDA approves an NDA, it publishes a listing of the drug together with the patent exclusivity information pertaining to the drug in a compilation called *Approved Drug Products with Therapeutic Equivalence Evaluations*, colloquially known as the “Orange Book.”¹⁸

The FDA also promulgated rules that provide additional guidance as to the types of patents for which information must be submitted for listing in the Orange Book. Before it was amended in November 2003, that patent listing provision read:

Patents for which information must be submitted. An applicant described in paragraph (a) of this section shall submit information on each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes of this part, such patents consist of drug substance (ingredient) patents, drug product

¹⁴ 21 U.S.C. § 355(a) (2000).

¹⁵ *Id.* at § 355(b)(1).

¹⁶ *Id.*

¹⁷ *Id.* Moreover, because the NDA as filed may have different parameters from the NDA that is approved, an applicant must amend the patent submission to list only the patents that meet the listing criteria for the approved drug product. 21 C.F.R. § 3.14.53(c)(2)(ii) (2004).

¹⁸ 21 U.S.C. §§ 355(j)(7)(A)(iii), (b)(1); *see also id.* at § 314.53(c)(2). The document is referred to as the “Orange Book” because of its orange-colored cover. *See* 68 Fed. Reg. 36676 (June 18, 2003).

(formulation and composition) patents, and method of use patents. Process patents are not covered by this section and information on process patents may not be submitted to FDA. For patents that claim a drug substance or drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application, or that claim a drug substance that is a component of such a product. For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application.¹⁹

Moreover, before it was amended in 2003, subsection 314.53(c) indicated that, for each patent contemplated in subsection 314.53(b), an NDA applicant had to include the following information: (i) patent number and date on which the patent will expire; (ii) the type of the patent (i.e., whether it is a drug, drug product, or a method of use patent); (iii) the name of the patent owner; and (iv) information as to the person authorized to receive notice of a patent certification if the patent owner is outside of the United States.²⁰ This information must be updated, according to subsection 314.53(d)(2), if a supplement to the NDA is filed with the FDA to change the formulation or strength, or due to any other patented change to the approved drug, or to add a new indication or other condition of use such as a change in the route of administration. Subsection 314.53(d)(3) indicates that, if a relevant patent issues after the NDA is approved, the NDA applicant must submit the required patent information to the FDA within 30 days of the date of issuance of the patent. This 30 day period from issuance within which to submit patent information also applies if a patent is issued after the NDA application is filed but before it is approved.²¹

Furthermore, subsection 314.53(f) sets forth what used to be the only procedure available to challenge a patent listing in the Orange Book.²² Under this procedure, disputes as to the accuracy of patent listings are to be directed to the FDA in writing. The FDA “will then request of the applicable new drug application holder that the correctness of the patent information or omission of patent information be confirmed.”²³ However, “[u]nless the application holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list[.]”²⁴ and will require generic applicants to provide “certifications” for

¹⁹ 21 C.F.R. § 314.53(b) (2002).

²⁰ *Id.* at § 314.53(c). As we shall see *infra* § V, both this and other information must be provided pursuant to the new requirements of 21 C.F.R. § 314.53(c) (2004).

²¹ *See* 21 C.F.R. § 314.53(d)(1) (2002).

²² 21 C.F.R. § 314.53(f) (2002); 21 C.F.R. § 314.53(f) (2004).

²³ *Id.*

²⁴ *Id.*

each listed patent.²⁵

It is notable that this procedure does not require the FDA to ensure that the patent information submitted is complete and applicable to the particular NDA. When challenged on this point in a comment to this rule, which at that time had only been proposed, the FDA responded:

As stated elsewhere in this rule, FDA does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA. Therefore, the agency declines the comment's requests to ensure that patent information is complete and relevant to an NDA and to confirm, upon request, the validity of patent information submitted to the agency. The agency believes that the declaration requirements under §314.53(c), as well as an applicant's potential liability if it submits an untrue statement of material fact, will help ensure that accurate patent information is submitted.²⁶

This reluctance to review patent matters was echoed in many places in the FDA's comments accompanying the issuance of the rules set forth above. For example, in response to another comment reiterating that the FDA take on the obligation of reviewing the accuracy of patent listings, the FDA noted: "As stated elsewhere in this final rule, FDA does not have the expertise to review patent information. The agency believes that its scarce resources would be better utilized in reviewing applications rather than reviewing patent claims."²⁷

To understand why Orange Book patent listings even exist, it is necessary to know more about the legal framework for generic drug approvals and patent enforcement as set forth in the Hatch-Waxman Act. The Hatch-Waxman Act introduced streamlined drug approval routes for generic drug products.²⁸ These streamlined drug approval routes were intended and have, in fact, increased generic drug entry.²⁹ The introduction of a generic drug, in turn, introduces a tremendous downward pressure on the price of the innovative pharmaceutical that it copies, which equates to lower drug prices for consumers. As a result of the Hatch-Waxman Act, a company seeking to market a generic copy of an original new drug can obtain drug approval on such a copy by filing an abbreviated new drug application ("ANDA") with the FDA pursuant to 21 U.S.C. § 355(j). Instead, however, of filing the full safety and efficacy information required for a NDA, ANDA

²⁵ See *infra* note 39 and accompanying text for discussion regarding certifications.

²⁶ *Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50345 (Oct. 3, 1994).

²⁷ *Id.* at 50343.

²⁸ FTC Study, *supra* n. 10, at i.

²⁹ *Id.*

filers may rely in part on the NDA for the original drug being copied by submitting bioequivalence data between the original drug and the generic copy sought to be marketed.³⁰

A generic company can instead file a new drug application pursuant to 21 U.S.C. § 355(b)(2) (i.e., a “paper NDA”), which it might have to do, for example, if it were to seek approval for a drug that is not exactly the same as the innovative drug. Prior to the passage of the Hatch-Waxman Act, the FDA did not allow ANDAs where an approved NDA was sought to be marketed by a second firm.³¹ The FDA, however, became concerned that always requiring submission of full NDAs would lead to redundant clinical and preclinical testing.³² Consequently, in 1978, the FDA announced a “paper NDA” policy for drugs developed based on the requirements established by the FDCA of 1962.³³ By this policy, the FDA indicated that “in the case of duplicate NDAs for already approved post-62 drugs, the Agency will accept published reports as the main supporting documentation for safety and effectiveness.”³⁴ However, in 1999, the FDA substantially expanded the circumstances in which a generic company may rely on an innovative company’s safety and effectiveness data through the “paper NDA” process” by “accepting section 505(b)(2) applications that rely not only on published data, but also on the unpublished safety and effectiveness data in the innovator company’s approved new drug applications.”³⁵

Although the Hatch-Waxman Amendments at 35 U.S.C. § 271(e)(1) exempt from a finding of infringement otherwise infringing acts necessary to

³⁰ Another type of application for drug approval that is less involved than that set forth in 21 U.S.C. § 355(b)(1) for new drug approval is set forth in 21 U.S.C. § 355(b)(2). These drug approval applications will not be discussed at great length in this paper. However, it is worth noting that the patent listing features that are required for ANDAs generally parallel those that are required in the drug approval applications pursuant to 21 U.S.C. § 355(b)(2) (i.e., sometimes referred to as “§ 355(b)(2) applications” or “paper NDAs”).

³¹ See Hutt & Merrill, *supra* n. 7, at 495.

³² *Id.* at 494.

³³ *Id.* at 494-95.

³⁴ See *id.* at 495; see also Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. Chi. L. Rev. 93, 103 (2004).

³⁵ Kuhlik, *supra* n. 34, at 103-04. As noted by Mr. Kuhlik:

One significant example [of this approach] would be to allow a follow-on company to obtain approval of a different salt of an approved innovator drug, something that is not permitted under the abbreviated application route because the active ingredients are not identical. Depending on the scope of the innovator’s patent protection, this approach could allow closely related competing products to enter the market years before what had been anticipated.

prepare an FDA drug submission,³⁶ 35 U.S.C. § 271(e)(2) specifies that a generic drug manufacturer that files an ANDA to obtain FDA approval for the purpose of marketing a generic drug product claimed in a patent before it expires will infringe the patent.³⁷ Under the traditional concept of patent infringement, the filing of an ANDA to obtain FDA approval for a generic drug product generally would not amount to patent infringement because the generic drug manufacturer was not really making, using, offering to sell or selling a patented invention (i.e., the innovative drug being copied) without the innovative drug company's authorization.³⁸ Therefore, the Hatch-Waxman Amendments introduced an artificial form of infringement to trigger the resolution of patent disputes within the framework described further below.

Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii), whether or not an ANDA applicant will be vulnerable to a charge of infringement depends on the certification that it makes in its ANDA as to each patent listed in the Orange Book relevant to the drug sought to be copied. According to 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV), the following certifications can be made: (i) that no patent information has been submitted to the FDA; (ii) that the patent has expired; (iii) that the patent is set to expire on a certain date; or (iv) that the patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the new generic drug for which the ANDA is submitted.³⁹ These are commonly referred to as "paragraph I to IV certifications." The Hatch-Waxman scheme also permits a company to altogether avoid making a certification to a method-of-use patent if it is not seeking approval for any of the uses claimed in the patent. This requires the company to file a "Section viii Statement" with the FDA, in which it must state that the patent does not relate to the uses for which the ANDA applicant seeks approval.

Whereas an ANDA containing a Paragraph I or II certification may

³⁶ 35 U.S.C. § 271(e)(1) is analyzed in depth in two recent prior articles of the author. See *infra* n. 447.

³⁷ 35 U.S.C. § 271(e)(2).

³⁸ The traditional notion of patent infringement is set forth in 35 U.S.C. § 271(a) which states that: "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." One may argue that, even under a traditional notion of infringement, a generic company might be said to be "using" a patented invention when submitting an ANDA for a generic that is based on an NDA for a patented innovative drug. This is not, however, how patent infringement has been thought about traditionally.

³⁹ This "unenforceable" aspect of a paragraph IV certification was added by FDA regulation. See 59 Fed. Reg. at 50339.

be approved without delay, ANDAs with Paragraph III certifications cannot be approved until the patent expires because this certification indicates that the applicant does not intend to market the drug until after the expiration of the patent.⁴⁰ If an ANDA contains a Paragraph IV certification, the ANDA applicant must give notice to the patentee and must provide detailed bases for its belief that the patent is invalid, unenforceable or not infringed.⁴¹ Also, if an applicant's ANDA is pending while the original drug manufacturer lists additional patents in the Orange Book as to the drug being copied, the applicant has to make certifications as to the additional patents, which are to be submitted within thirty days after they were issued.⁴²

It is in the Paragraph IV scenario that the original Hatch-Waxman scheme gave the patentee forty-five (45) days within which to sue the ANDA applicant for patent infringement.⁴³ If the patentee did not sue within that time, the ANDA technically could be approved. However, if a suit was commenced, the FDA could not approve the ANDA "until 30 months [had] passed, unless the case [was] decided before then or the 30-month period was modified by the court before which the infringement action [was] pending."⁴⁴ That is, shorter or longer stays on the approval time could be authorized by the Court if either party was not cooperating appropriately to expedite the infringement action.⁴⁵ It is important to recognize that this 30-month stay on approval would run concurrently with any remaining patent term.

Finally, to provide an incentive to generic companies to challenge innovative companies' patents by making paragraph certifications, the Hatch-Waxman Act introduced a 180-day period of marketing exclusivity to the first ANDA applicant that files a paragraph IV certification as to a patent, under certain circumstances.⁴⁶

⁴⁰ 21 U.S.C. §§ 355(j)(5)(B)(i)-(ii).

⁴¹ *Id.* at § 355(j)(2)(B)(i); 21 C.F.R. at § 314.95(c)(6).

⁴² 21 U.S.C. §§ 355(c)(2), (j)(2)(A)(vii).

⁴³ *Id.* at § 355(j)(5)(B)(iii).

⁴⁴ *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1339 (Fed. Cir. 2003) (describing 21 C.F.R. at § 314.107(b)(1)(iv)).

⁴⁵ 21 U.S.C. § 355(j)(5)(B)(iii).

⁴⁶ *Id.* at § 355(j)(5)(B)(iv). Although, at one time, the FDA had interpreted that entitlement to the 180-day exclusivity period required a "successful defense" against patent infringement, this interpretation was eventually struck down. See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998). For a further discussion, see *infra* § III.2.

III. STRATEGIC BEHAVIOR RELATING TO ORANGE BOOK LISTING AND LITIGATION

In the late 1990s, evidence began to surface of strategic behavior⁴⁷ being undertaken by both innovative and generic companies pursuant to the Hatch-Waxman Act that effectively slowed down the entry of certain generic drugs.⁴⁸ This strategic behavior was even found to be anticompetitive in some instances. The rules encouraged innovative companies and generic companies to behave strategically to their own benefit but at the expense of consumer interests.⁴⁹ I will explore this behavior in more detail in this part.

I look first at the problem of extensive patent listings and multiple 30-month stays. Both of these related problems illustrate that the legal boundaries established by the original Hatch-Waxman Act allowed some innovative companies to use their patent rights as leverage to maximize the

⁴⁷ Katz describes the notion of strategic behavior as behavior that a person might not otherwise choose to do but that is undertaken because of its effect on others' behavior. Avery Wiener Katz, *Foundations of the Economic Approach to Law* 147 (Oxford U. Press 1998).

⁴⁸ FTC Study, *supra* n. 10, at i. As stated in the FTC Study:

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.

⁴⁹ In fact, one might say that the rules encouraged these companies to act as “rational monopolist[s] [that] recognize[d] that [their] actions affect[ed] the market price, and thus ha[d] an incentive to restrict supply in order to drive away bargain-seekers and earn extra profits from the high-price customers who remain[ed].” Katz, *supra* n. 47, at 147. Katz’s mention of monopolistic behavior as being the classic example of strategic behavior seems to parallel the Hatch-Waxman experience with strategic behavior, and particularly the behavior of innovative companies as against potential market entrants. But, is this truly monopolistic behavior? At the root of the Hatch-Waxman strategic behavior discussed earlier is a patent or patents pertaining to an approved drug of an innovative company sought to be copied by a generic company. Numerous commentators confirm that a patent does not tend to confer monopolies on a patent owner. See e.g. Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 Fordham Intell. Prop. Media & Ent. L.J. 185, 202-03 (1999). Nonetheless, there are elements of the Hatch-Waxman strategic behavior that makes the monopoly model seem rather appropriate in this instance. See also Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. Leg. Stud. 247, 249-50 (1994).

amount of market exclusivity that they had for their pharmaceutical products. Second, I explore the settlement agreement problem, which illustrates that the Hatch-Waxman Act created the possibility for a generic company and an innovative company, intentionally or unintentionally, to act together in a manner that was beneficial for each of their financial interests but not in the interest of consumers. That is, by acting in concert, innovative companies and generic companies were able to maximize their own self-interest at the expense of consumers seeking to obtain lower cost drugs more rapidly.

1. Orange Book Patent Listings and Multiple 30-Month Stays

A. Procedural Difficulties in Challenging Orange Book Patent Listings

As described in Part II, the original Hatch-Waxman scheme required generic companies filing ANDAs to make certifications to all patents listed with respect to the innovative drug for which they wished to introduce a generic copy. If a paragraph IV certification was made as to any of the listed patents, this would put into motion an entire cascade of events. In particular, the innovative company owning the drug sought to be copied could commence an infringement action against the generic company within 45 days and, by doing so, could obtain an essentially automatic 30-month stay on approval of the generic drug.⁵⁰ Moreover, the original Hatch-Waxman scheme directed innovative companies to list any additional patents that issued following approval of their NDA within 30 days of a patent's issue date.⁵¹ The generic company was then required to provide certifications to such subsequently-added patents, which again put in motion the Hatch-Waxman scheme by which an innovative company could obtain subsequent 30-month stays.⁵² Consequently, one of the major frustrations of generic companies with the original Hatch-Waxman legislation is that it allowed innovative companies to obtain multiple 30-month stays on FDA approval of generic drugs. For example, SmithKline Beecham Corporation obtained multiple 30-month stays with regards to a generic copy of its drug Paxil.⁵³ Moreover, because the 30-month stay was so readily available, this created a tremendous incentive for innovative companies to broadly interpret the law governing what types of patents could be listed.

⁵⁰ 21 U.S.C. § 355(j)(5)(B)(iii).

⁵¹ *Id.* at § 355(c)(2).

⁵² *Id.* at § 355(j)(5)(B)(iii).

⁵³ *See Apotex, Inc.*, 347 F.3d at 1339 (describing multiple 30-month stays).

One strategy used by generic companies to prevent an innovative company from obtaining multiple 30-month stays was to challenge an innovative company's Orange Book patent listing and request, as a remedy, to delist a patent. The Federal Circuit, however, noted that the original Hatch-Waxman regime "[did] not include any explicit provisions either enabling or prohibiting an action to challenge a patentee's listing of a patent in the Orange Book."⁵⁴ Consequently, the question of how to challenge an Orange Book listing became an issue that received a great deal of attention by the Federal Circuit. The Federal Circuit's jurisprudence on this point yielded a problematic result, namely, that there was no clear way by which to challenge inappropriate Orange Book patent listings.

In *Mylan Pharm., Inc. v. Thompson*, Bristol, one of the joined defendants, had an FDA-approved drug on the market called "BuSpar," and had a patent, U.S. Patent No. 4,182,763 ("the '763 patent"), directed to the treatment of anxiety through the administration of buspirone hydrochloride, which was listed in the Orange Book with respect to BuSpar.⁵⁵ Since this patent was set to expire on November 21, 2000, Mylan Pharmaceuticals ("Mylan") prepared to begin selling its generic version of BuSpar immediately thereafter. It had received tentative approval to do so after having filed an ANDA for its buspirone product under a Paragraph III certification. However, about eleven hours before the expiry of the '763 patent, Bristol sought to have another patent listed in the Orange Book as pertaining to BuSpar which had issued the day before, namely, U.S. Patent No. 6,150,365 ("the '365 patent"). The sole claim in that patent was directed to a method of treating anxiety by administering a metabolite of buspirone apparently not previously thought to be the source of buspirone's activity.⁵⁶ Upon receiving Bristol's communication requesting that the '365 patent be listed, the FDA suspended approval of Mylan's and other generic companies' ANDAs. Mylan took the matter to court, arguing that the '365 patent was improperly listed and should be removed from the Orange Book.

The United States District Court for the District of Columbia held that Mylan was entitled to declaratory relief stating that the '365 patent was improperly listed in the Orange Book.⁵⁷ Such declaratory relief was said by the Court to be pursuant to the Declaratory Judgment Act, as a defense to the infringement suit that Bristol could have brought against Mylan under 35

⁵⁴ *Mylan Pharm. Inc. v. Thompson*, 268 F.3d 1323, 1327 (Fed. Cir. 2001).

⁵⁵ *Id.*

⁵⁶ See U.S. Pat. No. 6,150,365 (col. 2, ll. 33-51).

⁵⁷ *Mylan Pharm. Inc. v. Thompson*, 139 F. Supp. 2d, 1, 29 (D.D.C. 2001).

U.S.C. § 271(e)(2).⁵⁸ As a result, the United States District for the District of Columbia granted the preliminary injunction motion of Mylan.⁵⁹ The injunction directed Bristol to take measures to delist United States Patent No. 6,150,365 from the “Orange Book.”⁶⁰ The injunction also directed the FDA to grant final approval of Mylan’s ANDA for a generic version of buspirone.⁶¹

On appeal, however, the Federal Circuit decided that Mylan’s true assertion was not a recognized defense to patent infringement, and that no provision of the Hatch-Waxman Act allowed an accused infringer to defend against infringement by challenging the propriety of the Orange Book listing of the patent.⁶² That is, the Federal Circuit held that there was no private cause of action that could be brought against an NDA holder to delist a patent. Accordingly, the Court reversed the District Court’s judgment.⁶³

The procedural aspects of Orange Book patent listings were again considered by the Federal Circuit in *Andrx Pharms, Inc. v. Biovail Corp.*⁶⁴ There, Biovail’s affiliate, Biovail Laboratories, Inc. (hereinafter collectively referred to as “Biovail”), was in possession of an NDA for a drug used to

⁵⁸ *Id.* at 12.

⁵⁹ *Id.* at 29.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Mylan Pharm. Inc.*, 268 F.3d at 1333.

⁶³ Interestingly, the Federal Circuit had earlier held that “as part of its inherent power to give effect to a judgment, a court may order the delisting of a patent in the context of a properly filed patent infringement suit.” *Abbott Laboratories v. Novopharm Ltd.*, 104 F.3d 1305, 1309 (Fed. Cir. 1997). That is, the Court suggested that delisting a patent from the Orange Book can be a remedy in a patent infringement case but not a proper defense. In *Mylan*, however, Chief Judge Mayer felt that Abbott did not provide the Court with “authority to hear an independent cause of action seeking delisting outside a properly filed patent case.” *Mylan Pharm. Inc.*, 268 F.3d at 1333.

Abbott Laboratories involved a dispute wherein Novopharm submitted that Abbott had improperly listed a particular patent (i.e., the ’097 patent) in the Orange Book, thereby holding up approval for its generic copy of Abbott’s drug containing terazosin hydrochloride. Novopharm’s specific complaint as to the patent listing was that the patent had, in fact, expired and so should be removed from the Orange Book. After applying the terms of the Uruguay Round Agreements Act, the Federal Circuit affirmed the District Court’s decision that the divisional patent in question had expired, and also supported the District Court’s decision to utilize its inherent power to order the parties to act in a certain manner so as to enforce its judgment. This matter arose in the context of a summary judgment motion by the defendant, Novopharm, seeking to dismiss Abbott’s patent infringement complaint based on the ’097 patent.

⁶⁴ 276 F.3d 1368, 1370-71 (Fed. Cir. 2002).

treat hypertension and angina called Tiazac, the active ingredient of which was diltiazem hydrochloride.⁶⁵ Biovail received FDA approval for Tiazac on September 11, 1995, and listed U.S. Patent No. 5,529,791 (“’791 patent”) claiming Tiazac in the Orange Book.⁶⁶ The sole independent claim in the ’791 patent was directed to an extended-release composition of diltiazem hydrochloride.⁶⁷ Andrx filed an ANDA with the FDA for approval of a generic version of Tiazac, and the ’791 patent became the subject of a paragraph IV certification in Andrx’s ANDA.⁶⁸ Biovail subsequently sued Andrx in district court for infringement of the ’791 patent.⁶⁹ By commencing an infringement action, Biovail obtained an automatic 30-month stay of approval for Andrx’s ANDA from the day that Biovail received notice of the Paragraph IV certification, which could be shortened if the patent litigation was resolved earlier.⁷⁰ Following a bench trial, the district court entered a judgment of noninfringement in favor of Andrx, which the Federal Court affirmed on February 13, 2001.⁷¹ Consequently, but for the proceeding described here, the FDA would have approved Andrx’s ANDA on that date.⁷²

However, U.S. Patent No. 6,162,463 (“the ’463 patent”) issued on December 19, 2000, and was exclusively licensed to Biovail in January, 2001.⁷³ The ’463 patent contains a claim⁷⁴ directed to a specific extended-release formulation of diltiazem hydrochloride suggested in the ’463 patent as being different from Tiazac.⁷⁵ On January 8, 2001, Biovail requested the FDA to list the ’463 patent in the Orange Book.⁷⁶ As a result, on February 2, 2001, the FDA informed Andrx that its ANDA could not be approved in view of the ’463 patent.⁷⁷ Andrx protested to the FDA about the listing of the

⁶⁵ *Id.* at 1371-72.

⁶⁶ *Id.* at 1372.

⁶⁷ U.S. Pat. No. 5,529,791 (col. 8, ll. 59-67, col. 9, ll. 1-13).

⁶⁸ *Andrx Pharms.*, 276 F.3d at 1372.

⁶⁹ *Biovail Corp. Intl. v. Andrx Pharms., Inc.*, 239 F.3d 1297, 1299 (Fed. Cir. 2001).

⁷⁰ 21 U.S.C. § 355(j)(5)(B)(iii).

⁷¹ *Biovail*, 239 F.3d at 1299.

⁷² *Andrx Pharms.*, 276 F.3d at 1372.

⁷³ *Id.*

⁷⁴ U.S. Pat. No. 6,162,463 (col. 11, ll. 1-12).

⁷⁵ *Id.* at (col. 1, ll. 54-59). The existing Tiazac drug product was described in the Background of the Invention in U.S. Patent No. 6,162,463 (col. 1) with the claimed invention being an improvement thereon.

⁷⁶ *Andrx Pharms.*, 276 F.3d at 1372.

⁷⁷ *Id.*

'463 patent and requested its delisting.⁷⁸ The FDA sought Biovail's position on the matter, and continued to list the patent once Biovail reconfirmed that it was relevant.⁷⁹

On appeal, the Federal Circuit held that the District Court for the Southern District of Florida exceeded its authority under 21 U.S.C. § 355(j)(5)(B)(iii) when it shortened the statutory thirty-month delay of approval of Andrx Pharmaceuticals, Inc.'s ("Andrx's") pending ANDA by the FDA, and ordered that the ANDA be approved by the FDA.⁸⁰ Accordingly, it vacated the district court's order and remanded the case for further proceedings.⁸¹ As to the patent delisting issue, the Federal Circuit held that an ANDA applicant can bring a delisting action against the FDA under the Administrative Procedure Act.⁸²

The procedural route for Orange Book patent listings defined by the Federal Circuit in the cases discussed above was criticized from "within the Court" by Judges Lourie and Gajarsa in an opinion written by Judge Lourie dissenting from an order of the Federal Circuit denying rehearing *en banc* of a case which considered the sufficiency of a notice accompanying a paragraph IV certification under the Hatch-Waxman Amendments.⁸³ In the

⁷⁸ *Id.*

⁷⁹ *Id.* at 1373. It appears that Biovail took the position that it changed its manufacturing process for Tiazac, and that this brought the drug within the claims of the '463 patent. Moreover, Biovail argued that the manufacturing change did not change the safety or efficacy of Tiazac and so a supplemental NDA was not needed. However, it appears that the FDA was not in complete agreement with this characterization at the time this case was considered by the Federal Circuit.

⁸⁰ *Id.* at 1376.

⁸¹ *Id.* at 1380.

⁸² *Id.*

⁸³ *Minn. Mining & Mfg. Co. v. Barr Laboratories, Inc.*, 295 F.3d 1274, 1275 (Fed. Cir. 2002) (Lourie, J., dissenting). *Minn. Mining & Mfg. Co. v. Barr Laboratories, Inc.*, 289 F.3d 775, 776-77 (Fed. Cir. 2002) can be summarized as follows:

This case presents a question under the Hatch-Waxman Amendments Appellants . . . [3M] and [Alphapharm] urge that the district court should have dismissed 3M's infringement action against appellee, [Barr], without prejudice pursuant to Rule 41(a)(2) of the Federal Rules of Civil Procedure, so that the dismissal of that suit would not have triggered the running of a 180-day waiting period under 21 U.S.C. § 355(j)(5)(B)(iv)(II) for approval of Barr's [ANDA]. Appellants urge that a dismissal without prejudice was required because Barr improperly caused the 3M suit to be brought. Barr allegedly did so by failing to provide 3M with information (before 3M filed suit) showing that Barr did not infringe. In particular appellants alleged that Barr failed to comply with the requirement of 21 U.S.C. § 355(j)(2)(B)(ii) that it provide "a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." Pursuant to our

dissent, Judge Lourie distinguished *Andrx* and *Mylan* and then indicated that he would even overrule these cases.⁸⁴ It is not surprising that there was disagreement within the Federal Circuit on the question of how to proceed to challenge the Orange Book patent listings. The *Andrx* and *Mylan* cases created an unworkable situation since the Federal Circuit placed the FDA in a position of having to address the issue of whether patent listings are correct, when the FDA indicated all along that it was not equipped to address patent issues. Consequently, the situation was ripe for intervention by Congress to overrule the *Andrx* and *Mylan* decisions and clarify by which route patent listings could be challenged.

Moreover, additional cases at the district court level exacerbated the confusion regarding patent delisting. For example, in January 2001, about ten months before the Federal Circuit handed down its decision in *Mylan* and about a year before the court handed down its decision in *Andrx*, the district court in Maryland decided a case that also dealt with the procedural issues surrounding challenges to Orange Book patent listings, and specifically considered the listing of the same Buspirone patent considered in *Mylan*, namely, U.S. Patent No. 6,150,365.⁸⁵ In that case, Watson Pharmaceuticals, Inc. (“Watson”) sued the FDA, seeking to obtain a mandatory injunction ordering the delisting of the ’365 patent. Judge Smalkin of the district court in Maryland held that the action was fundamentally a request for judicial review of the FDA’s patent listing decision.⁸⁶ Judge Smalkin found that it was appropriate and reasonable for the FDA to rely on Bristol-Myers Squibb’s declaration as to patent coverage, and to let patent infringement issues to be resolved in other proceedings.⁸⁷ He did not feel that it was appropriate for the FDA or for him, within a proceeding for judicial review that, as such, was governed by the Administrative Procedure Act, to consider the scope of patent claims and the issue of a patent’s listing in the Orange Book.⁸⁸ Accordingly, he granted the FDA summary judgment on the merits,

decisions in [*Mylan*] and [*Andrx*], we hold the § 355(j)(2)(B) cannot be enforced by a private party in a patent infringement action, but must be enforced, if at all, only in the context of an action under the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 702-706. We also conclude that the district court did not lack subject matter jurisdiction to determine the form of dismissal or otherwise abuse its discretion in declining to dismiss without prejudice. We accordingly affirm the judgment of the district court.

⁸⁴ *Minn. Mining*, 295 F.3d at 1275.

⁸⁵ *Watson Pharms., Inc. v. Henney*, 194 F. Supp. 2d 442, 444 (D. Md. 2001).

⁸⁶ *Id.* at 445.

⁸⁷ *Id.* at 446.

⁸⁸ *Id.*

and dismissed the case as to Bristol-Myers Squibb.⁸⁹ The judge seemed to suggest that the propriety of a patent listing was a matter to be determined in private litigation between the parties, not as part of agency adjudication.

Watson Pharms. Inc. deepened the procedural hole that generic companies found themselves in when trying to challenge a patent listing. Not only did the Federal Circuit direct potential generic company plaintiffs to challenge patent listings by seeking judicial review of the FDA's listing decision, but a district court indicated that this route was a dead end since the FDA likely would be found to have acted appropriately if it properly followed an approved drug holder's request to list a patent that that entity argued claimed the approved drug.⁹⁰

A subsequent Federal Circuit case confirmed that, although the FDA's listing decision could be judicially reviewed, generic companies would obtain no benefit from the challenge.⁹¹ The *Apotex* decision stemmed from an Apotex ANDA pertaining to SmithKline Beecham Corporation's ("SmithKline's") antidepressant drug called Paxil. Due to three waves of patent listings by SmithKline, three consecutive 30-month stays were automatically imposed on FDA approval of Apotex's ANDA.⁹² Prior to the Federal Circuit appeal, SmithKline voluntarily requested the FDA to delist patents listed in the third wave of patent listings and thus remove the third 30-month stay on the approval of Apotex's ANDA.⁹³ Although the FDA

⁸⁹ *Id.*

⁹⁰ *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1078, 1086 (D.C. Cir. 2001). In at least one case, a court actually disagreed with the FDA's patent listing decision, because the FDA chose not to list a patent that the approved drug holder wanted to have listed. American Bioscience sought to list one of its patents directed to a safer and more effective delivery method of Taxol in the Orange Book as being related to Bristol-Myers Squibb's (BMS's) approved drug, Taxol. It initially did this by successfully obtaining a temporary restraining order from the U.S. District Court for the Central District of California compelling BMS to list the patent. Although initially BMS did not wish to have the patent listed, thereafter, BMS changed its mind and informed the FDA that it approved of the listing and so the patent should be listed. The FDA, however, did not list the patent. Instead, it approved a generic company's ANDA, and took the position that BMS's request to list the '331 patent was untimely. The Court decided that the FDA's actions were improper since BMS had clearly indicated that it supported the listing of the patent from the date that American Bioscience sought to make the listing (which was within the allowable time period for making a proper listing). Accordingly, it vacated the FDA's approval of the ANDA, and decided that the patent is and should remain properly listed.

⁹¹ *Apotex*, 347 F.3d at 1342.

⁹² *Id.* at 1339-40.

⁹³ *Id.* at 1341.

terminated the third 30-month stay, it refused to delist the patents in question immediately, citing a need to review the effect that such an act might have on other ANDA applicants' entitlement to share with Apotex in the 180-day market exclusivity period.⁹⁴ Thereafter, but still prior to the Federal Circuit appeal, the FDA granted final approval to Apotex's ANDA for a generic version of Paxil and informed Apotex that it would be entitled to the 180-day period market exclusivity but would have to share the exclusivity with certain other ANDA holders.⁹⁵ Nonetheless, Apotex proceeded with its Federal Circuit appeal against the FDA and SmithKline as to delisting of certain of SmithKline's patents pertaining to Paxil.⁹⁶

The Federal Circuit decided that it had jurisdiction to hear the matter and that the delisting issues raised by Apotex were not entirely moot.⁹⁷ The challenge to FDA policy allowing multiple 30-month stays, however, was moot in view of new rules promulgated by the FDA in June 2003 that came into effect on August 18, 2003.⁹⁸ Turning to the merits of the delisting issue, Judge Bryson reasoned:

Because we find nothing in the Hatch-Waxman Act that supports Apotex's argument that the FDA has a duty to screen Orange Book submissions by NDA applicants and to refuse to list those that do not satisfy the statutory requirements for listing, we conclude that the agency's interpretation of the Act set forth in 21 C.F.R. § 314.53(f) is a reasonable one: that the Act does not require it to police the listing process by analyzing whether the patents listed by NDA applicants actually claim the subject drugs or applicable methods of using those drugs. We therefore reject Apotex's contention that, pursuant to the dictates of the Hatch-Waxman Act, the district court should have ordered the FDA to review the contents of the '132, '423, '759, '944, and '233 patents and to remove from the Orange Book any of those patents that do not comply with the statutory listing requirements as applied to SmithKline's NDA for Paxil.⁹⁹

Judge Bryson also dismissed Apotex's argument that the Hatch-Waxman Act is unconstitutional because it denies ANDA applicants such as itself due process.¹⁰⁰ In Judge Plager's concurrence, however, he wholeheartedly disagreed, stating that, if the patent listing scheme did not amount to an "improper delegation of government power," it was "at least [a

⁹⁴ *Id.*

⁹⁵ *Id.* at 1341-42.

⁹⁶ *Id.* at 1339.

⁹⁷ *Id.* at 1344.

⁹⁸ *Id.* at 1347.

⁹⁹ *Id.* at 1349.

¹⁰⁰ *Id.*

poorly conceived administration of the laws.”¹⁰¹

Evident from this lineage of case law discussed above, the original Hatch-Waxman Act was grossly inadequate in dealing with Orange Book listing challenges, and was ripe for reform in this respect. Moreover, there were divergent opinions voiced in the courts, including within the Federal Circuit, on whether patent listing challenges were to be asserted pursuant to an APA proceeding or pursuant to private litigation, such as a patent infringement action. A void existed in the law relating to patent listings because no adequate oversight mechanism existed to monitor the activities of private parties listing patents, or to resolve disputes resulting therefrom. Judge Plager, for one, actively voiced the need for reform:

It does not seem to me to be an unreasonable expectation that the FDA have on its staff a handful of competent patent analysts, along with its multitude of scientific specialists, who, at a minimum, could make an initial judgment about the propriety of a listing, consistent with the statutory requirements that the NDA holder file required patent information. See 21 U.S.C. § 355(c)(2). The FDA claims the power to police the listing process to the extent of ensuring that patents that should be listed are listed; it is a relatively straightforward step to ensure that those patents that obviously should not be listed are not. This would provide a neutral arbiter between the NDA holder and the ANDA applicant regarding an important matter of process, and would provide some balance between these competing interests, a balance that the Hatch-Waxman Act was intended to establish in the first place.

The need for the FDA to properly police the administration of the Act in this regard was made even more acute by our decision in [*Mylan*], in which we held that an ANDA applicant has no private cause of action against an NDA holder to require the NDA holder to remove improperly listed patents from the Orange Book. If neither the Administration nor the courts see fit to make clear FDA’s obligation to administer the act in a responsible way, Congress should consider doing so.¹⁰²

In July 2002, the FTC issued its study regarding the pharmaceutical industry (“FTC Study”) in which it recommended, among other things, that the Hatch-Waxman laws be amended so that only one automatic 30-month stay be provided to innovative pharmaceutical companies.¹⁰³ The FTC reasoned that “[permitting] only one 30-month stay per drug product per ANDA should eliminate most of the potential for improper Orange Book listings to generate unwarranted 30-month stays.”¹⁰⁴

¹⁰¹ *Id.* at 1353 (Plager J., concurring).

¹⁰² *Id.* at 1353-54.

¹⁰³ FTC Study, *supra* n. 10, at v.

¹⁰⁴ *Id.*

B. Unclear Directives for What Constitutes a Proper Orange Book Patent Listing

While the problems with multiple 30-month stays and an inability to challenge innovative companies' patent listings might be enough to galvanize government into action, additional issues arose regarding patent listings to provide the needed final incentive. One of the causes of the strategic behavior pursuant to Orange Book patent listings was that the rules for patent listing provided much room for interpretation and uncertainty as to what patents were required to be listed. Moreover, before the reforms in 2003, neither the FDA nor the U.S. Patent and Trademark Office (PTO) shed much light on the matter. Courts also did not engage in a great deal of analysis on the point.

One commentator, Terry Mahn, described the consequences of the Orange Book patent listing scheme, prior to the recent reform efforts.¹⁰⁵ He indicated that “*Orange Book* listing elevates every patent as a potential source of delay to generic competition . . . [by] giving the patentee/NDA holder almost automatic injunctive relief for even marginal infringement claims.”¹⁰⁶ Furthermore, Mann felt that the FDA rules encouraged NDA holders to “evergreen their drug patents:”

By filing and refiling “improvement” patents for the same basic drug product, they are able to create a minefield for generic applicants. Routinely cited by generic drug companies as examples of such evergreening are claims for disectable tablets and special coatings, new formulations, crystalline forms of the same drug, and variations on drug delivery technologies.¹⁰⁷

He also indicated that, although “a wrongfully listed drug patent—a so-called ‘trip wire’ listing—can have anticompetitive consequences”¹⁰⁸:

Inactive ingredient and device-related claims that are drafted carefully . . . can be bootstrapped into the *Orange Book* with little risk of such exposure. For example, a patent that broadly claims an extended release formulation without reference to an approved drug may be listed improperly in the *Orange Book*, whereas one that claims extended release for a specific drug (or group of drugs) would be listed properly. The same is true for patents that claim a drug delivery system. Patent agents and attorneys acutely aware of the advantages that accrue from *Orange Book* listing have learned to tip the Hatch-Waxman balance in favor of

¹⁰⁵ Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 Food Drug L.J. 245, 250 (1999).

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 251.

patentees.¹⁰⁹

Mahn provides a stark explanation of a patent listing scheme that invited strategic behavior from innovative companies seeking to slow down generic drug entry to protect their market share for innovative drugs for as long as possible.

To be fair, it should be recognized that improvement patents are not altogether bad. Presumably, such patents were issued because they were directed to new, useful and non-obvious improvements over the original drug product. An improvement in the way in which a drug needs to be administered (e.g., an improvement from an intravenous mode of administration of the drug, which could require hospitalization or constant medical supervision, versus an orally administered product, which could be taken at home) is clearly an improvement for a patient that would require some effort on the part of the innovative company to accomplish, and should be afforded patent protection if the improvement is considered new, useful and non-obvious.

Nonetheless, such “evergreening” could lead to a fundamental problem if the improvement, for example, was one that was so closely related to the original drug product that the U.S. Patent and Trademark Office (PTO) found that the patent applicant (i.e., the innovative company seeking the patent) was trying to get two patents on highly-similar inventions. This is known as an obviousness type double-patenting problem.¹¹⁰ This situation can—but does not exclusively—occur when the patent application pertaining to the improvement is, in fact, directly related to the originally-issued patent on the same product.¹¹¹ Before the law was amended on June 8, 1995, to implement the United States’ obligations under the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, such situations were potentially problematic in terms of evergreening because the patent term was based on 17 years from the date of

¹⁰⁹ *Id.*

¹¹⁰ See e.g. Manual of Patent Examining Procedure, 804.II.B (U.S. Pat. & Trademark Off. 2003) [hereinafter MPEP].

¹¹¹ In U.S. patent practice, a patent application (i.e., a “child” application) that might be directly related to an earlier patent application (i.e., a “parent” application) and take priority therefrom, is referred technically to as a “continuation” or a “divisional” of the earlier patent application. See *id.* at 201.06 as to divisional applications. See *id.* at 201.07 as to continuation applications. They are directly related in that the description of the invention in each is exactly the same. If the description of the invention is changed even slightly in the child application as compared to the parent application, then the child application is referred to as a “continuation-in-part” application. See *id.* at 201.08.

issuance of the patent.¹¹² Consequently, later-filed patent applications relating to earlier filed ones could have been used in certain instances to extend protection over related subject matter beyond the initial 17 year term of a first patent. In such situations, however, particularly if an obviousness type double-patenting problem had arisen during prosecution, a PTO Examiner should have required the applicant to file what is known as a “terminal disclaimer,” providing that any patent issuing from the later-filed application would expire at the same time as the earlier-issued patent.¹¹³ Yet the term of all patents now runs 20 years from the first U.S. filing date.¹¹⁴ Consequently, any such improvement patent issuing from a patent application related to an earlier-filed U.S. application would expire on the same date as any original patent issuing from the earlier-filed application. This means that the incentives to “evergreen patents” illegitimately have been significantly curtailed by these developments as to the patent term. Pursuant to *Schering Corp. v. Geneva Pharms., Inc.*, discussed below, patent evergreening may now be increasingly discouraged.¹¹⁵

When considering what types of patents might be listed in the Orange Book, it should be recognized that the original listing directives could lead, as suggested earlier, to legitimate uncertainty as to what types of patents must be listed. The relevant statutory language pertaining to Orange Book listing provides as follows:

The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.¹¹⁶

Consequently, any patent to be listed must satisfy two criteria. First, the patent must “claim[] the drug for which the applicant submitted the

¹¹² See 35 U.S.C. § 154(a)(1) (1988).

¹¹³ 37 C.F.R. § 1.321 (2004) (providing for terminal disclaimers).

¹¹⁴ 35 U.S.C. § 154(2) (2000).

¹¹⁵ *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1382 (Fed. Cir. 2003) [hereinafter *Schering I*]; *infra* nn. 286-90 and accompanying text.

¹¹⁶ 21 U.S.C. § 355(b)(1).

application” or must “claim[] a method of us[ing] such [a] drug.”¹¹⁷ Second, the patent must include claims “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”¹¹⁸ As is often the case, however, the statutory language for patent listing is fraught with ambiguities. For example, what is the “drug for which the applicant submitted the application”? Does the phrase “claims a method of using such drug” suggest that any method of using the drug chemically identified in the application is acceptable, or must the method of use be only with respect to those indications for which drug approval was sought? And does the second test regarding patent infringement pertain to patents that claim the “drug” and patents that claim the “method of using such [a] drug”? One point is clear, namely, that the statute mandates patent listing in accordance with the parameters set forth therein, rather than being permissive.

The relevant FDA regulation, as it read prior to being amended in June 2003, provided more specific information regarding the patents that should be listed in the Orange Book:

Patents for which information must be submitted. An applicant described in paragraph (a) of this section shall submit information on each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes of this part, such patents consist of drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents. Process patents are not covered by this section and information on process patents may not be submitted to FDA. For patents that claim a drug substance or drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application, or that claim a drug substance that is a component of such a product. For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application.¹¹⁹

As with the statutory language, the regulatory language pertaining to patent listing was also mandatory.

The relevant regulation at 21 C.F.R. § 314.53(b) sheds light on some of the ambiguities introduced by the statutory provision. For example, the regulation more clearly indicated that a patent “that claims the drug or a method of using the drug that is the subject of the new drug application or

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ 21 C.F.R. § 314.53(b) (2002).

amendment or supplement to it” was to be listed.¹²⁰ That is, “the new drug application or amendment or supplement to it” was a phrase that defined both what type of “drug” patents and what type of “method of using the drug” patents were to be listed.¹²¹ Furthermore, the regulatory language more clearly indicated that both “drug” patents and “method of using the drug” patents had to satisfy the additional requirement that “a claim of patent infringement could reasonably be asserted [with respect to it] if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.”¹²²

However, in determining what constituted a properly listed patent, where was one to look to determine what drug was “the subject of the new drug application”? Also, how strictly should the phrase be interpreted? The appropriate document to look at to determine whether a patent is properly “the subject of the new drug application” is the labeling for the drug. After all, “[t]he FDCA, which many legal scholars maintain is a law that is based first and foremost on product labeling, clearly specifies that drug safety and effectiveness are contingent on a product label that specifies the conditions of safe and effective use.”¹²³ Furthermore, the NDA is to contain, among other things, samples of the proposed labeling.¹²⁴ Consequently, any patent properly listed in the Orange Book will claim either a drug product, drug substance or method of using a drug product as contemplated by the labeling for the drug in question.

Subsection 314.53(b) also provided additional guidance as to what type of patent claims “the drug.”¹²⁵ Both drug substance (ingredients) patents and drug product (formulation and composition) patents were included.¹²⁶ That is, the “drug product” had to be “the subject of a pending or approved application,” and any “drug substance” had to be “a component of such a product.”¹²⁷ This language provided for broader listings of patents than the language of earlier regulations, which tracked the language of the statute at 21 U.S.C. § 355(b)(1), and required that patents only be listed if they claimed

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Expediting Drug and Biologics Development—A Strategic Approach* 53-54 (Steven E. Linberg ed., 2d ed., Parexel 1999). Sections of a package insert are provided *id.* at 54.

¹²⁴ 21 U.S.C. § 355(b)(1).

¹²⁵ 21 C.F.R. § 314.53(b) (2002).

¹²⁶ *Id.*

¹²⁷ *Id.*

“the drug for which the [NDA] applicant submitted [an] application.”¹²⁸ This was a narrower directive, since the FDA used to interpret the term “drug” to mean “drug product” for which the NDA was filed and not “drug substance.”¹²⁹

However, the regulations did not provide any guidance as to whether patents directed to metabolites, polymorphs (e.g., such as various crystalline forms) or drug delivery modalities could be appropriately listed. Moreover, the regulation was unclear on the question whether patents directed to unapproved uses were to be listed in the Orange Book. This suggests that there was much uncertainty as to the types of patents that could be listed. Consequently, patent listings did not fall into two categories, i.e., proper and clearly improper attempts to “evergreen” a patent so as to extend a company’s market exclusivity.

One case illustrates the complexity that existed prior to the rules being rewritten in June 2003 in determining whether a patent was to be listed in the Orange Book.¹³⁰ In *Ben Venue*, the generic drug company, moved for a preliminary injunction requiring Novartis to remove its Orange Book patent listing related to its drug for Aredia, approved for treating bone loss and similar complications from cancer.¹³¹ The patent in question was U.S. Patent No. 4,711,880 (“the ’880 patent”), which appeared to cover a crystalline pentahydrate form of pamidronate.¹³² Ben Venue filed an ANDA to manufacture a generic version of Aredia and made a paragraph IV certification as to the ’880 patent, stating that Ben Venue’s “lyophilized material”¹³³ will not infringe on the crystalline hydrate material claimed in the ’880 patent. Within 45 days of giving notice of its certification, Ben Venue also filed a declaratory judgment action asserting that the ’880 patent was improperly listed in the Orange Book because the ’880 patent did not “claim” Aredia.¹³⁴ More specifically, Ben Venue argued that the ’880 patent “is directed to various crystalline forms of Pamidronate that include water of

¹²⁸ 21 U.S.C. § 355(b)(1).

¹²⁹ *Id.*

¹³⁰ *Ben Venue Laboratories, Inc. v. Novartis Pharm. Corp.*, 10 F. Supp. 2d 446, 448 (D.N.J. 1998).

¹³¹ *Id.*

¹³² *Id.* at 450.

¹³³ *Id.* at 453 n. 7 (stating that, “‘Lyophilization’ is ‘the removal of water under vacuum from a frozen sample; a relatively gentle process for the removal of water in which the water sublimates from the solid to the gaseous state.’” J. Stenesh, *Dictionary of Biochemistry and Molecular Biology* (2d ed., 1989)).

¹³⁴ *Id.* at 450.

crystallization, i.e., various hydrates of Pamidronate, particularly the pentahydrate,” whereas Aredia was not found to contain any crystalline Pamidronate.¹³⁵ Novartis admitted that the dosage form of the Aredia drug product contains the anhydrous (lacking water) form of pamidronate, however, the NDA for Aredia lists the generic and chemical names of the drug as the pentahydrate. Accordingly, the compound covered by the '880 patent is the “drug substance” or “active ingredient” of Aredia. In the meantime, Novartis filed both a motion to dismiss and a patent infringement suit against Ben Venue which triggered an automatic 30-month stay on the approval of Ben Venue’s ANDA. Ben Venue then filed a preliminary injunction motion requesting that the court “preliminarily enjoin Novartis from asserting any rights arising from its improper listing and ultimately order Novartis to delist the '880 patent.”¹³⁶

Considering Ben Venue’s likelihood of success on the merits, Judge Bassler held that, even though the final drug product Aredia did not contain the pentahydrate form of pamidronate, as claimed in the '880 patent, it was not necessary in order for the '880 patent to be properly listed.¹³⁷ Pursuant to 21 C.F.R. § 314.53(b), properly listed patents include drug product (formulation and composition) patents, and drug substance (ingredient) patents, where the drug substance is a component of a drug product.¹³⁸ After canvassing the FDA’s use of the terms “component” and “drug substance,” the court found that a patented drug product need not appear in the final drug product in order to be properly listed.¹³⁹ The FDA has noted that an “active ingredient” includes:

¹³⁵ *Id.*

¹³⁶ *Id.* at 450, 452. Interestingly, Judge Bassler decided that it was completely appropriate for Ben Venue to have filed its declaratory judgment action requesting delisting of the '880 patent within 45 days from its ANDA filing and Paragraph IV certification. In a footnote, Judge Bassler made a statement that is at odds with the Federal Circuit’s recent decision in *Mylan*:

Novartis is correct that a challenge to the appropriateness of an Orange Book listing may be raised as a counterclaim in a patent infringement suit. See *Abbott Laboratories v. Novoharm Ltd.*, 104 F.3d 1305 (Fed. Cir. 1997) (claim that listed patent was expired raised as counterclaim in patent infringement suit). This however, is not the only way such a challenge can be brought. The Court sees no reason why a party must wait until it is sued for patent infringement to raise the issue of an improper Orange Book listing.

Id. at 451, n. 4.

¹³⁷ *Id.* at 455.

¹³⁸ *Id.*

¹³⁹ *Id.* at 457-58.

any *component* that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or of animals. *The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.*¹⁴⁰

Consequently, the '880 patent was "very likely properly listed in the Orange Book."¹⁴¹ Judge Bassler also found that Ben Venue failed to show that it would suffer irreparable harm if a preliminary injunction is not granted, and that the public interest favored denial of the preliminary injunction.¹⁴² Accordingly, the court denied Novartis' motion to dismiss, granted Ben Venue's motion for leave to file a supplemental complaint, and denied Ben Venue's motion for a preliminary injunction.¹⁴³

In addition to the ambiguities and complexities surrounding the question of what was a "listable" drug substance or drug product patent, there was also a great deal of uncertainty as to what method of use patents could be listed. The issue concerned whether patents directed to unapproved uses could be listed in the Orange Book. The language of the relevant statutory and regulatory provisions was unclear. Consequently, innovative companies interpreted the listing requirements broadly and listed method of use patents directed to methods of using an approved drug substance or drug product to treat an unapproved indication.¹⁴⁴

Not until six months before the FDA amended its patent listing regulations in June 2003 did the Federal Circuit decide a case in which the question of listed patents directed to unapproved uses was tangentially

¹⁴⁰ *Id.* at 457 (citing 21 C.F.R. at § 60.3(b)(2)) (emphasis in original).

¹⁴¹ *Id.* at 458.

¹⁴² *Id.* at 459.

¹⁴³ *Id.* at 454-56. In reaching his decision, Judge Bassler distinguished *Pfizer v. Food & Drug Administration*, 753 F. Supp. 171 (D. Md. 1990), which Ben Venue had relied on to support its argument that "Novartis improperly listed a patent for a drug substance that does not appear in the drug product." *Id.* The *Pfizer* case dealt with FDA's refusal to list a patent that claimed a drug product. *Pfizer*, 753 F. Supp. at 171. Judge Bassler found the *Pfizer* case to be distinguishable since that case "turned in large part on the applicant's attempt to list a patent for a new, unapproved tablet drug product." *Ben Venue*, 10 F. Supp. 2d at 455. Furthermore, the case was decided before "the FDA promulgated formal regulations on patent certifications, making clear that certain drug substance patents may be listed." *Id.* at 456. Judge Bassler also considered *Zenith Laboratories, Inc. v. Abbott Laboratories* 1996 U.S. Dist. LEXIS 22567 at *2 (D.N.J. Aug 7, 1996). *Id.*

¹⁴⁴ See e.g. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003).

considered.¹⁴⁵ Warner-Lambert's drug Neurontin® was at issue. Although that drug had been covered by patents that had expired, including a method directed to the approved use of treating epilepsy and a patent directed to the active ingredient, gabapentin, there remained an unexpired patent directed to the use of gabapentin in the treatment of an unapproved indication, neurodegenerative diseases.¹⁴⁶ Warner-Lambert listed this patent and Apotex, an ANDA applicant, formally filed a paragraph IV certification, arguing that its generic drug was indicated for use in the treatment of epilepsy, not neurodegenerative disease, and therefore could not infringe Warner-Lambert's listed patent.¹⁴⁷ Judge Lourie framed the issue before the court and the court's conclusion as follows:

The central issue in the present case is whether it is an act of infringement under 35 U.S.C. § 271(e)(2)(A) to submit an ANDA seeking approval to make, use, or sell a drug for an approved use if any other use of the drug is claimed in a patent, or if it is only an act of infringement to submit an ANDA seeking approval to make, use, or sell a drug if the drug or the use *for which FDA approval is sought* is claimed in a patent. That issue presents a matter of first impression for this court. . . . For the reasons stated below, we conclude that it is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA.¹⁴⁸

In reaching this conclusion, Judge Lourie was impressed by a passage in the legislative history suggesting that Congress did not intend for patents to unapproved uses to slow down ANDA applicants seeking to get generic drugs on the market.¹⁴⁹

The case did not deal directly with the question of whether method-of-use patents directed to unapproved uses were properly listed. However, by not permitting Warner-Lambert to rely on the unapproved use patent to establish an act of infringement pursuant to 35 U.S.C. § 271(e)(2), which is the point of listing patents in the first place, Judge Lourie certainly called the practice into question. Nonetheless, it is noteworthy that a subsequent case pertaining to the same patent directed to the treatment of neurodegenerative disease using gabapentin (i.e., the '479 patent) revealed that the FDA decided to delist this patent in response to the *Warner-Lambert Co.* decision, deciding it should not have been listed in the first place.¹⁵⁰

¹⁴⁵ *Id.*

¹⁴⁶ *Id.* at 1352.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.* at 1354-55 (emphasis in original).

¹⁴⁹ *Id.* at 1361.

¹⁵⁰ See *Purepac_Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004). Although

As the various disputes pertaining to Orange Book patent listings were winding their way through the court system, the Federal Trade Commission (FTC) took notice and recognized that there were ambiguities in determining what was an appropriate patent listing. Consequently, on May 16, 2001, it filed a Citizen Petition to the Commissioner of Food and Drugs pursuant to 21 C.F.R. §§ 10.25(a) and 10.30, requesting that the Commissioner provide “guidance concerning the criteria that a patent must meet before it can be listed in the Orange Book.”¹⁵¹ More specifically, the FTC sought guidance on questions such as: (1) the proper test for determining whether a patent can be listed in the Orange Book; and (2) whether a patent “claiming an unapproved aspect of an approved drug” can be filed.¹⁵²

In July 2002, the FTC came out with its FTC Study referred to earlier¹⁵³ in which it recommended that the FDA clarify its patent listing requirements. Accordingly, this is exactly what the FDA did when it issued its new patent listing rules, which we will consider in Part V of this article. In fact, in a letter dated September 3, 2003, Mr. William Hubbard of the FDA officially wrote to the FTC in reply to the FTC’s Citizen Petition, indicating that “FDA’s answers to the questions posed by the FTC are fully provided and explained” in those rules.¹⁵⁴

this decision was rendered well after June 2003 when the FDA reformed the listing requirements, as will be discussed *infra* § V, the Court in that case mentioned in passing:

Method-of-use patents—which cover specific uses for drugs—can be included in the Orange Book only if they cover drug uses that the FDA has approved 21 C.F.R. § 314.53(b). In other words, companies cannot use the Orange Book to claim protection for uses that the FDA has not approved.

Id. at 886.

¹⁵¹ Citizen Pet. from Seth Silber, Atty. at Fed. Trade Commn., to the Commr. of Food and Drugs, 2 (May 16, 2001) (available at <http://www.fda.gov/ohrms/dockets/dailys/01/May01/052901/cpa.pdf>).

¹⁵² *Id.* at 2-3.

¹⁵³ FTC Study, *supra* n. 10, at v.

¹⁵⁴ Ltr. from William K. Hubbard of the Food and Drug Administration to Joseph J. Simons & Todd J. Zywicki of the Fed. Trade Commn. (Sept. 3, 2003) (available at <http://www.fda.gov/ohrms/dockets/dailys/02/May02/050602/050602.htm>). In addition, the FDA acknowledged in that letter that it “made extensive use of the information and analysis contained in [the FTC’s] report entitled “Generic Drug Entry Prior to Patent Expiration: An FTC Study.” See also FTC study, *supra* n. 10.

2. Settlement Agreements and the 180-Day Exclusivity Period

Although the Hatch-Waxman provisions pertaining to automatic 30-month stays and patent listings led to its share of problems, as discussed above, yet another aspect of the Hatch-Waxman provision, namely, the 180-day exclusivity period led to substantial problems as well, in the form of anticompetitive settlement agreements, as will be described below.

To be able to understand the problem that arose regarding anticompetitive settlement agreements, it is necessary to glean an understanding of the 180-day exclusivity period, and how it was applied by the FDA. Prior to the 180-day marketing exclusivity provision being recently amended by the Medicare Reform Legislation, it stated:

(iv) If the [ANDA] application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous [ANDA] application has been submitted under this subsection continuing [*sic-containing*] such a certification, the application shall be made effective not earlier than one hundred and eighty days after:

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.¹⁵⁵

The purpose of the 180-day exclusivity period was to provide incentives to generic companies to file ANDAs containing paragraph IV certifications, such that they challenged patents listed by the NDA applicant, i.e., the brand name company.¹⁵⁶ The 180-day exclusivity provision, however, was prone to manipulation by generics and innovators.

Initially, the FDA implemented the 180-day exclusivity provision by requiring that the first generic applicant “successfully defen[d]” against a patent claim of the brand-name company to be eligible for the exclusivity.¹⁵⁷ However, this interpretation was rejected in *Mova Pharmaceuticals, Corp. v. Shalala*.¹⁵⁸ Thereafter, the FDA revoked the “successful defense” requirement and began making exclusivity decisions on a first-to-file basis.¹⁵⁹

¹⁵⁵ 21 U.S.C. § 355(j)(5)(B)(iv).

¹⁵⁶ FTC Study, *supra* n. 10, at v.

¹⁵⁷ *Id.* at 58.

¹⁵⁸ 955 F. Supp. 128, 130 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998).

¹⁵⁹ FTC Study, *supra* n. 10, at 58. “The FDA also subsequently published guidance for industry entitled ‘180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act’ (June 1998), describing its

However, there was still some question as to what type of court decision would trigger the 180-day period of exclusivity to commence, which is a different question from the eligibility question considered in *Mova*:

The FDA originally interpreted the definition of a court that would trigger 180-day exclusivity to be “the court that enters final judgment from which no appeal can be or has been taken.” In *Mylan Pharms, Inc. v. Shalala*, [81 F. Supp. 2d 30 (D.D.C. 2000)], the District Court for the District of Columbia found FDA’s interpretation of “court” to be incorrect; the court instead held that “court” means “district court.” The FDA [then] amended its rules to implement the *Mylan* decision by defining the “court” decision that triggers the running of the 180-day marketing exclusivity period as the decision of a district court. This definition [applied], however, only to ANDAs containing paragraph IV certifications filed with the FDA after March 2000. Thus, if a generic applicant filed its ANDA with the paragraph IV certification prior to March 2000, the definition of a court [remained] “the court that enters final judgment from which no appeal can be or has been taken.” [FDA, Guidance for Industry, Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the FDCA (March 2000)].¹⁶⁰

While there was uncertainty and complexity over the application of the 180-day exclusivity period, its effect on subsequent ANDA applicants was clear. As stated by the Federal Trade Commission in a study of the original Hatch-Waxman 180-day exclusivity provision prior to its being amended:

[I]n addition to encouraging entry by the first generic applicant, the 180-day exclusivity can delay when the FDA approves any subsequent eligible generic application that also contains a paragraph IV certification. 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.¹⁶¹

By entering into agreements to settle pending patent infringement litigation, both innovative and generic companies took advantage of this delaying effect of the 180-day exclusivity provision to maintain market exclusivity for a drug and prevent subsequent market entry by other generic applicants.¹⁶² As noted by the FTC in its study, “14 of the 20 of the settlement agreements obtained through the study, at the time they were executed, had the potential to ‘park’ the first generic applicant’s 180-day exclusivity for some period of

approach to 180-day exclusivity.” *Id.* at 59 n. 11.

¹⁶⁰ *Id.* at 59-60 nn. 14-15 (footnote text in brackets). “The FDA also ha[d] proposed new regulations to address issues” on the 180-day exclusivity that, as of July 2002, had been pending since August 1999 (64 Fed. Reg. 42873 (Aug. 6, 1999)). *Id.* at 59 nn. 11-12.

¹⁶¹ *Id.* at 62-63.

¹⁶² *Id.* at 63.

time, thus preventing FDA approval of any subsequent eligible applicants.”¹⁶³ In certain instances, the settlement agreements were found to be anticompetitive.

For example, in *In the Matter of Abbott Laboratories and Geneva Pharms, Inc.*,¹⁶⁴ the FTC launched an antitrust investigation against Abbott Laboratories and Geneva Pharmaceuticals because of an agreement that these parties entered into to settle patent infringement litigation that was launched pursuant to a paragraph IV certification under the Hatch-Waxman Act. Further to this investigation, consent orders from each of the two companies were obtained by the FTC,¹⁶⁵ thereby resolving what the FTC termed as “the first resolution of an antitrust challenge by the government to a private agreement whereby a brand name drug company paid the first generic company that sought FDA approval not to enter the market, and to retain its 180-day period of market exclusivity.”¹⁶⁶

In that case, Abbott introduced Hytrin containing terazosin hydrochloride in tablet form in 1987 and in capsule form in 1995, principally to treat enlarged prostate and hypertension.¹⁶⁷ Geneva introduced a generic copy of Hytrin in August 1999, based on ANDAs that it filed covering both tablet and capsule forms, respectively in January 1993 and December 1995.¹⁶⁸ In early 1996, Abbott listed the '207 patent, and in April 1996, Geneva filed a paragraph IV certification with regards to that patent, claiming that neither its capsule nor its tablet products infringed the '207 patent.¹⁶⁹ Within 45-

¹⁶³ *Id.* The FTC described trends as to settlement agreements more generally, mostly as between brand name companies and generic companies, but also between generic companies. However, the FTC “does not reach any conclusions about the competitive effects of the settlements.” *Id.* at 25.

¹⁶⁴ Fed. Trade Commn., *In the Matter of Abbott Laboratories*, <http://www.ftc.gov/os/caselist/c3945.htm> (accessed Feb. 20, 2005).

¹⁶⁵ See Fed. Trade Commn., *In the Matter of Geneva Pharm., Inc.: Agreement Containing Consent Order*, <http://www.ftc.gov/os/2000/03/genevaagre.htm> (accessed Feb. 20, 2005); see also Fed. Trade Commn., *In the Matter of Geneva Pharm., Inc.: Decision and Order*, <http://www.ftc.gov/os/2000/03/genevad&o.htm> (accessed Feb. 20, 2005).

¹⁶⁶ Fed. Trade Commn., *Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary: Abbott Laboratories and Geneva Pharmaceuticals, Inc.*, <http://www.ftc.gov/os/2000/03/hoeschtandrxcmmstmt.htm> (accessed Feb. 20, 2005).

¹⁶⁷ Fed. Trade Commn., *In the Matter of Abbott Laboratories, and Geneva Pharms, Inc.: Complaint*, <http://www.ftc.gov/os/2000/03/abbottcmp.htm> at ¶¶ 10, 11, 14 (accessed Feb. 20, 2005).

¹⁶⁸ *Id.* at ¶ 16.

¹⁶⁹ *Id.* at ¶ 17.

days, in June 1996, Abbott sued Geneva, but only made an infringement claim as to Geneva's tablet product, not its capsule product.¹⁷⁰ Consequently, Abbott obtained an automatic 30-month stay on FDA's approval of Geneva's tablet product but the FDA continued to review Geneva's generic capsule version of Hytrin and approved it on March 30, 1998.¹⁷¹ Because Geneva was the first generic company to submit paragraph IV certifications as to both the tablet and capsule forms of Hytrin, it was entitled to the 180-day exclusivity period for each of these products.¹⁷² Moreover, as noted by the FTC, "[u]nless and until Geneva's 180-day Exclusivity Period had been triggered and had expired, or Geneva relinquished its entitlement to this period of exclusivity, only Geneva would be approved by the FDA to market a generic terazosin HCL product."¹⁷³

According to the FTC, the anticompetitive behavior began thereafter. Once Geneva obtained approval to market generic Hytrin in capsule form, the parties negotiated an agreement whereby Geneva "agreed not to enter the market with any generic terazosin HCL capsule or tablet product until the earlier of: (1) the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, including review through the Supreme Court; or (2) entry of another generic terazosin HCL product."¹⁷⁴ Geneva "also agreed . . . not to transfer, assign, or relinquish its right to a 180-day Exclusivity Period."¹⁷⁵ In return, Abbott agreed to pay Geneva \$4.5 million per month in non-refundable payments until such time as a district court rendered a judgment in the patent infringement case.¹⁷⁶ Thereafter, Abbott would pay this monthly amount into an escrow fund, the monies in which would ultimately be paid out to the prevailing party in the litigation.¹⁷⁷ Whereas Abbott's payments under the settlement agreement began in April 1998, on September 1, 1998, the district court invalidated Abbott's patent based on an on-sale bar pursuant to 35 U.S.C. § 102(b), and this decision was affirmed by the Federal Circuit on July 1, 1999.¹⁷⁸ Although Geneva did not market its generic drug, as per the settlement agreement, up to this point, it

¹⁷⁰ *Id.* at ¶ 18.

¹⁷¹ *Id.* at ¶¶ 19-22.

¹⁷² *Id.* at ¶ 23.

¹⁷³ *Id.*

¹⁷⁴ *Id.* at ¶ 26.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.* at ¶ 27.

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at ¶¶ 30-33.

did begin to do so on August 13, 1999, when it became aware of the FTC's investigation, despite the terms of the settlement agreement.¹⁷⁹

The FTC alleged that the Abbott-Geneva settlement agreement constituted an unreasonable restraint of trade in violation of section 5 of the Federal Trade Commission Act ("FTC Act"), as amended.¹⁸⁰ Moreover, the actions of the parties were alleged to have been taken with the specific intent that Abbott monopolize the market, in furtherance of a conspiracy to monopolize the relevant market, which also was a violation of section 5 of the FTC Act.¹⁸¹ In addition, Abbott had monopoly power in the relevant market and monopolized that market, contrary to section 5 of the FTC Act,¹⁸² and the parties' activities surrounding the settlement agreement were "anticompetitive in nature and tendency and [constituted] unfair methods of competition," also in violation of that section.¹⁸³ This case was resolved when Abbott and Geneva entered into consent orders with the FTC.

However, on March 16, 2000, the same day as the resolution of the Abbott/Geneva settlement agreement, the FTC issued an administrative complaint against two other pharmaceutical companies; Hoechst Marion Roussel, Inc. (now Aventis) ("Hoechst") and Andrx Corporation ("Andrx").¹⁸⁴ The FTC alleged that Hoechst and Andrx engaged in anticompetitive practices pursuant to § 5 of the FTC Act when Hoechst, the maker of widely-prescribed Cardizem CD for the treatment of hypertension and angina, agreed to pay Andrx millions of dollars to keep Andrx from keeping its generic version of Cardizem CD off the market.¹⁸⁵

In its Complaint, the FTC found that Hoechst had monopoly power in the U.S. market for once-a-day diltiazem.¹⁸⁶ In terms of salient facts, the

¹⁷⁹ *Id.* at ¶ 33.

¹⁸⁰ *Id.* at ¶ 40.

¹⁸¹ *Id.* at ¶ 41.

¹⁸² *Id.* at ¶ 42.

¹⁸³ *Id.* at ¶ 43.

¹⁸⁴ Fed. Trade Commn., *FTC Charges Drug Manufacturers with Stifling Competition in Two Prescription Drug Markets*, <http://www.ftc.gov/opa/2000/03/hoechst.htm> [¶ 1] (accessed Feb. 20, 2005).

¹⁸⁵ *Id.*

¹⁸⁶ Fed. Trade Commn., *In the Matter of Hoechst Marion Roussel, Inc. and Andrx Corp.: Complaint*, <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.html> [¶ 14] (accessed Feb. 20, 2005) (containing the complaint for *In the Matter of Hoechst Marion Roussel, Inc. and Carderm Capital L.P. and Andrx Corporation*). Since Carderm Capital L.P. is directly or indirectly owned and controlled by Hoechst, I refer to both Hoechst and Carderm collectively as "Hoechst."

FTC found that, in about September 1995, Andrx was the first to file an ANDA with the FDA for a generic version of Cardizem CD, and in December 1995, was the first to make a paragraph IV certification as to Hoechst's listed patents for Cardizem CD.¹⁸⁷ This entitled Andrx to the Hatch-Waxman 180-day exclusivity period.¹⁸⁸ Hoechst launched a patent infringement suit in January 1996 based on Andrx's certifications and obtained an automatic 30-month stay.¹⁸⁹ Subsequently, other companies, namely, Purepac and Biovail, filed ANDAs for generic versions of Cardizem CD.¹⁹⁰ While their lawsuit was ongoing, Hoechst and Andrx agreed not to settle the lawsuit, but rather agreed as follows:

23. Andrx would not enter the market with a generic version of Cardizem CD covered by its ANDA until the earliest of (1) the entry of final judgment in the patent lawsuit, (2) Andrx's obtaining a license from Hoechst . . . or (3) Hoechst MRI's providing notice that it intended to license a third party or sell its own bioequivalent or generic version of Cardizem CD . . . Andrx also agreed . . . to refrain from selling any other bioequivalent or generic version of Cardizem CD, regardless of whether such product would infringe Hoechst MRI's or Cardizem's patents. In addition, Andrx agreed not to withdraw its pending ANDA or to relinquish or otherwise compromise any right accruing under its ANDA, including its right to a 180-day Exclusivity Period, until the entry of final judgment in the patent lawsuit.

24. In exchange for Andrx's various agreements, Hoechst MRI agreed to pay Andrx \$10 million per quarter, beginning upon final FDA approval of Andrx's ANDA (i.e., once Andrx could otherwise have marketed) and continuing until the occurrence of either (1), (2) or (3) described above in Paragraph 23 . . . [Moreover,] should Hoechst . . . lose the patent infringement suit, Hoechst MRI would pay Andrx an additional \$ 60 million per year for that same time period.¹⁹¹

Hoechst began making its quarterly payments when Andrx obtained final approval for its ANDA in July 1999, and Andrx refrained from selling its generic product.¹⁹² In September 1998, Andrx submitted a Supplemental ANDA for a modified version of its generic Cardizem CD product, and filed a paragraph IV certification.¹⁹³ Thereafter, Hoechst and Andrx abrogated the Stipulation and Agreement and cleared the way for Andrx to begin marketing

¹⁸⁷ *Id.* at ¶ 17.

¹⁸⁸ *Id.*

¹⁸⁹ *Id.* at ¶ 18.

¹⁹⁰ *Id.* at ¶¶ 19-20.

¹⁹¹ *Id.* at ¶¶ 23-24.

¹⁹² *Id.* at ¶ 27.

¹⁹³ *Id.* at ¶ 28.

a generic version of Cardizem CD in June, 1999.¹⁹⁴ By its conduct, the FTC claimed that the parties unreasonably restrained competition in the Cardizem CD market and the Agreement intentionally delayed entry not only of Andrx but also of other manufacturers of generic versions of Cardizem CD into the market.¹⁹⁵ The FTC claimed that the activities described constituted unreasonable restraints of trade in violation of section 5 of the FTC Act.¹⁹⁶ Moreover, allegations similar to those alleged in the Abbott/Geneva case also were alleged against Hoechst and Andrx.¹⁹⁷ The parties entered into a consent order with the FTC as to this matter on May 11, 2001.¹⁹⁸

Finally, it is worth noting a third FTC matter involving a settlement agreement between an innovative company and generic companies, namely *In the Matter of Schering-Plough Corp., et al.*¹⁹⁹ Unlike the other two cases identified above, which ended with consent orders, this third matter proceeded to a hearing and was subject to a Final Order and an Opinion of the Commission.²⁰⁰ This final decision of the FTC reversed the Initial Decision of an administrative law judge, who had dismissed the FTC's complaint, and entered an order finding that the two settlement agreements in question did violate section 5 of the FTC Act but providing for prospective relief only.²⁰¹ This FTC decision was later overturned by a Federal Appeals Court ruling that Schering-Plough did not violate antitrust laws.²⁰²

¹⁹⁴ *Id.*

¹⁹⁵ *Id.* at ¶¶ 29-33.

¹⁹⁶ *Id.* at ¶ 36.

¹⁹⁷ *Id.* at ¶¶ 37-39.

¹⁹⁸ See Fed. Trade Commn., *In the Matter of Hoechst Marion Roussel, Inc. and Andrx Corp.: Decision and Order*, <http://www.ftc.gov/os/2001/05/hoechstdo.html>, (accessed Feb. 20, 2005).

¹⁹⁹ Fed. Trade Commn., *In the Matter of Schering-Plough Corp., et al.*, <http://www.ftc.gov/os/adjpro/d9297/index.htm> (accessed Feb. 20, 2005).

²⁰⁰ See *In the Matter of Hoechst Marion Roussel: Decision and Order*, *supra* n. 198.

²⁰¹ Fed. Trade Commn., *In the Matter of Schering-Plough Corp., et al., Final Order*, <http://www.ftc.gov/os/adjpro/d9297/031218finalorder.pdf> (accessed Feb. 20, 2005); Fed. Trade Commn., *In the Matter of Schering-Plough, et. al.: Opinion of the Commission*, <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf> (accessed Feb. 20, 2005) [hereinafter Opinion of Commissioner Leary]. Prospective relief only was said to be provided because “the agreements in question were consummated well before the Commission launched the investigations that resulted ultimately in complaints and consent orders in comparable situations.”

²⁰² *Schering-Plough Corp. v. FTC*, Case No. 04-10688, Docket No. FTC9297 (11th Cir. March 8, 2005) (available at <http://www.ca11.uscourts.gov/opinions/weekops.php>) (accessed March 10, 2005).

In this case, the FTC issued a complaint on March 30, 2001 charging that Schering-Plough Corporation (“Schering”), Upsher-Smith Laboratories, Inc. (“Upsher”) and American Home Products Corporation (“AHP”) violated section 5 of the FTC Act “by entering into agreements to delay the entry of low-cost generic competition to Schering’s prescription drug K-Dur 20.”²⁰³

More specifically, in August 1995, Upsher filed an ANDA to market a generic version of K-Dur 20, which is used to treat patients with low potassium or hypokalemia, and made a paragraph IV certification to Schering’s listed formulation patent. Schering then sued Upsher within the requisite time period and obtained an automatic 30-month stay. On June 17, 1997, the eve of trial, the parties settled their litigation. In the settlement agreement, Schering agreed to pay Upsher \$60 million and Upsher agreed not to enter the market with any generic version of K-Dur 20 before September 2001, which was four years later. As part of the settlement agreement, Upsher also licensed Schering to market six Upsher products in prescribed territories. The complaint alleged that the \$60 million payment was to induce Upsher to delay generic entry and was not related to the value of the Upsher products.²⁰⁴

In addition, in December 1995, ESI Lederle Inc., a division of AHP, also submitted an ANDA for a generic version of K-Dur 20, also with a paragraph IV certification. This litigation also was settled with final agreements in June 1998: “As part of this settlement, AHP agreed that it would not market any generic version of Schering’s K-Dur 20 before January 2004, and Schering agreed to make payments totaling \$30 million. Schering also licensed two products from AHP.”²⁰⁵ The complaint as to this settlement agreement similarly alleged that “the Schering payments were not related to the value of the licenses, and thus induced AHP to agree to the delay of its own generic product.”²⁰⁶

In view of the antitrust concerns that were raised by the various settlement agreements considered above, the FTC issued a recommendation in its FTC Study to “[p]ass legislation to require brand-name companies and first generic applicants to provide copies of certain agreements to the [FTC].”²⁰⁷ Moreover, the FTC recommended that legislation be passed to clarify that “commercial marketing” in the Hatch-Waxman 180-day exclusivity provision “includes the first generic applicant’s marketing of the

²⁰³ Opinion of Commissioner Leary, *supra* n. 201, at 2.

²⁰⁴ *Id.* at 4.

²⁰⁵ *Id.* at 5.

²⁰⁶ *Id.*

²⁰⁷ FTC Study, *supra* n. 10, at vi.

brand-name product,” since there were instances where supply agreements were entered into between brand-name and generic companies to settle patent infringement lawsuits arising from paragraph IV certifications filed in the context of ANDA applications.²⁰⁸ In addition, the FTC recommended that the 180-day exclusivity provision be amended to specify that any court decision is sufficient to start the running of the 180-day period of exclusivity, as two courts of appeal have held and the FDA has issued guidance on.²⁰⁹

IV. THE FALLOUT RESULTING FROM HATCH-WAXMAN STRATEGIC BEHAVIOR

From Part III, it is apparent that, while Hatch-Waxman may have led to more rapid generic drug entry on the whole, there is certain strategic and even anticompetitive behavior that was undertaken by innovative companies, sometimes in concert with generic companies, that slowed down generic drug entry in certain instances. An analysis of Hatch-Waxman strategic behavior and Hatch-Waxman reforms would not be complete without considering what happened between these two endpoints. In this part, we look at the antitrust problems that arose as a result of the Orange Book patent listings and multiple 30-month stays that were at issue in the *Mylan* and *Andrx* cases. That is, patent listings pertaining to the drugs Buspirone and Tiazac not only were the subject of Federal Circuit appeals as we saw earlier in the *Mylan* and *Andrx* cases, but also were subjected to the FTC’s anticompetitive scrutiny. As well, we consider a failed Congressional reform effort in 2002 that sought to fix the problems in the Hatch-Waxman Act.

1. An Antitrust Response to Orange Book Patent Listing Problems and Multiple 30-Month Stays

The cases discussed above regarding allegedly improper Orange Book patent listings do not paint the complete picture of the myriad clashes that innovative and generic pharmaceutical companies have had over Orange Book listings. As suggested by Mahn, Orange Book patent listings can have anticompetitive consequences.²¹⁰ Consequently, it should not be a surprise to the reader that patent listings in the Orange Book also became an issue of

²⁰⁸ *Id.* at ix.

²⁰⁹ *Id.*

²¹⁰ Mahn, *supra* n. 105.

interest to the Federal Trade Commission (FTC).²¹¹

Anticompetitive issues as to Buspirone, which was at issue in the *Mylan* case, were considered in the case *In re Buspirone*.²¹² FTC Chairman Muris made the following comments regarding this litigation after the fact:

One of the principal focuses of the Commission's second generation litigation has been improper Orange Book listings. Unlike the [first generation patent] settlement cases . . . [between generic and innovative companies], which typically involve collusion between private parties, an improper Orange Book listing strategy involves abuse of the Hatch-Waxman process itself to restrain trade.²¹³

In the *In re Buspirone* case, it was alleged that Bristol-Myers monopolized the market for its drug, BuSpar, by improperly listing a patent in the Orange Book. The case was heard in the Southern District of New York. The Court adopted much of the FTC's reasoning presented in FTC's amicus brief when it ruled against Bristol-Myers on February 14, 2002.²¹⁴ The case involved Bristol-Myers Squibb's motion to dismiss all of the claims raised by the various antitrust plaintiffs in the various antitrust actions that had been consolidated.

All of the complaints in the *In re Buspirone* motion to dismiss alleged that Bristol-Myers Squibb:

attempted to extend and/or extended an unlawful monopoly over the

²¹¹ The FTC has been extremely busy in recent years in monitoring competition in the pharmaceutical industry, and has scrutinized the activities of innovative and generic companies under the Hatch-Waxman Act. In a prepared statement, the Chairman of the FTC, Timothy Muris, described the FTC's activities in this area. See Timothy Muris, *Prepared Statement of the FTC Before the Committee on Commerce, Science, and Transportation*, <http://www.ftc.gov/os/2002/04/pharmtestimony.htm> (accessed Feb. 20, 2005) [hereinafter FTC Statement]. For example, the Chairman described the FTC's initial litigation activities as to these issues:

The Commission's first generation litigation focused on patent settlement agreements between brands and generics that the Commission alleged had delayed the entry of one or more generics. Resolving patent infringement litigation through settlement can be efficient and procompetitive. Certain patent settlements between brands and generics, however, drew the Commission's attention when it appeared that their terms may have maintained monopolies through abuses of the Hatch-Waxman regime.

Id. at § III.A.

²¹² 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

²¹³ See FTC Statement, *supra* n. 211, at § III.B.1.

²¹⁴ See generally *In re Buspirone*, 185 F. Supp. 2d 363; Fed. Trade Commn., *Memorandum of Law of Amicus Curiae the Federal Trade Commission in Opposition to Defendant's Motion to Dismiss*, <http://www.ftc.gov/os/2002/01/busparbrief.pdf> (accessed Feb. 20, 2005).

market in buspirone tablets in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, by abusing a number of provisions of the Hatch-Waxman Amendments . . . The antitrust plaintiffs argue that Bristol-Myers thereby prevented the FDA from approving generic buspirone products that competitors sought to market after the '763 Patent expired. The Complaints allege, in particular, that Bristol-Myers (i) listed a newly-obtained patent (the "'365 Patent") in [the Orange Book], on November 21, 2000, less than one day before the '763 Patent expired; (ii) fraudulently represented to the FDA in these listing submissions that the new '365 Patent covered uses of buspirone and that a reasonable claim of patent infringement could be asserted against generic producers of the drug, when Bristol-Myers knew these uses of buspirone clearly would be in the public domain after the '763 Patent expired; and then (iii) immediately brought patent infringement suits against generic competitors who were seeking to enter the buspirone market, thereby triggering an automatic stay of the FDA's approval of these generic products for up to thirty months under the Hatch-Waxman Amendments . . .²¹⁵

Bristol-Myers unsuccessfully moved to dismiss these claims on the basis that its listing activities amounted to lawful petitioning activities which it argued, pursuant to the Noerr-Pennington doctrine, were protected from antitrust scrutiny.²¹⁶

²¹⁵ *In re Buspirone*, 185 F. Supp. 2d at 363.

²¹⁶ *Id.* at 367-73. The Noerr-Pennington doctrine was articulated in *E. R.R. Press. Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). As explained by the court in *In re Buspirone*:

In *Noerr*, the Supreme Court held that "the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly."

...

However, the Supreme Court also carved out a limited exception to this rule for so-called "sham" petitioning.

...

In *Cal. Motor Transport Co. v. Trucking Unlimited*, 404 U.S. at 509, the Supreme Court clarified that the Noerr-Pennington doctrine extends to petitioning activity before "administrative agencies . . . and . . . courts." In this context, there is also a limited exception to Noerr-Pennington immunity for so-called "sham" litigation

...

Moreover, there are some circumstances in which there is an additional exception to Noerr-Pennington immunity for conduct in which a party knowingly and willfully makes false representations to the government. For example, in *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965) . . . the Supreme Court held that a party that had monopolized a market through threats of suit and through a subsequent patent infringement suit based on a patent that the party had obtained by making fraudulent representations to the Patent Office did not qualify for Noerr-Pennington immunity.

185 F. Supp. 2d at 368-69 (internal citations omitted).

The Court considered whether the Noerr-Pennington doctrine applied to Bristol-Myers'

Like the *Mylan* case, the patent listing issues raised in *Andrx* also were subjected to antitrust scrutiny. The FTC's "first enforcement action to remedy the effects of an allegedly anticompetitive Orange Book listing"²¹⁷ was in the dispute between *Andrx* and *Biovail* over *Biovail*'s allegedly improper listing of patents pertaining to *Tiazac* in the Orange Book. The FTC issued a complaint against *Biovail* for its allegedly anticompetitive conduct in this dispute in 2002, after the Federal Circuit issued its opinion in the dispute.²¹⁸ On April 23, 2002, the FTC announced that it had:

accepted for public comment an agreement and proposed consent order with *Biovail* Corporation settling charges that *Biovail* illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book for the purpose of blocking generic competition to its branded drug *Tiazac*. (Footnotes omitted.)²¹⁹

The FTC also prepared an "Analysis to Aid Public Comment" describing the facts at issue and delineating the proposed terms of the consent agreement between the FTC and *Biovail*.²²⁰ The FTC's Complaint and Consent

conduct in listing the '365 patent, and rejected *Bristol-Myers*' argument that its conduct in listing the '365 patent was a request for governmental action (i.e., specifically a request for the FDA to publish patent information). *Id.* at 373-73. The Court found that the patent listings are required by law and do not reflect any exercise of discretion on the part of the FDA as to evaluating the accuracy or correctness of the patent listings. In this way, the Court felt that they were akin to tariff filings that were required of AT&T in the Federal Communications Commission which similarly were held not to constitute "petitioning" activity for *Noerr-Pennington* purposes. *Id.* at 369-73. Consequently, the Court found that the *Noerr-Pennington* doctrine did not apply to *Bristol-Myers*' actions.

Moreover, the Court found that, even if the *Noerr-Pennington* doctrine were to apply, the plaintiffs had pleaded sufficient facts to warrant applying an exception to immunity based on a *Walker Process* line of reasoning. According to the Court, there was a parallel between fraud on the Patent Office, and fraudulent Orange Book patent listings "[b]ecause a private party can effectively extend a patent monopoly by listing a patent in the Orange Book and then filing suit against generic competitors in that context." *Id.* at 373. Additionally, the Court found that *Bristol-Myers*' conduct was such that an exception applied to any immunity from antitrust liability available from the *Noerr-Pennington* doctrine. *Id.*

²¹⁷ FTC Statement, *supra* n. 211, at § III.B.2.

²¹⁸ Fed. Trade Comm., *In the Matter of Biovail Corp.: Complaint*, <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm> (accessed Feb. 20, 2005) [hereinafter *FTC Complaint*].

²¹⁹ FTC Statement, *supra* n. 211, at § III.B.2.

²²⁰ 67 Fed. Reg. 21248 (Apr. 30, 2002) [hereinafter *Complaint Analysis*]. The *Complaint Analysis* specifically noted that "[t]he proposed consent order has been entered into for settlement purposes only and does not constitute an admission by *Biovail* Corporation that it violated the law or that the facts alleged in the complaint, other than the

Agreement with Biovail was summarized by the FTC as follows:

According to the Commission's complaint, Biovail knew that the new patent did not claim the form of Tiazac that it had been marketing, and Biovail did not need this new patent to continue marketing Tiazac without infringement risk. In fact, the FDA later learned that Biovail's position was that the newly listed patent covered a new formulation of Tiazac that Biovail had developed only after it acquired and listed the patent. The newly listed patent did not cover the version of Tiazac that the FDA had approved and that Biovail had been marketing. FDA told Biovail that the new Tiazac formulation therefore lacked FDA approval and that it would de-list the patent from the Orange Book unless Biovail certified that the patent claimed the approved version of Tiazac.

The Commission alleges that Biovail misleadingly represented to the FDA that the new patent claimed existing-and-approved, rather than revised-and-unapproved, Tiazac, to avoid de-listing from the Orange Book and termination of the stay against Andrx. The Commission alleges that Biovail's patent acquisition, wrongful Orange Book listing, and misleading conduct before the FDA were acts in unlawful maintenance of its Tiazac monopoly, in violation of Section 5 of the FTC Act, and that the acquisition also violated Section 7 of the Clayton Act and Section 5 of the FTC Act.

The proposed consent order would require Biovail to divest the illegally acquired patent to its original owner, except as to new product developments outside the Tiazac market; to dismiss its infringement case against Andrx, which would end the stay, thereby allowing entry of generic Tiazac to the benefit of consumers; and to refrain from any action that would trigger another 30-month stay on generic Tiazac entry. Further, the order prohibits Biovail from unlawfully listing patents in the Orange Book and requires Biovail to give the Commission prior notice of acquisitions of patents that it will list in the Orange Book for Biovail's FDA-approved products.²²¹

2. *Unsuccessful Reform Efforts (S. Bill 812)*

In 2002, Congress considered reforms to the Hatch-Waxman Act to address some of the practices of innovative companies discussed in this paper, including listing multiple patents in the Orange Book, repeated 30-

jurisdictional facts, are true." *Id.*

²²¹ FTC Statement, *supra* n. 211, at § III.B.2 (internal citations omitted). This statement was with respect to the proposed Consent Agreement. Following a public comment period, however, the FTC approved the issuance of a final consent order in this matter. *See generally In the Matter of Biovail Corp.*, 2002 FTC LEXIS 56 (F. Trade Commn. 2002) (available at <http://www.ftc.gov/os/2002/10/biovaildo.pdf> (accessed Feb. 20, 2005)). The consent order was modified only slightly from the proposed consent order as to timing of the relevant asset divestment that the FTC required of Biovail. *See generally* Fed. Trade Commn., *Commn. Approval of Modified Final Consent Order*, <http://www.ftc.gov/opa/2002/10/fyi0253.htm> (accessed Feb. 20, 2005).

month stays on generic market entry, and manipulation of the 180-day exclusivity period for generic applicants.²²² Under a bill sponsored by Arizona Republican Sen. John McCain and New York Democrat Sen. Charles Schumer (i.e., S. 812), a pharmaceutical company would be limited to one 30-month stay for each patent filed on a brand-name drug within 30 days of its approval by the FDA.²²³ Furthermore, any patents filed after that period would not be eligible for the 30-month stay.²²⁴ On July 31, 2002, the McCain-Schumer bill passed in a Democratic-led Senate on a 78-21 vote.²²⁵ This was one day after the FTC Study was issued.²²⁶

The full name of this bill was the “Greater Access to Affordable Pharmaceuticals Act of 2002” [hereinafter S. 812 or GAAP].²²⁷ The bill was said to be designed to increase public access to affordable drugs by improving the competitive position of generic drug companies. The legislation endeavoured to achieve this goal by curtailing patent rights of innovative pharmaceutical companies.

Section 103 of the GAAP was entitled “Filing of Patent Information with the Food and Drug Administration.” In GAAP section 103(a)(2), the legislation discussed the type of patent information to be filed with regard to approved drugs. The GAAP indicated that only patents that “claim an approved method of using the drug” could be listed.²²⁸ This slight change in language would have narrowed the scope of method of use patents that might be listed. As discussed previously,²²⁹ the FDA’s pre-June 2003 patent listing rules were ambiguous on this point. Although the matter became somewhat

²²² See generally Sen. Rpt. 107-812 (May 1, 2001) [hereinafter S. 812 or GAAP].

²²³ See Janelle Carter, *Senate Panel OKs Generic Drug Bill*, Associated Press Online ¶ 7 (July 11, 2002); see also Laurie McGinley & Chris Adams, *Shot in the Arm: Generic Dugs Find Potent New Formula: Friends in Cong.*, Wall St. J. (N.Y.C.) A1 (July 29, 2002).

²²⁴ McGinley & Adams, *supra* n. 223, at A1.

²²⁵ See Joanne Kenen, *Senate Eases Generic Drug Rules*, Reuters (July 31, 2002); see also Robert Pear, *Senate Kills Plan for Drug Benefits Through Medicare*, N.Y. Times A1 (July 31, 2002).

²²⁶ 149 Cong. Rec. S8689-90 (daily ed. June 26, 2003).

²²⁷ This bill also contained provisions for drug importation from Canada. See S. 812 at Title II: Importation of Prescription Drugs § 201. Originally, the bill was tied with amendments seeking to add prescription drug coverage to Medicare; however, the Senate was unable to reach any consensus on the politically-delicate Medicare issue, and so this issue was removed from the legislation. See Pear, *supra* n. 220, at A1, A19.

²²⁸ GAAP, *supra* n. 222, at § 103(a)(2)(E)(i)(II)(bb).

²²⁹ See *supra* § III.1.B.

clearer after the *Warner-Lambert*²³⁰ decision was decided in January 2003, this was several months after the GAAP reform efforts were occurring in Congress. Consequently, when the GAAP was drafted, innovative companies could still reasonably take a broad interpretation of FDA's listing requirements and list method of use patents directed to unapproved uses. In both product and method of use patents, the GAAP also specified that it had to be possible to reasonably assert patent infringement against a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.²³¹

In addition to requiring the filing of the patent number and the expiration date of any relevant patent, as before, the legislation required that the following be filed:

- (iii) with respect to each claim of the patent –
 - (I) whether the patent claims the drug or claims a method of using the drug; and
 - (II) whether the claim covers –
 - (aa) a drug substance;
 - (bb) a drug formulation;
 - (cc) a drug composition; or
 - (dd) a method of use;
- (iv) if the patent claims a method of use, the approved use covered by the claim;
- (v) the identity of the owner of the patent (including the identity of any agent of the patent owner); and
- (vi) a declaration that the applicant, as of the date of the filing, has provided complete and accurate patent information for all patents described in subparagraph (A) [i.e., that satisfy the two-part test for patent listing that we have considered earlier].²³²

The GAAP also introduced in section 103(a)(2)(D) an obligation on the FDA to publish the information discussed above. By requiring that the approved drug holder publicly characterize the patent on a claim-by-claim basis and provide a declaration, lawmakers probably thought that the public would be provided greater assurance that patents listed in the Orange Book were being appropriately listed. This scheme, however, would have been rather unfair for innovative companies who would have been forced by the legislation to publicly construe their patent claims in a vacuum, namely, outside of the scope of a patent infringement or declaratory judgment case.

²³⁰ *Warner-Lambert*, 316 F.3d at 1348; see also *supra* § III.

²³¹ GAAP, *supra* n. 222, at § 103(a)(2)(A)(ii).

²³² *Id.* at § 103(a)(2)(C).

At the same time, generic companies would have had to file claim-by-claim certifications for listed patents that claimed both a drug and a method of using a drug, or more than one method of using a drug.²³³

The GAAP also created a civil action for correcting or deleting patent information provided in FDA patent listings in section 103(a)(2)(E). Essentially, this provision would have allowed a generic company to seek an order requiring that the holder of an approved drug either correct patent information that it filed, or delete patent information in its entirety on the basis that the patent did not claim the drug for which the application was approved, or an approved method of using the drug.²³⁴ This section would have provided an answer to the problems created by *Mylan* and *Andrx* for companies, namely generics, seeking to challenge Orange Book patent listings.

One of the most controversial aspects of GAAP was in sections 103(a)(2)(F) and 103(a)(2)(A),²³⁵ which provided that innovative companies that failed to file the patent listing information required by the bill for future and also all prior patent filings would have been “barred from bringing a civil action for infringement of the patent” against an ANDA applicant or a paper-NDA applicant (i.e., a generic company) either at the application stage or thereafter during the manufacturing and selling stage of the generic drug. Similarly, GAAP sections 104(a)(2) and 104(b)(2) provided that, if a patent notice was provided to a patent owner and the patent owner failed to launch a patent infringement suit within forty-five (45) days of receiving the notice, the patent owner would have been barred thereafter from bringing such a lawsuit. These provisions could have extinguished innovative company’s patent rights just for failing to file patent information or launch a patent suit within the requisite time period.

The GAAP also amended the Hatch-Waxman Act in such a way as to ensure that an approved drug holder could only obtain one automatic 30-month stay to protect it from generic drug entry. Section 104 of the legislation did this by creating two types of patents being listed, namely, those listed within thirty days of the drug to which they relate being approved, and those listed thereafter but within thirty days of having issued.²³⁶ Only the formerly noted patents could be relied upon to trigger a 30-month stay. Since all of these patents were listed at the same time, a

²³³ See generally *id.* at § 103(b).

²³⁴ *Id.* at § 103(a)(2)(E).

²³⁵ There appears to be a typo in GAPP since § 103(a)(2)(A) in the context discussed above probably should be § 103(a)(3)(a).

²³⁶ Compare *id.* at § 103(a)(2)(A) with *id.* at §§ 103(a)(2)(B), 104(a)(1)(A)(ii).

generic drug maker filing an ANDA presumably would certify its position as to each of these patents at the same time, and the approved drug holder would have to launch any desired infringement actions against the generic drug maker for any listed patents subject to a paragraph IV certifications within the same time frame. This, in turn, suggests that only one 30-month stay would be available (since the stays would all run concurrently if more than one paragraph IV certification were made). As to subsequently-listed patents, an approved drug holder was entitled to sue the generic drug company for infringement, but had to file a motion to preliminarily enjoin the generic drug company from engaging in the commercial manufacture or sale of the drug within forty-five days of the generic drug company's notice.²³⁷

Finally, GAAP section 105 addressed the question of the 180-day patent exclusivity provision for first generic company entrants. In particular, it introduced a scheme by which the first generic company entrant could forfeit its entitlement to the 180-day patent exclusivity period if a forfeiture event occurred. Section 105(a)(2) introduced the definition of a "forfeiture event." Such an event included a failure on the part of the generic company to market within a prescribed period of time, a failure to obtain approval for its ANDA or a withdrawal of the application, and conduct deemed by the FTC to be unlawful. In addition, the 180-day exclusivity period would only apply if a patent infringement action was brought relating to the patent to which the first generic entrant provided a paragraph IV certification. Moreover, the forfeiture scheme contemplated that, if the first generic entrant forfeited its 180-day right of exclusivity, it would pass to subsequent generic entrants. Consequently, it was a "rolling exclusivity" provision.²³⁸

The Council for the American Bar Association (ABA) Section of Intellectual Property Law adopted four resolutions expressing opposition to provisions of GAAP that would curtail patent protection.²³⁹ For example, the ABA opposed the provisions "that . . . preclude enforcement of patents for failure to comply with administrative reporting requirements and for failure to bring an enforcement action within an administratively defined time period following filing of a generic application."²⁴⁰ The ABA also opposed

²³⁷ *Id.* at § 104(a)(1)(C)(iv)(1).

²³⁸ *Id.* at §105(a)(2)(D)(ii)(I). The characterization of this exclusivity provision as a "rolling exclusivity" provision was made, for example, by Senator Hatch. See *infra* n. 319 and accompanying text.

²³⁹ Hayden W. Gregory, *Hatch-Waxman Act Amendments Would Restrict Patent Rights*, ABA Sec. of Intell. Prop. Law Chair's Bull. 2 (Sept. 2002), <http://www.abanet.org/intelprop/sep02chair.html> (accessed Feb. 20, 2005).

²⁴⁰ *Id.*

the “provisions that would curtail the right of a patent holder to a 30-month stay of FDA action in generic drug applications that are the subject of patent infringement suits.”²⁴¹ The American Intellectual Property Law Association (AIPLA), the biotech industry, and the U.S. Patent and Trademark Office also opposed the Bill for going way beyond what was necessary to curb anti-competitive activity within the Hatch-Waxman regime.²⁴²

Although it is usually the Judiciary Committee that has jurisdiction over patent matters, S. 812 was neither acted on by nor even referred to this congressional committee.²⁴³ After Senate passage, the bill moved to the U.S. House of Representatives.²⁴⁴ The House version of the bill was H.R. 1862.²⁴⁵ This version of the bill was referred to the Subcommittee on Health.²⁴⁶ The bill died in Congress thereafter.²⁴⁷

V. REFORMING ORANGE BOOK PRACTICES AND THE HATCH-WAXMAN ACT

We are now in a position to scrutinize the recent, regulatory and legislative reform efforts that have transformed both Orange Book patent listings and the other aspects of the Hatch-Waxman Act that we have been considering, namely, the automatic 30-month stay provisions and the 180-day exclusivity periods. In reviewing these reforms, it will become apparent that they are directed to amending details in the regulations and legislation forming the Hatch-Waxman scheme. It is important not to discount a consideration of such detailed amendments as being too technical and thus not important from either an academic or a practical perspective. On the contrary, the minor tweaking around the edges of a legislative and regulatory scheme can, in fact, have a major impact on the group or groups being

²⁴¹ *Id.*

²⁴² 149 Cong. Rec. at S8690.

²⁴³ Gregory, *supra* n. 239, at 2-3.

²⁴⁴ *Id.*

²⁴⁵ Even if this bill were to pass in the House, if there are any differences between both versions of the bill, it would be necessary to have the legislation go to a Standing Committee to resolve the differences. If this committee is successful and the House and Senate both vote in favor of the bill becoming law, the President still needs to approve the bill.

²⁴⁶ See Bill Summary and Status for the 107th Congress <http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR01862:@@L&summ2=m&> (summary of H.R. 1862) (accessed Feb. 20, 2005).

²⁴⁷ *Id.*

regulated. This is particularly the case in the pharmaceutical industry. The phenomenon arises because of the costly nature of drug development²⁴⁸ and drug purchases, as well as the fierce competition that arises once generic companies enter into the market for a particular drug.²⁴⁹ Thus, whether an innovative company or a first generic company entrant has market exclusivity over a drug for an additional month can have a tremendous impact to the revenue stream of each company and, of course, will have a substantial impact on the cost of pharmaceuticals to consumers.²⁵⁰

1. *New FDA Patent Listing Regulations*

In a likely attempt to counteract the activities of the Democratically-led Senate to the passage of GAAP, President Bush proposed new FDA regulations²⁵¹ shortly thereafter that would do some of the same things that the GAAP was intended to do. The President indicated that the new FDA rule would implement FTC recommendations for improving access to generic drugs.²⁵² Like the GAAP, the White House proposal would grant innovative drug companies one 30-month stay only for each drug manufactured, and would tighten patent listing requirements.²⁵³ The

²⁴⁸ For example, a 1998 Congressional Budget Office study found that drug development takes 11-12 years on average and costs about \$200 million per successful product (in 1990 dollars). See Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, 14 (July 1998) (This document is said to be available at <http://www.cbo.gov>; it looks like Anna Cook wrote the study on behalf of the CBO.) [hereinafter CBO Study]; see also Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 *Fordham Intell. Prop. Media & Ent. L.J.* 185, 209 (1999) (quoting a Boston Consulting Group study which places the costs of developing a drug in 1990 at \$500 million (1993 dollars) before taxes. More recent figures quote the cost of the drug development at \$802 million).

²⁴⁹ CBO Study, *supra* n. 248, at 28 (indicating that during the first full calendar year in which 21 innovator drugs whose first generic competitors entered the market between 1991 and 1993, generic drugs already accounted for an average of 44 percent of prescriptions dispensed through pharmacies).

²⁵⁰ *Id.* (indicating that generic drugs cost one-fourth less than brand-name drugs).

²⁵¹ CNN, *Bush Proposes Rules to Boost Generic Drugs*, <http://archives.cnn.com/2002/ALLPOLITICS/10/21/bush.generic.drugs/index.html> (accessed Nov. 15, 2004).

²⁵² White House Press Release, *President Takes Action to Lower Prescription Drug Prices by Improving Access to Generic Drugs* (October 21, 2002), <http://www.whitehouse.gov/news/releases/2002/10/20021021-4.html> (accessed Feb. 20, 2005).

²⁵³ *Id.*

President provided the following details as to the tighter requirements and increased disclosures for drug patent listings:

Drug manufacturers would no longer be allowed to list patents in the FDA Orange Book for drug packaging, drug metabolites, and intermediate forms of a drug. Permitted listings [would] include patents on active ingredients, drug formulations, and uses of a drug. In addition, a more detailed signed attestation accompanying a patent submission [would] be required, and false statements in the attestation [could] lead to criminal charges. This [would] significantly reduce opportunities to list inappropriate patents just to prevent fair competition from generic drugs.²⁵⁴

Further to the President's announcements, on June 18, 2003, the FDA issued a Final Rule directed to these matters.²⁵⁵ In issuing these regulations, the FDA was motivated by the fact that prior FDA regulations led to multiple 30-month stays which delayed generic drug entry—a consequence not intended either by Congress or the FDA.²⁵⁶ In their comments to the Final Rule, the FDA described its contents as follows:

The final rule limits to one per ANDA or 505(b)(2) application the maximum number of statutory 30-month stays of approval to which an innovator will be entitled when it submits multiple patents for the same NDA. Eliminating multiple 30-month stays will speed up the approval and market entry of generic drugs. The final rule also clarifies patent submission and listing requirements, which will reduce confusion and help curb attempts to take advantage of this process. Specifically, patents claiming packaging, intermediates, or metabolites must not be submitted for listing. Patents claiming a different polymorphic form of the active ingredient described in the NDA must be submitted if the NDA holder has test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA.²⁵⁷

Consequently, the FDA's listing regulations, which are now in force, clarify much of the confusion that existed under the old patent listing rules. Yet the FDA declined the invitation to create an administrative process for delisting patents, indicating that the agency had a purely "ministerial" role as to patent listing issues.²⁵⁸

It is important to recognize that the new patent listing rules are prospective and apply only to patents listed after August 18, 2003, the date

²⁵⁴ *Id.*

²⁵⁵ *See generally* 68 Fed. Reg. 36676 (June 18, 2003) (the effective date of this Final Rule is August 18, 2002, and the compliance date for the submission of information on polymorph patents is December 18, 2003. The proposed rule had been published at 67 Fed. Reg. 65448 (Oct. 24, 2002)).

²⁵⁶ *Id.* at 36694.

²⁵⁷ *Id.* at 36676.

²⁵⁸ *Id.* at 36683.

on which these new rules came into force.²⁵⁹ This means that the old patent listing rules that were discussed earlier in Part III, Section 1.(B) are still applicable to any patents listed prior to August 18, 2003 and so are still relevant today to all stakeholders in the pharmaceutical drug industry and cannot be discarded. NDA applicants can, however, voluntarily subscribe to the new patent listing rules by submitting patent information previously provided prior to August 18, 2003 after that time on a form that has been created by the FDA for patent listing submission under the new rules.²⁶⁰ These forms are discussed later. Generally though, NDA applicants/holders will favor the old rules that allow for broader patent listings, for reasons soon to become apparent.

21 C.F.R. § 314.53(b), as set forth at the beginning of this article and discussed in Part III, Section 1(B) of this article, is no longer in force. Now, a much longer version of this provision is in effect:

(b) Patents for which information must be submitted and patents for which information must not be submitted – (1) General requirements. An applicant described in paragraph (a) of this section shall submit the required information on the declaration form set forth in paragraph (c) of this section for each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes of this part, such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents. For patents that claim the drug substance, the applicant shall submit information only on those patents that claim the drug substance that is the subject of the pending or approved application or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending application. For patents that claim a polymorph that is the same as the active ingredient described in the approved or pending application, the applicant shall certify in the declaration forms that the applicant has test data, as set forth in paragraph (b)(2) of this section, demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the new drug application. For patents that claim a drug product, the applicant shall submit information only on those patents that claim a drug product, as is defined in § 314.3, that is described in the pending or approved application. For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use that are described in the pending or approved application. The applicant shall separately identify each pending or approved method of use and related patent claim. For approved applications, the applicant submitting the method-of-use patent shall identify with specificity the section of the approved labeling that corresponds to the method of use claimed by the patent submitted.

²⁵⁹ *Id.* at 36696.

²⁶⁰ *Id.*

Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this section, and information on these patents must not be submitted to [the] FDA.²⁶¹

Therefore, section 314.53(b)(1), as set forth above, provides the new general requirements for patent listing. As before, the FDA requires that patents directed to the drug substance (i.e., active ingredient), and drug product (i.e., formulation and composition), as well as method of use patents, should be submitted for listing in the Orange Book.²⁶² The language of the new listing rule, however, prohibits listing process patents (as before), as well as patents claiming packaging, metabolites and intermediates, thereby resolving much previous uncertainty.²⁶³

Also, this provision clarifies what type of method of use patents might be listed. Whereas the old rule provided that “[f]or patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use *of a pending or approved application*,”²⁶⁴ the new rule has replaced the italicized phrase with the words “*that are described in the pending or approved application*,” as seen above.²⁶⁵ Consequently, now there is no ambiguity on the point—only method of use patents directed to approved uses are to be listed. Drug substance and drug product patents are subject to essentially the same limiting language.²⁶⁶

In section 314.53(b)(1), however, there appears to be some ambiguity in the description of the drug substance patents that must be listed since such patents include not only “patents that claim the drug substance that is the subject of the pending or approved application” but also patents “that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending application.”²⁶⁷ This ambiguity is resolved if one assumes that the latter category of patents pertains to patents that “claim a polymorph that is the same as the active ingredient described in the approved or pending application.”²⁶⁸ In fact, in their comments accompanying the Final Rule, the FDA explains that “[d]rug substances that

²⁶¹ 21 C.F.R. § 314.53(b)(1) (2004).

²⁶² *Id.*; 68 Fed. Reg. at 36678.

²⁶³ 68 Fed. Reg. at 36677-78.

²⁶⁴ 21 C.F.R. § 314.53(b)(1) (2002) (prior to this regulation’s amendment in June 2003) (emphasis added).

²⁶⁵ 21 C.F.R. § 314.53(b)(1) (2004) (emphasis added).

²⁶⁶ *Id.*

²⁶⁷ *Id.*

²⁶⁸ *Id.*

are the same active ingredient, but that are in different physical forms, are often called ‘polymorphs.’”²⁶⁹ For example, polymorphs include chemicals having different crystalline forms, waters of hydration, solvates, and amorphous forms.²⁷⁰ The FDA stresses that its interpretation of “sameness” does not involve a patent law analysis.²⁷¹ Essentially, the test to determine whether the drug substance is the “same” as the active ingredient in the NDA is “whether the drug substances can be expected to perform the same with respect to such characteristics as dissolution, solubility, and bioavailability.”²⁷² Consequently, to list polymorph patents, 21 C.F.R. section 314.53(b)(1) indicates that the applicant must certify that it has test data “demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the new drug application.” 21 C.F.R. section 314.53(b)(2) provides information regarding test data to be provided to establish that a polymorph patent should be listed in the Orange Book.

The patent listing rules also added 21 C.F.R. §§ 314.52(a)(3) and 314.95(a)(3), based on a reinterpretation of its understanding of 30-month stays. Under such reinterpretation, generic drug applicants (i.e., ANDA and 505(b)(2) applicants) would continue to file appropriate certifications but would only be required to provide notice to the NDA holder and patent holder when a paragraph IV certification was to be made in the original ANDA/505(b)(2) submission or when the submission were to be amended for the first time to include a paragraph IV certification. The FDA theory was that, if no notice had to be provided, there would be no triggering mechanism for the patent holder to obtain subsequent 30-month stays.²⁷³ Interestingly, in its comments to the Final Rule, the FDA addressed the double patenting scenario mentioned earlier in the context of the old patent listing rules,²⁷⁴ where numerous patents might issue relating to the same inventive subject matter but all subject to terminal disclaimers. As to this scenario, the FDA pointed out that, even if such patents are filed, there is still only one 30-month stay; therefore, such patents should not create an abuse problem under the new rules even if they are all listed.²⁷⁵

Moreover, new 21 C.F.R. § 314.53(c) sets forth the reporting

²⁶⁹ 68 Fed. Reg. at 36678.

²⁷⁰ *Id.*

²⁷¹ *Id.*

²⁷² *Id.* (citing 67 Fed. Reg. at 65452).

²⁷³ *Id.* at 36688.

²⁷⁴ *Id.* at 36678.

²⁷⁵ *Id.* at 36681.

requirements for patents to be listed in the Orange Book. Under the new rules, patent information required to be submitted is to be provided on declaration forms.²⁷⁶ Such forms are to be completed when submitting information to the FDA both with an NDA and after the NDA is approved.²⁷⁷ The forms to be used make any willful and knowingly false statements thereon a criminal offense, and essentially require that an innovative company characterize, *i.e.*, construe, its patents.²⁷⁸ In particular, the forms require a claim-by-claim characterization of method-of-use patents claiming approved methods of use.²⁷⁹ Like the provisions that existed in S. 812 requiring claim characterization, the patent and claim characterization requirements in these forms are problematic for innovative companies since they require that such characterization be done in a vacuum and in advance of an invalidity or infringement challenge, which could potentially create estoppels for such companies.

Another feature of these forms is that they are set up to require mostly “yes” or “no” answers from NDA applicants/holders. This makes it easy for FDA personnel who, without knowing anything of the science pertaining to the drug, can easily characterize a patent as being listable or not by applying a simple algorithm (e.g., if the answers to 2.1 and 2.2 are no then do not list the patent).²⁸⁰ These algorithms are set forth right on the forms. This really puts NDA applicants in a straightjacket that can be unfair, particularly if the question eliciting a “yes” or “no” answer has been poorly phrased and thus its meaning is unclear. For example, question 2.2 may be unclear on the forms. That question states essentially: “Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the NDA?”²⁸¹ It would have been better to remove the term “different” since this term is not found in the regulatory language and, in fact, is somewhat contrary to that language which requires that the polymorph be the “same as the active ingredient”²⁸² to qualify a patent for listing in the Orange Book.

As we shall see in the next section, the FDA regulatory provisions

²⁷⁶ 21 C.F.R. § 314.53(c) (2004).

²⁷⁷ 68 Fed. Reg. at 36677 (the two forms are FDA Form 3542 and 3542a).

²⁷⁸ *Id.* at 36686.

²⁷⁹ *Id.*

²⁸⁰ See Food and Drug Administration, Form 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, 2 (July 2003).

²⁸¹ *Id.*; see also Food and Drug Administration, Form 3542a, *Patent Information Submitted with the Filing of an NDA, Amendment or Supplement* (July 2003).

²⁸² 21 C.F.R. § 314.53(b) (2004).

pertaining to 30-month stays have been overridden by a new 30-month stay provision introduced in the Medicare Reform Legislation, which uses a different mechanism to ensure that innovative companies can only obtain one 30-month stay, but still requires that notice be provided whenever a paragraph IV certification is made.²⁸³ Consequently, this aspect of the FDA regulations is no longer the “law of the land” when it comes to the application of 30-month stays.²⁸⁴ The rules set forth for patent listing, however, are still effective and no doubt will constrain the number of patents that can be listed in the Orange Book.

The rules also create a more level playing field for NDA applicants by clarifying what patents might be listed. Given that a narrower pool of patents will be appropriate for listing, there may be less incentive for innovative companies to file improvement patents relating to their original patents on a drug substance, drug product, or method-of-using such drug, often referred to as “evergreen patents”.

In all likelihood, however, legitimate improvement patents likely still will be sought since the Hatch-Waxman Act does not extinguish patent rights that an innovative company would otherwise have available to it to enforce its patents. Consequently, even if the innovative company will not be able to enforce such improvement patents within the context of the Hatch-Waxman Act, infringement of such patents could nonetheless still be pursued via regular channels for patent infringement, for example, based on 35 U.S.C. § 271(a) or (c).²⁸⁵

Yet, this discussion raises the interesting question, namely, what

²⁸³ See *infra* nn. 363-66 and accompanying text. See also U.S. Department of Health and Human Services—Food and Drug Administration—Center for Drug Evaluation and Research (CDER), *Draft Guidance for Industry—Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers*, 7 (Oct. 2004).

²⁸⁴ In fact, this aspect of the FDA regulations has been revoked. See 69 Fed. Reg. 11309, 11310 (Mar. 10, 2004).

²⁸⁵ That traditional patent infringement analysis was kept intact following passage of the Hatch-Waxman legislation is apparent from the legislative history. For example, the following was stated in the legislative history: “The provisions of this bill relating to the litigation of disputes involving patent validity and infringement are not intended to modify existing patent law with respect to the burden of proof and the nature of the proof to be considered by the courts in determining whether a patent is valid or infringed.” H.R. Rpt. 98-857 at 28 (June 24, 1984). That this is the case is also apparent from Judge Lourie’s comments in *Warner-Lambert*, in which he noted that although an inducement to infringe argument was not presently available in the context of an infringement analysis pursuant to 35 U.S.C. § 271(e)(2), it might, in theory, be available against a generic company at a later date. 316 F.3d at 1364-65.

remedies might be available to a patentee seeking to prevent patent infringement by a third party (e.g., a generic) of a patent that should have been listed in the Orange Book but was not? Although Hatch-Waxman-type benefits/remedies are unlikely to be available, the legislative history referred to above suggests that non-Hatch-Waxman patent remedies should still be available. An argument, however, might be made that, just as over-listing patents could lead to anticompetitive concerns, under-listing patents may do the same. In the latter case, the allegations might be that, instead of providing proper notice of a patent through Orange Book listing, the patent was sprung upon the generic without notice once it began selling the allegedly infringing product to impart maximum damage to it and perhaps permanently drive it out of competition. Whether such an argument is persuasive would depend very much on the facts underlying the dispute.

There remains one question to ponder when evaluating the amount of evergreen (i.e., improvement) patenting that might be expected in the post-reform Hatch-Waxman universe, namely, the impact that the *Schering Corporation v. Geneva Pharmaceuticals*²⁸⁶ decision might have on such practices of innovative pharmaceutical companies. This is a particularly interesting issue to consider in the context of FDA's new listing regulations preventing the listing of patents directed to metabolites, intermediates and packaging. In *Schering*, the Federal Circuit affirmed the District Court's decision finding that a patent to a prodrug, namely to the drug that is actually administered to a patient, inherently anticipates a patent to the metabolite that is produced from the prodrug in the body.²⁸⁷ Judge Rader reasoned as follows:

Patent law . . . establishes that a prior art reference which expressly or inherently contains each and every limitation of the claimed subject matter anticipates and invalidates . . . In . . . prior cases, however, inherency was only necessary to supply a single missing limitation that was not expressly disclosed in the prior art. This case, as explained before, asks this court to find anticipation when the entire structure of the claimed subject matter is inherent in the prior art.

Because inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter. The extent of the inherent disclosure does not limit its anticipatory effect. In general, a limitation or the entire invention is inherent and in the public domain if it is the "natural result flowing from" the explicit disclosure of the prior art.

This court sees no reason to modify the general rule for inherent anticipation in a case where inherency supplies the entire anticipatory

²⁸⁶ *Schering I*, 339 F.3d at 1373.

²⁸⁷ *Id.* at 1377.

subject matter.²⁸⁸

In a dissent to Schering's petition to rehear the matter *en banc*, Judge Lourie noted that the *Schering* decision "effectively [precludes] virtually all patents on human metabolites of drugs."²⁸⁹ Judge Rader, however, does point out that patent claims "to a pure and isolated form" of a metabolite, to "a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier)" or to "a method of administering the metabolite or the corresponding pharmaceutical composition" would all be patentable.²⁹⁰

What impact might the *Schering* decision have on innovative companies' practices of evergreening patents? Although the decision will prevent patenting of metabolites themselves in certain circumstances, as Judge Rader suggests, other types of metabolite claims will still be patentable despite the *Schering* decision. Consequently, to the extent that patenting a metabolite might be construed as evergreening, such incentives will be dampened but not eliminated. As to evergreening by obtaining patents on improvements related to packaging or intermediates, the *Schering* decision will affect such future patenting only to the extent to which an existing patent or patents on the original drug might be found to inherently anticipate such improvements. Incentives to obtain improvement patents with respect to metabolites, packaging or intermediates may, however, be further reduced given that such patents cannot be listed in the Orange Book.

2. The Medicare Reform Legislation

As mentioned at the very beginning of this article and unbeknownst to many, the legislative fix to the Hatch-Waxman strategic behavior problem occurred within the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("the Medicare Reform Legislation.")²⁹¹ This "landmark legislation" was enacted by Congress on November 25, 2003, and was signed into law by President Bush on December 8, 2003.²⁹² Although the

²⁸⁸ *Id.* at 1379.

²⁸⁹ *Schering Corp. v. Apotex, Inc.*, 348 F.3d 992, 995 (Fed. Cir. 2003) (dissenting, J. Newman) [hereinafter *Schering II*].

²⁹⁰ *Schering I*, 339 F.3d at 1381.

²⁹¹ H.R. Res. 1, 108th Cong. (2003) (enacted).

²⁹² Amy Goldstein and Helen Dewar, *Medicare Bill Headed to Bush—Senate Vote Clears Way for Drug Benefit, Competition*, *The Washington Post* A1 (Nov. 26, 2003) (available at <http://www.washingtonpost.com>) (accessed Dec. 3, 2003).

media focus was on the Medicare prescription drug benefit,²⁹³ the Medicare Reform Legislation made important changes to the Hatch-Waxman regime. In this section, we first review the legislative history pertaining to the Hatch-Waxman amendments in the Medicare Reform Legislation. Secondly, we examine the actual amendments that have been made and evaluate whether they are likely to bring an end to the strategic behavior that had been occurring previously pursuant to the original Hatch-Waxman scheme.

A. Legislative History Pertaining to Hatch-Waxman Amendments in the Medicare Reform Legislation

The pertinent legislative history for the Hatch-Waxman amending provisions of the Medicare Reform Legislation has its roots in previously-discussed S. 812, which passed in the Senate but died in the House of Representatives in the 107th Congress in 2002.²⁹⁴ As discussed earlier, one of the main reasons for the Bill's demise was that it contained some rather draconian provisions that were highly prejudicial to pharmaceutical patent rights.

Thereafter, in the 108th Congress, efforts to amend the Hatch-Waxman regime began afresh. For example, on June 17, 2003, the Senate Judiciary Committee held a hearing entitled "Legislative and Regulatory Response to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace."²⁹⁵ In addition, a Senate Bill, S. 1225, was introduced that contained improvements over S. 812. Another bill, S. 54 was also introduced in January 2003 containing various amendments to Hatch-Waxman.

All of these bills, however, were abandoned in favor of adding the Hatch-Waxman Amendments previously found in S. 1225 to S.1, the Prescription Drug and Medicare Improvements Act.²⁹⁶ This amendment to S. 1 was sponsored by Senators Gregg and Schumer. Meanwhile, a parallel Bill

²⁹³ See e.g. *id.*; see also Edward Walsh and Bill Brubaker, *Drug Benefit's Impact Detailed—Many Will Face Big Out-of-Pocket Costs*, The Washington Post A10 (Nov. 26, 2003) (available at <http://www.washingtonpost.com>) (accessed Dec. 3, 2003).

²⁹⁴ See *supra* § IV.2.

²⁹⁵ Sen. Jud. Comm., *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace*, 108th Cong. (June 17, 2003) (during this hearing, Senators Hatch and Leahy provided statements and various witnesses, including the Chairman of the FTC, Timothy Muris, Chief Counsel of the FDA, Dan Troy, Esq., and representatives again of both the generic and innovative pharmaceutical industries, provided testimony).

²⁹⁶ 149 Cong. Rec. S8195 (daily ed. June 19, 2003).

in the House of Representatives, namely, H.R. 1, the Medicare Prescription Drug and Modernization Act was being considered.²⁹⁷ As the name of each bill suggests, both S. 1 and H.R. 1 were directed to Medicare program amendments. In addition, each of these bills contained amendments to the Hatch-Waxman regime. In H.R. 1, however, the Hatch-Waxman amendments were in Title XI (as in the finally issued law), whereas in S. 1, these amendments were in Title VII.²⁹⁸ Shortly after the June 17, 2003 hearing of the Senate Judiciary Committee, both the House of Representatives and the Senate passed, respectively, H.R. 1 and S. 1 on June 26, 2003.²⁹⁹ The proposed Hatch-Waxman provisions in each of these bills appear to have been quite similar to one another and also to the ultimate amendments that became law in December 2003 and included: requiring a more detailed statement to accompany a paragraph IV certification; permitting only one 30-month stay; introducing a declaratory judgment action that a generic company might commence if the innovative company does not file an infringement action within forty-five days; permitting an Orange Book patent delisting counterclaim to a paragraph IV infringement lawsuit; providing for forfeiture events to the 180-day exclusivity period for the first ANDA applicant; and requiring agreements between innovative and generic companies regarding the sale or manufacture of a generic drug to be submitted to the FTC and the Assistant Attorney General for review within 10 days of completion.³⁰⁰

Thereafter, on July 7, 2003, the Senate considered and passed H.R. 1, struck out all of the material after the enacting text, and inserted in lieu thereof the text of S. 1.³⁰¹ As a result, the House disagreed with the Senate amendments to H.R. 1 and requested a conference on July 14, 2003.³⁰² A Senate Judiciary Committee Hearing was then held on August 1, 2003 to examine the differences between the House and Senate versions of the Medicare Reform Bill. At this hearing, in addition to statements having been provided by Senators Hatch and Leahy, testimony was provided by various

²⁹⁷ *Id.*

²⁹⁸ Compare 149 Cong. Rec. S8992 (daily ed. July 7, 2003) with 149 Cong. Rec. H12098 (daily ed. Nov. 20, 2003).

²⁹⁹ 149 Cong. Rec. S8695 (daily ed. June 26, 2003); 149 Cong. Rec. H6256 (daily ed. June 26, 2003).

³⁰⁰ Wendy H. Schacht & John R. Thomas, *Hatch-Waxman Related Provisions of the Medicare Prescription Drug Bills (H.R. 1 and S. 1): A Side-by-Side Comparison*, Congressional Research Service (Sept. 15, 2003) (available at <http://pennyhill.com>).

³⁰¹ 149 Cong. Rec. S8898-997 (daily ed. July 7, 2003).

³⁰² 149 Cong. Rec. H6658, H6681 (daily ed. July 14, 2003).

individuals including representatives from the FTC, PTO and FDA, DOJ and Eli Lilly, an innovative pharmaceutical company.³⁰³

After several months during which time the Medicare Reform Bill was in conference, a conference report emerged on November 21, 2003 containing a revised H.R. 1³⁰⁴ that was essentially approved by the House³⁰⁵ and then, after several days of debate, was approved by the Senate on November 25, 2003.³⁰⁶

Although H.R. 1 contained Hatch-Waxman-amending provisions even before the Bill went into Conference, it appears that members of the House were not aware of, knowledgeable about or particularly interested in these provisions, as evidenced by the lack of any substantial debate about these provisions in the House. In fact, in the Senate, it appears that only a handful of senators were well-versed with these provisions, namely, Senators Kennedy, McCain, Schumer, Gregg, Grassley, Frist and Hatch. This is not that surprising given that the Medicare Program amendments were clearly the more high-profile amendments that were of most direct concern to U.S. citizens. In contrast, although the Hatch-Waxman amendments will certainly affect U.S. citizens, the effect is substantially more indirect. Moreover, these provisions are densely written and require some expertise and analysis to understand. As a result, there was no media attention on the Hatch-Waxman amendments, but tremendous media attention on the Medicare Program amendments.

In the Senate, while considering S. 1 and certain amendments thereto, a number of interesting statements were made by various senators.³⁰⁷ While, as noted above, the provisions of H.R. 1 were essentially the ones that went forward and eventually became law, since the provisions of H.R. 1 bore similarity to S. 1 and since the House did not appear to consider the Hatch-Waxman provisions at any length, it is useful to consider some of the debate and comment surrounding S. 1. For example, Senator McCain described the purpose and intent of S. 1 as follows:

My intention in supporting this amendment is not to weaken patent laws to the detriment of the pharmaceutical industry, nor is it to impede the tremendous investments they make in the research and

³⁰³ Sen. Jud. Comm., *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act"*: Hearings on Sen. 1 and H.R. 1, 108th Cong. III (Aug. 1, 2003) (list of Witnesses and Submissions for the Record).

³⁰⁴ H.R. Rpt. 108-391 (Nov. 21, 2003).

³⁰⁵ H.R. Rpt. 108-394 (Nov. 21, 2003) (to accompany H.R. Res. 463, 108th Cong. (Nov. 21, 2003)).

³⁰⁶ 149 Cong. Rec. S15914, S15918, H12314 (daily ed. Nov. 25, 2003).

³⁰⁷ See 149 Cong. Rec. S8169-216, S8246-55 (daily ed. June 19, 2003).

development of new life-sustaining drugs. The purpose of the underlying legislation is to close loopholes in the Hatch-Waxman Act, which established the generic drug industry we know today, and to ensure more timely access to generic medications. This is an important distinction which must be made clear.

Nonetheless, to believe that patent laws are not being abused, is to ignore the mountain of testimony from consumers, industry analysts, and the Federal Trade Commission (FTC)

... The intent of the Hatch-Waxman Act was to address the escalating costs of prescription drugs by encouraging generic competition, while at the same time providing incentives for brand name drug companies to continue research and development into new and more advanced drugs. To a large extent, Hatch-Waxman has succeeded in striking that difficult balance between bringing new lower-cost alternatives to consumers, while encouraging more investment in U.S. pharmaceutical research and development in the pharmaceutical industry, which has increased exponentially. Unfortunately, however, some bad actors have manipulated the law in a manner that delays and, at times, prohibits generics from entering the marketplace.

I believe that this amendment will improve the current system while preserving the intent of Hatch-Waxman . . .³⁰⁸

Moreover, Senator Kennedy had the following comments regarding the underlying purpose of the Hatch-Waxman amendments in the Medicare Reform Bill:

We want to maintain on the one hand the incentives for the industry, the pharmaceutical industry to move ahead with breakthrough kinds of technologies. On the other hand, we want to make sure that available drugs in the form of generics will be accessible. This legislation is going to have an important impact in terms of the cost.³⁰⁹

Immediately after Senator Kennedy finished speaking, Senator Gregg offered the following remarks regarding the import and purpose of the Hatch-Waxman amendments in S. 1:

It is an important piece of legislation as has been outlined relative to the differential in cost. It will save people significant amounts of dollars on their pharmaceuticals, obviously, as they come off patent. It is important not to underestimate the innovation side. We didn't want to do something that basically undermines or chills innovation, because the ability of our health care system to function well today requires a pretty strong pharmaceutical industry. Pharmaceuticals are really the process by which we are going to be caring for people as we go into the future. That is where the true discoveries are occurring, especially in the biologics area

... In a free market society, dollars flow where there will be a return. If somebody is going to find that they invest in a drug and that drug research comes to fruition and they produce a drug and immediately

³⁰⁸ *Id.* at S8190.

³⁰⁹ *Id.* at S8192.

the drug is taken over or in too short of a time the drug's patent rights are taken over so there cannot be an adequate return on investment, people will not make the investment in trying to find a new drug. As a result, everyone will suffer. There will be few new and exciting drugs on the market that help people with health issues. So we have to have a strong and vibrant industry doing the research

... That being said, there is a time at which drugs need to come off patent. They have to be available at a lower price. They have to be available at a more reasonable price, the return having occurred on the original investment. What we saw, regrettably, under Hatch-Waxman, was [that] there were games being played This bill is an attempt to address those issues.³¹⁰

Senator Feingold also felt that the proposed Hatch-Waxman amendments in S. 1 would strike the right balance between innovation incentives and lowering drug costs.³¹¹ It is notable that, despite the enthusiasm for S. 1 as evidenced by the various statements provided above from June 19, 2003, Senator Hatch, sponsor of the original Hatch-Waxman legislation, did not support the bill at that time since he wanted to obtain more information on the impact of various amendments.³¹² Senator Frist also voiced some concerns about S. 1. Senator Frist, however, did indicate that S. 1 was an improvement over S. 812 from 2002, which, he felt, "went too far, way beyond the recommendations contained in the Federal Trade Commission's 2-year study."³¹³ Moreover, Senator Frist pointed out that "[t]he Hatch-Waxman law [had] almost 20 years of balance, and now [was] the time to go back and readjust and make sure that balance [was] well situated going forward."³¹⁴

Senator Frist's mention of the FTC Study, its mention by other senators, and FTC Chairman Muris' participation in various hearings regarding H.R. 1 and S. 1 reveal that the FTC Study is what truly provided the impetus and rationale for the Hatch-Waxman Amendments that ultimately passed in the Medicare Reform Legislation on December 8, 2003. Senator Hatch noted that "[b]oth the [FTC] and the [FDA] played a constructive role in attempting to end several mechanisms by which some research-based and generic drug firms were attempting to game the system put in place by the 1984 and subsequent court decisions to avoid competition in the marketplace."³¹⁵

³¹⁰ *Id.* at S8193.

³¹¹ *Id.* at S8194.

³¹² *Id.* at S8195.

³¹³ *Id.* at S8197.

³¹⁴ *Id.*

³¹⁵ 149 Cong. Rec. S8686, S8689-90 (daily ed. June 26, 2003).

On June 26, 2003, Senator Hatch again voted against the Gregg-Schumer amendment to S. 1.³¹⁶ He did, however, speak favorably about the one 30-month stay rule and the rule requiring certain agreements between innovative and generic companies to be provided to the FTC, both of which were recommended in the FTC Study.³¹⁷ Senator Hatch then highlighted his reasons for not supporting S. 1 at the time.³¹⁸ First, while Senator Hatch favored the “use it or lose it” 180-day exclusivity period in S.1225/S.1 as opposed to the “rolling exclusivity” policy previously found in S. 812, he did not like the fact that the trigger for the 180-day exclusivity period in S. 1225/S.1 was based on the first to have filed an ANDA, rather than being based on the first to have successfully defended an infringement or invalidity action.³¹⁹ He would have preferred to legislate the successful defense requirement.³²⁰ Second, Senator Hatch expressed concern about the

³¹⁶ *Id.* at S8686.

³¹⁷ *Id.* at S8689-90

³¹⁸ *Id.* at S8691.

³¹⁹ *Id.*

³²⁰ The successful defense requirement had previously been read into the statutory language by the FDA but this interpretation was knocked down by the courts in the 1998 D.C. Circuit decision, *Mova v. Shalala*, 955 F. Supp. 128; *see also supra* § III.2 (discussing settlement agreements and the 180-day exclusivity period). Since that 1998 decision, the literal words of the original Hatch-Waxman statute were interpreted by the FDA to provide the 180-day exclusivity to the first-to-file the ANDA application.

The Senator provided several reasons for preferring the successful defense requirement. First, he described the problem of ANDA applicants parking limousines or putting up tents in the FDA parking lot just so that they could be the first ones to file their ANDA application. Second, he raised the hypothetical of “a non-first filing generic drug challenger [winning] a court decision on grounds of non-infringement” but, under the current version of S. 1225/S. 1, not being able to market its generic drug until 6 months after the first-filing ANDA applicant began marketing its generic drug. Clearly, this is disadvantageous to consumers. Third, he delineated the related problem of invalidity and non-infringement challenges being considered as being quantitatively the same in the context of the 180-day exclusivity period when, in fact, they would be best treated separately. To explain this problem, Senator Hatch pointed to the reasoning of Al Engelberg, an attorney who represents generic companies and who helped draft the original Hatch-Waxman Act back in 1984:

In cases involving an assertion of non-infringement, an adjudication in favor of one challenger is of no immediate benefit to any other challenger and does not lead to multi-source competition. Each case involving non-infringement is decided on the specific facts related to that challenger’s product and provides no direct benefit to any other challenger. In contrast, a judgment of patent invalidity or enforceability creates an estoppel against any subsequent attempt to enforce the patent against any party. The drafters of the 180-day exclusivity provision failed to consider this important distinction.

constitutionality of the declaratory judgment (DJ) provision introduced in the bill allowing a generic company to launch a DJ action if an innovative company did not end up suing within 45 days of a paragraph IV certification by a generic company.³²¹ This issue dominated much of the Congressional debate.

The constitutionality of the DJ provision was considered during the August 1, 2003 Senate Judiciary Committee Hearing during which the Senate and House versions of the Medicare Reform Bill were considered (i.e., S. 1 and H.R. 1).³²² At that hearing, FTC Chairman Timothy Muris expressed his view that, setting aside the constitutional issue, the DJ provision was a good provision since it “may help ensure that a federal court has subject matter jurisdiction to resolve the patent issues.”³²³ Beyond this, Chairman Muris noted at the August 1, 2003 hearing that he was pleased about a number of the other provisions in the S. 1 and H.R. 1 bills.³²⁴

The FTC Chairman, however, had some concerns about the potential effect that the forfeiture provisions on the 180-day exclusivity period might have on generic drug entry.³²⁵ Specifically, by making an appeals court decision (and not a district court decision as was the case under the original Hatch-Waxman scheme) as being a triggering event for having to market the generic drug, Chairman Muris was concerned that generic entry might be

149 Cong. Rec. S8692 (daily ed. June 26, 2003); see e.g. Alfred B. Engelberg, *Special Patent Provisions For Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 389 n. *, 391 (1999) (describing Mr. Engelberg’s role in drafting the original Hatch-Waxman legislation and arguing for deregulating in the area of Hatch-Waxman, rather than legislating further amendments to the Hatch-Waxman scheme to fix the problems that arose under the original Hatch-Waxman legislation).

³²¹ 149 Cong. Rec. S8691 (daily ed. June 26, 2003).

³²² Sen. Jud. Comm., *Examining the Senate and House Versions of the “Greater Access to Affordable Pharmaceuticals Act”*: Hearings on Sen. 1 and H.R. 1, 108th Cong. 2 (Aug. 1, 2003) (opening statement of Sen. Orrin Hatch) [hereinafter Hearings].

³²³ *Id.* at 114 (prepared statement of Timothy Muris).

³²⁴ For example, he supported provisions pertaining to termination of the 30-month stay in both versions of the Medicare Reform Bill clarifying that, if a district court finds the patent infringed, the FDA cannot approve the ANDA unless an appeals court overturns the district court’s decision. *Id.* He also liked that both bills provided for a new counterclaim to correct Orange Book patent listing information as well as requiring the filing of patent settlement agreements with the FTC, as recommended in the FTC Study. *Id.* As to the 180-day exclusivity provision, Chairman Muris liked the fact that the suggested changes would make the provision operate on a per-product basis rather than on a per-patent basis, and would allow multiple first applicants to share in the exclusivity period. *Id.* at 115.

³²⁵ *Id.* at 116.

slowed down.³²⁶ Moreover, Chairman Muris would want the amendment to clarify that a subsequent applicant's dismissal of a declaratory judgment action for lack of subject matter jurisdiction constitutes a triggering event for the 180-day exclusivity period for the first applicant.³²⁷ This, the Chairman said, might be important "if a subsequent generic applicant develops a clearly non-infringing product and the brand-name company does not sue the applicant for patent infringement."³²⁸

At the August 1, 2003 Judiciary Committee Hearing, a PTO representative, Jon Dudas,³²⁹ expressed concern over the automatic grounds for a declaratory judgment action that S. 1 would provide for an ANDA applicant that has not been sued by a patent-holding innovative drug company.³³⁰ Mr. Dudas was concerned that such a right could lead to "unnecessary harassment of patent owners"³³¹ because it would require the patent owner to bear "significant litigation costs" and would lead to patent uncertainty. He also disfavored the provision in S. 1 that would deny treble damages³³² (i.e., a damage award that is three times the assessed value) to a patentee that failed to list certain patents in the Orange Book because any penalty for non-listing should be limited to a denial of benefits accruing from such a listing. Perhaps in response to this testimony, the Medicare Reform Legislation, as enacted, does not contain such a provision pertaining to treble damages.³³³

Testimony of the Deputy Assistant Attorney General of the U.S. Department of Justice (DOJ), Sheldon Bradshaw, focused on the declaratory judgment provision in S. 1.³³⁴ Mr. Bradshaw unequivocally took the position that § 702(c) was unconstitutional as being inconsistent with the case or controversy requirement in Article III of the U.S. Constitution and thus

³²⁶ *Id.*

³²⁷ Chairman Muris likely had in mind here the *Teva v. FDA* decision that Senator Kennedy referred to later when commenting on the meaning of "final court decision" in the 180-day exclusivity provision provided in the Medicare Reform Legislation. 182 F.3d 1003 (D.C. Cir. 1999); *see also infra* nn. 349-52 and accompanying text.

³²⁸ Hearings, *supra* n. 322, at 117 (prepared statement of Timothy Muris).

³²⁹ Specifically, Jon Dudas held the position of Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office.

³³⁰ Hearings, *supra* n. 322, at 81 (prepared statement of Jon W. Dudas).

³³¹ *Id.*

³³² *Id.* at 82; 35 U.S.C. § 284 (2000).

³³³ *See* H.R. Res. 1, 108th Cong. (2003) (enacted).

³³⁴ Hearings, *supra* n. 322, at 67-71 (prepared statement of Sheldon Bradshaw).

should be deleted or revised. That is, he found that “Congress cannot expand the courts’ power to hear cases beyond what the Constitution itself provides.”³³⁵

Finally, it is worth considering some of the testimony of Mr. Robert Armitage, Vice President and General Counsel of Eli Lilly and Company, a leading innovative pharmaceutical company, before the Senate Judiciary Committee Hearing on August 1, 2003. Mr. Armitage explained that patent protection from basic patents on active ingredients and approved uses were critical to fueling innovative pharmaceutical companies’ innovation efforts and that the proposed S. 1 bill would destroy innovation incentives, and, would be costly to consumers.³³⁶ Mr. Armitage was highly critical of provisions in S. 1 that encouraged “entirely speculative patent challenges” by generic companies because such provisions would amount to an innovation disincentive.³³⁷ More specifically, it would force innovative companies to focus on drugs with the strongest patent protection rather than those medicines that might be most beneficial to society. Mr. Armitage also asked “that Congress add a provision to S. 1 stating that once all of the innovator’s basic patents have expired and a competing generic company has demonstrated that it does not infringe any of the remaining innovator patents, the 180-day exclusivity period will be forfeited.”³³⁸

To complete our consideration of the legislative history pertaining to the Hatch-Waxman amendments in the recently enacted Medicare Reform Legislation, we should consider debates about the provisions that actually survived the Conference, and subsequently got passed by both the House and Senate. As suggested earlier, the bulk of this debate occurred in the Senate. It is notable that the Conference Report was approved by the House on Friday, November 21, 2003.³³⁹ The Senate worked feverishly over the

³³⁵ *Id.* at 69-70.

³³⁶ *Id.* at 51-52 (prepared statement of Robert Armitage).

³³⁷ *Id.* at 51.

³³⁸ *Id.* at 52. This, Mr. Armitage argued, would reduce incentives to launch speculative challenges and would allow generic competition to begin more rapidly. *Id.* By introducing the changes proposed by S. 1 to 180-day exclusivity and to forfeiture of this exclusivity period, Mr. Armitage was concerned that the first-to-file 180-day exclusivity trigger instead of the “successful defense” trigger would lead to the speculative challenges since generic companies would essentially get certain 180-day monopoly periods. *Id.* at 57. Moreover, Mr. Armitage reminded the Judiciary Committee members that the FDA had implemented its rule pertaining to a “successful defense” requirement since Congress had intended that exclusivity period to be a time during which a generic company that had successfully challenged a patent could recoup its litigation costs. *Id.* at 55.

³³⁹ 149 Cong. Rec. H12172 (daily ed. Nov. 21, 2003).

following few days, namely, over the weekend and then Monday and Tuesday so that by Tuesday, November 25, 2003 the legislation was passed in the Senate.³⁴⁰

First, it is worthwhile to note Senator Hatch's words of support for the Medicare Reform Bill, as it was revised in the Conference and approved thereafter by the House.³⁴¹ The Senator, for example, was pleased that the constitutional deficiencies with the declaratory judgment provision were removed, noting "that the presence of the two factors referred to in the statute, the filing of an ANDA application with a Paragraph IV patent challenge certification and the absence of a suit filed by the patent-holding innovator firm, do not alone satisfy the reasonable apprehension test."³⁴²

Although Senator Schumer did not feel that he could support the totality of the Medicare Reform Bill, he was pleased with the Hatch-Waxman-amending provisions,³⁴³ which the reader will recall originated from an amendment sponsored by Senator Schumer himself and Senator Gregg. Senator Schumer was pleased with the single 30-month stay that would likely run concurrently with FDA approval of the generic application and minimize delay.³⁴⁴ He also was pleased with the declaratory judgment provision, the provision allowing for counterclaims for Orange Book patent delisting and the revamped 180-day exclusivity provision for generics.³⁴⁵

Senator Kennedy provided a few statements regarding the Hatch-Waxman amendments as well. He was very supportive of the declaratory judgment provision, since the right to bring a declaratory judgment action would help bring a generic company the certainty that it might need to proceed with launching a generic action.³⁴⁶ Senator Kennedy indicated that "[w]ith this new provision, generic-drug companies never will be denied access to a declaratory judgment action on the basis of pending or potential license negotiations, at least so long as the suit otherwise is constitutionally sufficient for presentation in an Article III court."³⁴⁷

³⁴⁰ 149 Cong. Rec. S15915 (daily ed. Nov. 25, 2003).

³⁴¹ See generally 149 Cong. Rec. S15564-69 (daily ed. Nov. 22, 2003).

³⁴² *Id.* at S15567.

³⁴³ See generally 149 Cong. Rec. S15744-46 (daily ed. Nov. 24, 2003).

³⁴⁴ *Id.* at S15746.

³⁴⁵ *Id.*

³⁴⁶ 149 Cong. Rec. S15885 (daily ed. Nov. 25, 2003).

³⁴⁷ 149 Cong. Rec. S15751 (daily ed. Nov. 24, 2003). Senator Kennedy explained his comments in further detail with reference to a Federal Circuit decision, *EMC Corp. v. Norand Corp.* in which the Court found that the district court did, in fact, have jurisdiction to hear a dispute but "nevertheless allowed the district court to dismiss the

On the day that the Medicare Reform Bill was passed, November 25, 2003, Senator Kennedy provided further commentary regarding the Hatch-Waxman amendments.³⁴⁸ As to the forfeiture events for the 180-day exclusivity period, Senator Kennedy explained that one such event would be failure to market after a period of time after a final court decision.³⁴⁹ The final court decision, he claimed, would be a decision such as that of the D.C. Circuit's 1999 decision in *Teva Pharmaceuticals, USA, Inc. v. FDA*,³⁵⁰ "dismissing a declaratory judgment action for lack of subject matter jurisdiction because the patent owner has represented that the patent is not infringed."³⁵¹ This is something that Chairman Muris recommended when testifying before the Senate Judiciary Committee on August 1, 2003. Senator Kennedy noted:

action, holding that district courts may do so unless "there is no real prospect of non-judicial resolution of the dispute." *Id.* According to Senator Kennedy, "[t]he Federal Circuit apparently felt that a patentee should be able to use what may prove to be an invalid patent as a source of 'bargaining power' in license negotiations." *Id.*

In addition, Senator Kennedy liked the declaratory judgment provision because "[he] and other Senate proponents of this subsection believe that the reasonable-apprehension test demands more than is required by the constitutional case-or-controversy requirement." *Id.* at S15751. Citing two letters from Professor John Yoo of Boalt Hall School of Law at the University of California at Berkeley that were made of record, Senator Kennedy indicated that Prof. Yoo believes the reasonable-apprehension test "may be viewed as an exercise of the court's discretionary power." *Id.* at S15751-55. Therefore, Senator Kennedy believes that "[i]n deciding when a Hatch-Waxman declaratory judgment suit may meet the requirements of Article III, the courts should focus on the actual components of the case-or-controversy requirement." *Id.* Such components, Senator Kennedy indicated include the "triad injury in fact, causation, and redressability" and the "injury in fact" element invokes consideration of "the dispute's adverseness, definiteness, concreteness, and the specificity of the claims," factors which "[set] the constitutional standard for allowing declaratory judgments." *Id.* Senator Kennedy stated that he took this analysis from the Supreme Court's "1998 Steel Company decision" and the Supreme Court's "1937 *Aetna Life Ins. v. Haworth* decision." *Id.* Ultimately, the Senator believed that the main question to ask was "whether the would-be patent challenger has been reasonably and actually deterred from undertaking a profitable enterprise." *Id.* at S15752. However, he noted that "[b]y including the language 'to the extent consistent with the Constitution,' the conferees have allowed the courts to import as much of the reasonable-apprehension test as they feel is constitutionally necessary." *Id.*

³⁴⁸ See generally 149 Cong. Rec. S15884-86 (daily ed. Nov 25, 2003).

³⁴⁹ *Id.* at S15885.

³⁵⁰ 182 F.3d 1003 (D.C. Cir 1999). Senator Kennedy improperly referred to this case as "*Teva v. Shalala*." 149 Cong. Rec. at S15885.

³⁵¹ 149 Cong. Rec. at S15885.

Under the failure to market provision, the conditions for forfeiture are intended to be satisfied when a generic company has resolved patent disputes on all the patents that earned the first-to-file its exclusivity. After a court decision such as that at issue in *Teva v. [FDA]*, the patent owner is estopped from suing the generic applicant in the future and the patent dispute is resolved. So these sorts of decisions should be recognized as court decisions under the failure to market provision.³⁵²

Despite the fact that Senators McCain and Schumer initially sponsored the bill providing for amendments to the Hatch-Waxman regime, neither of these Senators voted for passage of the Medicare Reform Bill containing these amendments.³⁵³ Moreover, Senator Kennedy did not vote for passage of the Medicare Reform Bill, although he was deeply involved with the negotiations of the Hatch-Waxman amending provisions in the conference.³⁵⁴ Of senators who expressed some understanding of the Hatch-Waxman-amending provisions, Senators Frist, Hatch and Grassley voted in support of passing the Medicare Reform Bill.³⁵⁵ Once the Medicare Reform Bill was passed by the House, the ultimate vote for passage of the Medicare Reform Bill in a Republican Senate, including the Hatch-Waxman amendments in Title XI of the legislation, was 54 yeas and 44 nays.³⁵⁶

B. An Analysis of the Actual Hatch-Waxman Amending Provisions in the Medicare Reform Legislation

The part of the Medicare Reform Legislation that amends the Hatch-Waxman provisions is in Title XI—Access to Affordable Pharmaceuticals. Within that Title is Subtitle A bearing the same name, which contains densely drafted provisions that amend the scheme surrounding the automatic 30-month stay and the 180-day exclusivity period. Subtitle B provides for FTC review of certain agreements entered into between a generic company and a brand name drug company (i.e., an innovative company), or between generic companies. Subtitle C introduces a scheme for the importation of prescription drugs from Canada. The policy levers adjusted by these reforms will affect both the scope and the term of exclusivity that an innovative company has for its drug products.

In more detail, section 1101 is directed to the automatic 30-month

³⁵² *Id.*

³⁵³ *Id.* at S15915.

³⁵⁴ *Id.* at S15884.

³⁵⁵ *Id.* at S15915.

³⁵⁶ *Id.* at S15914-15.

stay. Subsection 1101(a) amends certain provisions in section 505(j) of the FDCA³⁵⁷ that pertain to generic company applicants that file ANDAs, whereas subsection 1101(b) amends, in a parallel fashion, certain provisions that pertain to section 505(b)(2) applicants. Our focus in this discussion is on the ANDA amendments. Essentially the same analysis could be applied, however, to section 505(b)(2) applications, with the exception of the 180-day exclusivity amending provision, since section 505(b)(2) applications are not eligible for 180-day exclusivity periods. As to the automatic 30-month stay provisions, amendments are made to the notice provisions that govern how and when an ANDA applicant must provide notice that it has filed an ANDA with a paragraph IV certification.³⁵⁸ Although the content of the notice and intended recipients of the notice are essentially the same as before, notice must now be provided within 20 days of when the FDA informs the ANDA applicant that the ANDA application has been filed, or at the time that an amendment or supplement is filed.³⁵⁹ As before, the notice must “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.”³⁶⁰

Section 1101 also adds a new subparagraph to the ANDA application provisions in the FDCA, namely, section 505(j)(2)(D), that provides that an ANDA applicant may not amend or supplement its original ANDA application to obtain drug approval for a drug that is different from the drug identified in the original ANDA application.³⁶¹ An amendment or supplement, however, may be filed to seek approval of a different strength of the original drug.³⁶² It appears that this language may have been introduced to preemptively address any efforts by ANDA applicants to circumvent the new 30-month stay provision to be applied to each ANDA by seeking to obtain approval for more than one generic drug per ANDA.

The new provision that indicates that only one 30-month stay will be applied to each ANDA application is obscurely set forth in section 1101(a)(2). That subsection amends section 505(j)(5)(B) of the FDCA to read:

505.(j)(5)(B) The approval of an [ANDA] application submitted under paragraph (2) shall [be] made effective on the last applicable date determined by **applying the following to each certification made under**

³⁵⁷ 21 U.S.C.A. § 355(j) (West Supp. 2004).

³⁵⁸ *Id.* at § 355(j)(2)(B).

³⁵⁹ *Id.* at § 355(j)(2)(B)(ii).

³⁶⁰ *Id.* at § 355(j)(2)(B)(iv).

³⁶¹ *Id.* at § 355(j)(2)(D)(i).

³⁶² *Id.* at § 355(j)(2)(D)(ii).

paragraph (2)(A)(vii);

- (i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or both such subclauses, the approval may be made effective immediately.
- (ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).
- (iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, **before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary determines to be substantially complete, was submitted.** If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action . . .³⁶³

As suggested earlier, the drafting of the Hatch-Waxman reforming amendments were not written in an easily-understandable manner. On the contrary, they require extremely careful reading to understand their import. Here, the Medicare Reform Legislation has amended the Hatch-Waxman scheme so that only one 30-month stay can be obtained for each ANDA application.³⁶⁴ This is because the only paragraph IV certifications that will trigger a 30-month stay on FDA approval of the ANDA application are those made as regards patents that had been listed in the Orange Book (i.e., the information submitted pursuant to “subsection (b)(1) or (c)(2)”) before the date that the ANDA application was approved by the FDA.³⁶⁵ Consequently, any patent infringement suits filed in response to paragraph IV certifications essentially will lead to concurrently-running 30-month stay periods. Therefore, this provision should close the chapter on multiple 30-month stays being imposed on generic drugs seeking drug approval. In turn, this in theory should lead to more rapid approval of new generic drugs, since multiple 30-month stays will no longer be possible.

It is important to note that the provisions introduced in the Medicare

³⁶³ *Id.* at § 355(j)(5)(B) (bold emphasis added to show amendment, and additional underlining added to show critically-added language) (emphasis not in original).

³⁶⁴ *Id.*

³⁶⁵ *Id.*

Reform Legislation pertaining to paragraph IV certification notices and 30-month stays are specifically intended to supercede the interpretation of 30-month stays provided by the FDA in its new listing regulations effective August 18, 2003 and that were considered in the preceding section of this article. This was done in the Medicare Reform Legislation by specifying that these provisions will be effective for any certifications or patent information submitted on or after August 18, 2003, the date on which the FDA's new listing regulations went into effect.³⁶⁶ The legislation thus prevents the confusion that would have resulted from having three different Hatch-Waxman regimes—the old regime from before August 18, 2003, an interim regime between August 18, 2003 and December 8, 2003 affected by the new FDA patent listing rules, and a new regime after December 8, 2003 affected by the new FDA patent listing rules and the Medicare Reform Legislation provisions.

In addition, the Medicare Reform Legislation has rewritten the provisions pertaining to the types of court decisions that might lead to a modification of the 30-month stay on ANDA approval following a paragraph IV certification by a generic applicant that led to a patent infringement lawsuit.³⁶⁷ These provisions also were very densely written. Essentially, if a district court decides in such a patent infringement action that the patent in question is invalid or not infringed, the ANDA approval shall be made on the date of the district court's judgment, or the date that a settlement agreement is filed with the court.³⁶⁸ This same reasoning would apply if a judge grants a preliminary injunction preventing the generic company from commercially manufacturing or selling the drug and later finds the patent in question to be invalid or not infringed.³⁶⁹ Otherwise, if the district court decides that the patent is infringed, then the ANDA will be approved on the day that the court of appeals reverses this holding or when a settlement is filed with the court.³⁷⁰ However, if the district court's decision is either not appealed or is affirmed on appeal, the ANDA approval date will be specified by the district court.³⁷¹ Again, if a preliminary injunction is imposed but the court decides that the patent in question is infringed, then the drug approval will be as described immediately above with respect to court decisions with infringement

³⁶⁶ 117 Stat. at 2457.

³⁶⁷ 21 U.S.C.A. § 355(j)(5)(B)(iii)(I)-(IV).

³⁶⁸ *Id.* at § 355(j)(5)(B)(iii)(I).

³⁶⁹ *Id.* at § 355(j)(5)(B)(iii)(III).

³⁷⁰ *Id.* at §§ 355(j)(5)(B)(iii)(II)(aa)(AA), (BB).

³⁷¹ *Id.* at § 355(j)(5)(B)(iii)(II)(bb).

findings.³⁷² These provisions should clarify the issue of when an ANDA application can be approved, if any of the court decisions just described is rendered prior to expiration of the automatic 30-month stay. To what extent these alternate terminating provisions for the 30-month stay will be used remains to be seen.³⁷³ However, the message that is provided from these provisions is that the 30-month stay cannot be used to effectively extend the market exclusivity that an innovator might enjoy from a patent vis-à-vis an incoming generic if the patent has been found to be either invalid or not infringed by the generic's drug product. In simpler terms, the 30-month stay cannot be used to extend a patent's term of exclusivity.

The reader might wonder about whether the 30-month stay might operate to block a generic company's use of the technology disclosed in an original, now-expired patent by being imposed with respect to an unexpired improvement patent. The short answer to this question is no, the 30-month stay should not block a generic company's use of technology set forth in an original, now-expired patent, since, when a patent term expires, the public is entitled to use the subject matter described in the claims of the patent. Of course, the generic company must still obtain drug approval from the FDA to sell its version of the product. However, if in addition to the original expired patent, the improvement patent somehow also covers the product approved in the NDA and has been legitimately listed in the Orange Book with respect thereto, and in the case of the new 30-month stay rule, the improvement patent was filed prior to the ANDA being submitted, a 30-month stay could be imposed on the FDA's approval of a generic copy of the approved drug because of the listed improvement patent.

Yet the Orange Book patent listing rules now provide stringent limitations on the types of improvement patents that might be listed and thus be eligible to trigger a 30-month stay.³⁷⁴ In addition, there are many patent law doctrines that would help ensure that an improvement patent legitimately claims something over and above the original patent, thus making it unlikely that the above-described scenario of an original patent and an improvement patent covering an original drug could be illegitimate. First, the doctrine of

³⁷² *Id.* at § 355(j)(5)(B)(iii)(IV).

³⁷³ Citing to the FTC Study, Wharton has noted that the average time between the filing of a patent infringement suit and the rendering of a district court opinion was about 25 months, whereas the average time between such a filing and an appellate decision was almost about 38 months. See Jacob S. Wharton, "Orange Book" Listing of Patents Under the Hatch-Waxman Act, 47 St. Louis U. L.J. 1027, 1037 (2003) (suggesting, in many cases, the 30-month stay will expire before certain decisions will be rendered triggering the need to rely on these alternative 30-month stay termination provisions).

³⁷⁴ See *supra* § V.1.

obviousness-type double-patenting discussed earlier³⁷⁵ traditionally ensures that only one patent is granted for a claimed invention and, if there is more than one patent containing obvious variants of a claimed invention, this doctrine helps ensure that a terminal disclaimer is imposed on such patents so that all such related patents expire at the same time and are commonly assigned to the same entity. Second, the *Schering* decision discussed earlier clarified that certain patented claims to a metabolite formed in the body are inherently anticipated by a patent on the prodrug that is administered to the patient.³⁷⁶ More broadly, the doctrine of inherency helps ensure that a later claimed invention is found to be unpatentable on grounds of anticipation in view of an earlier teaching that may inherently teach that which is sought to be claimed.³⁷⁷ Third, patent law dictates that when a patent drafter discloses but declines to claim some of the disclosed subject matter, the patentee cannot assert any right to the unclaimed subject matter at a later time.³⁷⁸ That is, what is not claimed is disclaimed. Finally and most recently, the doctrine of laches has been invoked to prevent a patentee from getting patent protection on subject matter that it might otherwise have been entitled to claim on the basis that the patentee waited too long to seek such claims.³⁷⁹

Therefore, if there were a situation where an NDA had been approved on an original, immediate-release drug and all the patents on the original drug had expired, a generic company could get an ANDA approved on the original drug immediately.³⁸⁰ On the other hand, if the innovative company developed a patented improvement on the original drug by, for example, developing an extended release formulation (where the original

³⁷⁵ See generally MPEP, *supra* n. 110 and accompanying text.

³⁷⁶ *Schering I*, 339 F.3d at 1381.

³⁷⁷ A discussion of the concept of inherency can be found not only in *Schering I*, but also in *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research*, 304 F.3d 1221 (Fed. Cir. 2002). As explained by Judge Newman for the majority, “[t]he purpose of the rule of inherency is to accommodate common knowledge, knowledge that judges might not know but that would be known to practitioners in the field.” *Id.* at 1229. In her reasoning, Judge Newman dismisses the dissenting position that the patentee who had a patent on a genetically engineered mouse capable of being used to study Alzheimer’s disease was seeking to patent something “inherently” found in the prior art. *Id.*

³⁷⁸ See *Johnston & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046 (Fed. Cir. 2002) (indicating that the doctrine of equivalence should not be used to recapture disclosed but unclaimed subject matter in a patent); see also *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098 (Fed. Cir. 1996) (indicating subject matter was dedicated to the public when patent disclosed subject matter in the specification without claiming it).

³⁷⁹ See e.g. *Symbol Techs., Inc. v. Lemelson Med.*, 277 F.3d 1361 (Fed. Cir. 2002) (illustrating the application of prosecution laches).

³⁸⁰ See 21 U.S.C.A. §§ 355(j)(5)(B), (j)(2)(A)(vii).

drug covered an immediate release formulation), the innovative company likely would have to file a Supplemental NDA.³⁸¹ Any improvement patent directed to the unique feature of the extended release formulation likely could only be listed with respect to the extended release formulation and not with respect to the immediate-release drug approved from the original NDA.³⁸² Thereafter, under the new 30-month stay rule, if the improvement patent were to be filed prior to an ANDA directed to the extended release formulation being submitted, a stay could be triggered that would prevent the FDA from approving this ANDA for 30 months.³⁸³ However, if the improvement patent were to be filed after the ANDA was submitted, then the innovative company could not get any 30-month stay with respect to that patent.³⁸⁴

It should be recognized that, even if innovative companies can only obtain one 30-month stay, they can still avail themselves of other aspects of Hatch-Waxman for Orange Book listed patents. That is, the Hatch-Waxman regime still requires a generic company to certify its position as to such patents, and innovative companies are still able to sue the generic company for patent infringement pursuant to 35 U.S.C. § 271(e)(2), if a paragraph IV certification is made. It will be recalled that, pursuant to section 271(e)(2), patent infringement actions can be filed well before a generic company commences marketing its generic copy of a brand-name drug. From society's perspective, early resolution of such patent disputes is generally considered beneficial since it helps clear the way for generic drug entry if a patent is in fact invalid, or if a patent is found to be valid but not infringed. Such resolution provides an early signal to the generic company of this fact before substantial resources are expended in launching, marketing and selling its generic copy of the brand-name drug.

In fact, authors have indicated that a finding of infringement for a generic company after they have begun marketing could be "devastating," whereas a finding of willful infringement with the imposition of treble (i.e., triple) damages could be "catastrophic."³⁸⁵ As Laura Robinson explains, because generic drugs are sold at substantially lower prices than innovative

³⁸¹ See e.g. 21 C.F.R. § 314.70 (2004) for requirements as to when supplemental applications need to be filed.

³⁸² This is because the extended-release patent likely would not satisfy the listing requirements with respect to the immediate release formulation. For a discussion of the revised patent listing requirements, see *supra* § V.1.

³⁸³ 21 U.S.C.A. § 355(j)(5)(B); see also *supra* n. 362 and accompanying text.

³⁸⁴ *Id.*

³⁸⁵ Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. Intell. Prop. L. 47, 78 (2003).

drugs, generic companies cannot risk selling their product if they believe that they might be infringing a patent held by the innovative drug company.³⁸⁶ Generic companies must resolve any infringement actions before going to market.³⁸⁷ If this is the case, one question worth asking is whether one 30-month stay will have any negative impact on generic drug entry. Wharton, for example, indicates that a generic company is not likely to enter the market with a generic drug even if the 30-month stay has expired if an infringement lawsuit is still pending.³⁸⁸

What all of this suggests is that, by eliminating the possibility of getting multiple 30-month stays, the Medicare Reform Legislation will help ensure that such stays will not slow down generic drug entry and that patent disputes will be resolved early on. That said, in general, one 30-month stay is probably not going to provide a tremendous benefit to innovative companies in terms of providing exclusive protection. ANDAs generally can be filed as early as about 4 years after an innovative company gets NDA approval where the NDA has a 5-year new chemical exclusivity (NCE) on the product.³⁸⁹ If one adds to the NCE period a 30-month stay arising from infringement litigation commenced pursuant to a paragraph IV certification made by the generic ANDA applicant, all such terms of exclusivity or stays on FDA approval will likely run out before the term of the patent subject to the lawsuit expires.³⁹⁰ In other words, these hypothetical facts suggest that, in terms of generic drug entry, one automatic 30-month stay may have essentially the same effect as not having one at all, since it appears that a generic company will not market its drug until after all relevant patents have expired. The automatic 30-month stay on generic drug approval might still be beneficial in helping preserve funds for innovative companies seeking to enforce what may be their more valuable patents (for example, since they have been first listed in the Orange Book). This is because innovators may not need to spend substantial funds trying to secure a preliminary injunction to prevent the generic from manufacturing or selling the allegedly infringing generic product while an infringement lawsuit is pending since the generic will not have drug approval to engage in such marketing anyway (Of course,

³⁸⁶ *Id.*

³⁸⁷ *Id.*

³⁸⁸ Wharton, *supra* n. 373, at 1037.

³⁸⁹ The 5-year NCE exclusivity period and the ability to file a paper NDA or ANDA within 4 years is provided, respectively, at 21 U.S.C.A. §§ 355(c)(3)(D)(ii), (j)(5)(F)(ii), as amended by the Medicare Reform Legislation.

³⁹⁰ See Kuhlik, *supra* n. 34, at 96-97 (indicating that the term of a patent likely to be remaining following FDA approval is about 11 to 12 years).

it is unclear, as noted above, that generic companies would seek to market their generic drug at this stage anyway).

In addition to the 30-month stay provisions, section 1101 of the Medicare Reform Legislation adds two new provisions to section 505(j)(5) of the FDCA, namely, a provision that specifically allows declaratory judgment (DJ) actions to be undertaken by a generic company to obtain patent certainty if a patent infringement is not commenced by a patent holder or brand name company within the 45-day post-notice period.³⁹¹ However, the provision only allows such DJ actions to be pursued if the notice to be filed containing a paragraph IV certification provides an offer of confidential access to the generic company's ANDA application.³⁹² Such access would be provided to the patent owner or ANDA applicant "for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the [paragraph IV certification]."³⁹³ This provision clarifies another aspect of the Hatch-Waxman provisions that had created a great deal of uncertainty in the courts, namely, whether generics could pursue such DJ actions. Like many of the other reforms introduced in the Medicare Reform Legislation, these provisions will help resolve patent disputes and clear the way to the introduction of new generic drugs by eliminating patents that are deemed by courts to be invalid or not infringed.

As is apparent from the legislative history, early versions of the DJ provision raised Constitutional concerns for Congress.³⁹⁴ Specifically, the concern was that earlier versions may be unconstitutional since they would force a court to find jurisdiction to hear a DJ action, when Article III of the U.S. Constitution leaves the decision of whether to hear the DJ action in the Court's discretion based on whether or not there is a sufficient case or controversy to hear the matter.³⁹⁵ It appears that concerned Senate members felt that the ultimately enacted wording of section 1101(d) would solve this problem. That provision amends the Patent Act at 35 U.S.C. § 271(e) to specify that, if a generic company (i.e., either an ANDA applicant or a paper NDA applicant) provides notice of its opinion that the innovative company's patent is invalid or not infringed but the innovator company (i.e., the NDA holder or patent holder) does not exercise its right to sue within 45 days of the notice, the generic company may seek a DJ action on infringement or invalidity and U.S. courts shall have subject matter jurisdiction to hear such

³⁹¹ 21 U.S.C.A. § 355(j)(5)(C).

³⁹² *Id.* at § 355(j)(5)(C)(III).

³⁹³ *Id.*

³⁹⁴ *See e.g.* 149 Cong. Rec. S8691-92 (June 26, 2003) (Senator Hatch's comments).

³⁹⁵ *See* Hearings, *supra* n. 322, at 1-2 (prepared statement of Sheldon Bradshaw).

an action “to the extent consistent with the Constitution.”³⁹⁶ Time will tell whether the provision will be subject to challenge. No doubt, much thought has been put into the provision to avoid it from being overturned because of constitutional defects.

Beyond the DJ action, the procedural hole created by the *Mylan* and *Andrx* cases considered earlier has been patched to an extent by another part of section 1101(a)(2)(C) of the Medicare Reform Legislation that provides that an ANDA applicant against which a patent infringement suit has been filed may assert a counterclaim to correct or delete patent information that has been submitted to the Orange Book.³⁹⁷ However, the provision specifically indicates that no independent cause of action for delisting patents from the Orange Book is authorized by the provision.³⁹⁸ Moreover, an ANDA applicant will not be entitled to damages pursuant to a patent delisting counterclaim or pursuant to the DJ action considered immediately above.³⁹⁹

Particularly for generic companies, Congress’s inclusion of a provision allowing only for a patent delisting argument to be made as a counterclaim to a patent infringement is an unfortunate outcome. For generics, a provision requiring the FDA to establish an administrative review mechanism for Orange Book patent listings probably would have been much more to their liking. In fact, based on Judge Plager’s comments in the *Apotex* case, he would agree that some kind of administrative mechanism beyond just allowing for a patent infringement counterclaim is in order.⁴⁰⁰ However, in its recently issued final rule on patent listing considered in the previous section, the FDA has again reiterated that its role as to monitoring patent listings is purely “ministerial.”⁴⁰¹ Consequently, now that Congress has specifically addressed the issue and has implicitly rejected the notion of an administrative delisting proceeding, it is unlikely that any such mechanism will be put into place in the future. On the other hand, now that the FDA has provided much more detailed guidelines as to which patents must and must not be listed in the Orange Book, there will be much less room left for interpretation as to which patents are appropriate for listing in the Orange Book. Moreover, given the attestation that must be provided by

³⁹⁶ 21 U.S.C.A. § 355(j)(5)(c).

³⁹⁷ *Id.* at § 355(j)(5)(C)(ii)(I); 117 Stat. at 2454 (indicating a similar provision exists for paper NDA applicants).

³⁹⁸ 21 U.S.C.A. § 355(j)(5)(C)(ii)(II).

³⁹⁹ *Id.* at § 355(j)(5)(C)(iii).

⁴⁰⁰ *Apotex*, 347 F.3d at 1346-47; *see supra* § III.1.A.

⁴⁰¹ *Apotex*, 347 F.3d at 1347.

any person seeking to submit a patent for listing in the Orange Book and the criminal penalties that might ensue for an improper listing, there is likely to be a great deal of discipline exercised by that person and reluctance by him or her to interpret FDA's listing regulations in any manner that might be characterized as a strained interpretation. Finally, since only one 30-month automatic stay will now be obtainable for an ANDA, there will be less incentive on the part of brand name companies to take a broad interpretation of what patents should be listed.

Beyond the reforms discussed above, section 1102 of the Medicare Reform Legislation has introduced a provision that provides numerous ways in which the 180-day exclusivity period can be revoked. In particular, the 180-day exclusivity period provision in section 505(j)(5)(B)(iv) has been stricken and replaced by a new 180-day exclusivity period provision. Now, if a "first applicant" has filed an ANDA application containing a paragraph IV certification, that applicant will obtain a 180-day period of exclusivity counted from the "first commercial marketing" of the drug.⁴⁰² The first applicant must submit a substantially complete ANDA application that contains and lawfully maintains a paragraph IV certification.⁴⁰³

Moreover, a new provision, section 505(j)(5)(D)(ii), has been added that indicates that the 180-day exclusivity can be forfeited by the first applicant if a "forfeiture event" occurs with respect to that first applicant.⁴⁰⁴ If all first applicants forfeit the 180-day exclusivity period, no other ANDA applicant will be eligible for such an exclusivity period.⁴⁰⁵ The term "forfeiture event," is defined in detail and includes events such as: (1) a failure to market by certain specified time periods that depend on when an application was approved and whether the application's approval was delayed by a patent infringement or a DJ action; (2) a withdrawal of the ANDA application; (3) an amendment or withdrawal of the paragraph IV certification that had previously qualified the first applicant for the 180-day period of exclusivity; (4) failure of the first applicant to obtain tentative approval for its ANDA application; (5) the first applicant enters into a settlement agreement to which the FTC files a complaint that the agreement violated antitrust laws, which is made final and cannot be appealed, other than to the U.S. Supreme Court; and (6) all of the patents as to which the first applicant submitted paragraph IV certifications have expired.⁴⁰⁶

⁴⁰² 21 U.S.C.A. § 355(j)(5)(B)(iv)(I).

⁴⁰³ *Id.* at § 355(j)(5)(B)(iv)(II)(bb).

⁴⁰⁴ *Id.* at § 355(j)(5)(D)(ii).

⁴⁰⁵ *Id.* at § 355(j)(5)(D)(iii)(II).

⁴⁰⁶ *Id.* at § 355(j)(5)(D)(i).

The “failure to market” forfeiture event for the 180-day exclusivity period is described in a very complicated manner. Legislators, it appears, intended that this forfeiture event be triggered when “a generic company has resolved patent disputes on all the patents that earned the first-to-file . . . exclusivity.”⁴⁰⁷ It seems that there are two alternative types of events that will trigger the “failure to market” forfeiture events, whichever of the two ends up being later. The first alternative event is the earlier of two dates: (1) 75 days after the date of FDA approval of the first applicant’s ANDA; or (2) 30 months after the first applicant submitted its ANDA.⁴⁰⁸ The second alternative event is 75 days after at least one of the following things have occurred with respect to each of the patents that was subject to a paragraph IV certification made by the first applicant as a result of any generic company: (1) a final court decision has been rendered that is not appealable (except by writ of certiorari to the Supreme Court) indicating that the patent is invalid or not infringed; (2) a settlement agreement has been entered into that includes a finding that the patent is invalid or not infringed; or (3) an innovative company withdraws the patent from the Orange Book.⁴⁰⁹ Once the first and second alternative events are identified, the later of the two will trigger the failure to market provision. The legislative history suggests that legislators intended that a decision such as in *Teva v. FDA*,⁴¹⁰ “dismissing a declaratory judgment action for lack of subject matter jurisdiction because the patent owner has represented that the patent is not infringed” would count as a “final court decision” for purposes of the failure to market provision.⁴¹¹ Also because the second alternative event is with respect to the activity of any generic company, the 180-day exclusivity period will have less, or potentially no, market-delaying effect for a subsequent generic applicant whose generic drug is found to not infringe the innovator’s patents in question. This could help alleviate the market delay problem identified by Senator Hatch.⁴¹²

The forfeiture events for the new 180-day exclusivity are essentially “no-parking” provisions that will prevent what used to be able to occur under the original Hatch-Waxman provisions, namely, a first ANDA applicant “parking” itself in the position of being the beneficiary of a 180-day exclusivity period, thereby preventing any subsequent ANDA applicant from

⁴⁰⁷ 149 Cong. Rec. at S15885; *see supra* nn. 349-52 and accompanying text.

⁴⁰⁸ 21 U.S.C.A. §§ 355(j)(5)(D)(i)(I)(aa)(AA), (BB).

⁴⁰⁹ *Id.* at §§ 355(j)(5)(D)(i)(I)(bb)(AA)-(CC).

⁴¹⁰ 182 F.3d 1003.

⁴¹¹ 149 Cong. Rec. at S15885; *see supra* nn. 349-52 and accompanying text.

⁴¹² 149 Cong. Rec. at S8692.

getting its ANDA approved.⁴¹³ In particular, the new 180-day exclusivity provision should prevent anticompetitive settlement agreements from being entered into, as discussed earlier. This is because generic companies will have an added incentive not to enter into any agreements with other generic companies or brand-name companies that might cause them to forfeit their 180-day exclusivity period. This incentive, of course, is in addition to the incentives already conferred by industry members' knowledge of the FTC's recent enforcement activities.

A few additional points about the revised 180-day exclusivity period are worth highlighting based on what we now know from the legislative history. First, eligibility for the 180-day exclusivity period is based strictly on the first applicant to file a substantially complete ANDA application containing a paragraph IV certification.⁴¹⁴ This means that the "successful defense" eligibility introduced by the FDA and knocked down in *Mova v. Shalala*, has not been endorsed.⁴¹⁵ Moreover, because the "first applicant" is determined with respect to filing an ANDA for a drug, this means that the exclusivity period is determined on a "per-product" basis rather than being based on the more confusing "per-patent" basis, as used to be the case. Second, it is interesting to note that Mr. Armitage's proposition in testimony before the Senate Judiciary Committee, that a forfeiting provision be included for the 180-day exclusivity once all innovator company patents are expired, was implemented by Congress. Mr. Armitage felt such a provision would help curb the flow of frivolous lawsuits.⁴¹⁶ Third, the reformed 180-day exclusivity provision makes no distinction between invalidity and non-infringement findings for the 180-day exclusivity provision, as Senator Hatch suggested might be useful.⁴¹⁷ In this regard, although a finding of invalidity might yield more benefit to generic companies generally, introducing such additional structure would have rendered the provision even more complex and, in the end, might have diluted generic company incentives to challenging invalid or un infringed patents. As it stands, together with its first filing entitlement, the 180-day exclusivity provision is sufficiently well defined to provide certainty as to the timing of generic drug entry, a factor that is important to both innovators and generics.

⁴¹³ See e.g. *FTC Study*, *supra* n.10, at x (indicating the "no parking" term has come to be used to describe this scenario).

⁴¹⁴ 21 U.S.C.A. § 355(j)(5)(B)(iv)(II)(bb).

⁴¹⁵ See 955 F. Supp. at 128 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998); 149 Cong. Rec. at S8692; *FTC Study*, *supra* n. 10, at 59-60; *supra* nn. 158-60, 320 and accompanying text.

⁴¹⁶ See Hearings, *supra* n. 322, at 52, 55, 57.

⁴¹⁷ 149 Cong. Rec. at S8692.

Finally, as an additional precautionary measure, the Medicare Reform Legislation provides in section 1112 that generic companies and brand name companies must provide notice to the FTC and the Assistant Attorney General of any agreements that they enter into pertaining to the 180-day exclusivity period, or the manufacture, marketing or sale of any generic drug that is the subject of an ANDA application or of the brand-name drug that is being copied.⁴¹⁸ Moreover, any agreements between generic companies regarding the 180-day period of exclusivity must also be brought to the FTC's and the Assistant Attorney General's attention.⁴¹⁹ Such agreements must be filed within ten business days after the agreements are executed but will be kept confidential.⁴²⁰ Companies are not, however, required to file agreements that solely concern purchase orders for raw material supplies, equipment and facility contracts, employment or consulting contracts, or packaging or labeling contracts.⁴²¹ Civil penalties are provided for failure to comply with the disclosure provisions.⁴²²

Although this provision requires that pharmaceutical companies file certain agreements with government authorities, it is worth noting that there has been no change in substantive law pertaining to what activities might and might not be anticompetitive. Perhaps most notably, settlement agreements between innovators and generics or between two generics in the patent law area were not, for example, declared *per se* antitrust violations. Many commentators would consider this a positive development.

For example, Lave cautioned against making such settlements *per se* illegal.⁴²³ According to Lave, “[w]ithout the possibility of settlement, generics would now face a much larger chance of losing and paying significant damages” that “may be beyond the generic’s ability to pay”⁴²⁴ Consequently, generics would be much less willing to take the chance and file a paragraph IV certification.⁴²⁵ At the same time, an innovative company may also prefer settlement given the inherent risks of litigation.⁴²⁶ Rather,

⁴¹⁸ 117 Stat. at 2461-62.

⁴¹⁹ *Id.* at 2462.

⁴²⁰ *Id.* at 2463.

⁴²¹ *Id.* at 2462-63.

⁴²² *Id.* at 2463.

⁴²³ Jonathan M. Lave, *Responding to Patent Litigation Settlements: Does the FTC Have It Right Yet?*, 64 U. Pitt. L. Rev. 201, 223 (2002).

⁴²⁴ *Id.* at 222-23.

⁴²⁵ *Id.* at 223.

⁴²⁶ *Id.* at 224-25.

Lave proposes an economic framework with supporting mathematical modeling whereby reverse payments in such settlements would be allowed if the value of the settlement to the generic company were equal to or less than the expected value of litigation.⁴²⁷

Hovenkamp, Janis and Lemley also studied the economics of the settlement problem between innovative and generic pharmaceutical companies and concluded that, “exclusion payments that exceed litigation costs should be presumptively illegal.”⁴²⁸ This analysis was in the context of devising a broader framework for resolving which agreements might amount to antitrust violations. The authors also suggested that it might be acceptable from an antitrust perspective for the parties to settle a case “by agreeing that the generic will not enter for a specified number of years, but then will be able to enter without paying a royalty.”⁴²⁹ This might occur, for example, where the patent at issue had 10 years of life remaining and was 50% likely to be held invalid.⁴³⁰ In response, however, Cotter responded to Hovencamp, Janis and Lemley that:

The danger of channeling Hatch-Waxman litigants toward settling on terms that allow the defendant to license the plaintiff’s patent and away from settling on terms that involve reverse payments is that doing so threatens to reduce the value of pharmaceutical patents, including valid pharmaceutical patents. Logically, if it were in the plaintiff’s interest to license the defendant, the plaintiff would do so voluntarily.⁴³¹

Interestingly, Judge Posner also offered some interesting *obiter dicta* comments about “reverse payment” patent settlements in response to Hovenkamp, Janis and Lemley:

“Reverse payment” patent settlements . . . in which the patentee explicitly pays the alleged infringer to stay out of the market, are criticized and sometimes invalidated on the theory that they prevent competition Whether it is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger’s settlement options should he be sued

⁴²⁷ *Id.* at 226-27, 231-35 (citing sections VII and Appendix A, respectively).

⁴²⁸ Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *The Interface Between Intellectual Property Law and Antitrust Law: Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1720 (2003).

⁴²⁹ *Id.* at 1762.

⁴³⁰ *Id.*

⁴³¹ Thomas F. Cotter, *The Interface Between Intellectual Property Law and Antitrust Law: Commentary: Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovencamp, Janis & Lemley*, 87 Minn. L. Rev. 1789, 1809 (2003).

for infringement, and so might well be thought anticompetitive.⁴³²

Presumably, in the future, as agreements subject to section 1112 of the Medicare Reform Legislation are filed with the prescribed government authorities, such authorities will keep these various perspectives in mind when deciding what agreements may be anticompetitive and when engaging in rulemaking pursuant to section 1116 of the Medicare Reform Legislation.⁴³³

This review of the provisions of the Medicare Reform Legislation, when read together with the FDA's new listing regulations, reveals that the legislative and executive branches have implemented detailed laws and regulations designed to prevent brand-name and generic companies from behaving strategically and anti-competitively pursuant to the Hatch-Waxman provisions. In particular, it appears that the new laws should prevent those problems that arose previously with regards to multiple patent listings, multiple 30-month stays and manipulations pertaining to the 180-day period of exclusivity.⁴³⁴ Without such strategic and often anticompetitive behavior

⁴³² *Asahi Glass Co., Ltd. v. Pentech Pharms, Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003); see also *Schering-Plough Corp. v. FTC*, Case No. 04-10688, Docket No. FTC9297, at *43 (11th Cir. March 8, 2005) (available at <http://www.ca11.uscourts.gov/opinions/weekops.php>) (accessed March 10, 2005) ("Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be (*sic*) the sole basis for a violation of antitrust law. . . . Given the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic. Such a result does not represent the confluence of patent and antitrust law.").

⁴³³ Pursuant to section 1116 of the Medicare Reform Legislation, the FTC and Assistant Attorney General may: (1) define the terms used in the Medicare Reform Legislation; (2) exempt classes of persons or agreements from the filing requirements provided in to § 1112(c) of the Medicare Reform Legislation; and (3) prescribe any other rules that may be necessary to give effect to the filing requirements. 117 Stat. at 2461-63.

⁴³⁴ Of course, some commentators would have preferred that much stricter provisions be implemented to bring the pharmaceutical industry in line. See e.g. Andrew A. Caffrey, III & Jonathan M. Rotter, *Consumer Protection, Patents and Procedure: Generic Drug Market Entry and the Need to Reform the Hatch-Waxman Act*, 9 Va. J.L. & Tech. 1 (2004). These authors' suggestions for reform would have gone even further than the amendments provided in S. 812 to eliminate any possible chance for misuse. For example, they (1) would require a duty to litigate, not settle, Hatch-Waxman infringement lawsuits, and (2) would provide a disgorgement of excess profits accrued during an automatic 30-month stay where an innovative pharmaceutical company was unsuccessful during litigation. *Id.* at 44.

slowing down the approval process for generic drugs, this new law seems destined to bring affordable pharmaceuticals to consumers at a faster rate than before, as the name of the legislation suggests. In addition, if one considers the Hatch-Waxman reforms in the larger context of the Medicare Reform Legislation, which also includes the better-known Medicare prescription drug benefit⁴³⁵ and Canadian drug importation provisions⁴³⁶ (if adopted),⁴³⁷ there is likely to be a significant downward pressure on the cost of drugs in the United States. In the short-term, all consumers will benefit from the lower cost of drugs.

VI. THE IMPACT OF THE HATCH-WAXMAN REFORMS ON LOWERING DRUG PRICES AND ON THE FUTURE OF PHARMACEUTICAL INNOVATION

In comments to its Final Rule reforming Orange Book patent listing requirements, the FDA provided a financial forecast for the pharmaceutical industry:

There will be an increasing number of patents expiring in the next few years covering innovator drugs currently on the market. According to our records, over 500 drug patents will expire between 2003 and 2009. We have identified 26 top-selling drugs subject to patents with expiration dates between 2003 and 2005. These 26 drugs had combined 2001 retail sales exceeding \$38 billion (over 25 percent of all 2001 prescription drug expenditures) and include 7 of the top 10 best selling drugs. The pressure on NDA holders and innovator companies to protect their market share

⁴³⁵ *Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Title I—Medicare Prescription Drug Benefit*, Pub. L. No. 108-173, §§ 101-11, 117 Stat. 2071, 2071-76 (2003).

⁴³⁶ *Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Title XI, Subtitle C—Importation of Prescription Drugs*, Pub. L. No. 108-173, §§ 1121-23, 117 Stat. 2464, 2464-69 (2003).

⁴³⁷ Section 1121 of the Medicare Reform Legislation amends § 804 of the FDCA to introduce prescription drug importation provisions. 117 Stat. at 2464. However, section 804(l)(1)(A)-(B) indicates that the drug importation scheme will only become effective if the Secretary of Health and Human Services certifies to Congress that the scheme's implementation will "pose no additional risk to the public's health and safety" and will "result in a significant reduction in the cost of covered products to the American consumer." *Id.* at 2468. Also, section 804(l)(2)(A) provides that if the Secretary submits a certification to Congress that the costs of a drug importation scheme outweighs the benefits, section 804 will cease to have effect. *Id.* Presumably in order to be able to provide an appropriate certification, section 1122 of the Medicare Reform Legislation directs the Secretary to conduct a study on the importation of drugs into the United States. *Id.* at 2469.

and delay generic competition into the market will continue to increase.⁴³⁸

Moreover, in these same comments, the FDA acknowledged that the primary economic impact of their regulations would be a monetary transfer from innovator drug firms to consumers and generic firms in an amount of several billion dollars over 10 years.⁴³⁹ The Hatch-Waxman reforms set forth in the Medicare Reform Legislation are likely to lead to a similar monetary transfer since such provisions should help precipitate generic drug entry. It follows then that revenues to innovative drug companies are likely to decrease as a result of these legal and regulatory amendments. To add to this, innovative companies have been grappling with dried-up innovative pipelines that place such companies' future earning capacity into question.⁴⁴⁰ In fact, for several years, we have been seeing the consequences of innovative companies' dried up innovation pipelines in the numerous mergers and consolidations that have occurred amongst such companies.⁴⁴¹ More recently, the increasing partnerships between innovative pharmaceutical companies and small biotechnology companies that have promising new drugs are another indication of innovative companies' targeted search for new drugs to fill their innovation pipelines and boost revenues.⁴⁴²

Up until now, the framework of discussion in this article has assumed that the desired endpoint for Hatch-Waxman reform was to remove strategic behavior that was occurring pursuant to the original Hatch-Waxman scheme in order to allow for more rapid generic entry and cheaper drugs for consumers. It appears that the combination of FDA regulatory reforms plus the Medicare Reform Legislation reforms should achieve this endpoint. However, before closing, we should verify whether the only desired endpoint by which to evaluate the success of the Hatch-Waxman reforms is to

⁴³⁸ 68 Fed. Reg. at 36694.

⁴³⁹ *Id.* at 36700. More specifically, the FDA "found that the increase in revenues to generic drug manufacturers would be \$19.117 billion over 10 years, or \$1.8 billion per year if annualized assuming a 7-percent discount rate. The benefit to consumers would be \$34.822 billion over 10 years or annualized in \$3.3 billion." *Id.* Moreover, the FDA "found that the reduction in revenues to innovator firms would be mitigated somewhat by the reduction in marketing expenses and that the cost would be \$51.508 billion over ten years, or an annualized \$4.9 billion. The 10-year net benefit is \$2.356 billion, and the annualized net benefit is approximately \$220 million." *Id.*

⁴⁴⁰ See Jim Hopkins, *Biotech Upstarts Get Injection of Capital—Money Flows Into Start-Ups That Move Fast, Take Risks*, USA Today B1 (Mar. 23, 2004); see also Marc Kaufman, *Decline in New Drugs Raises Concerns—FDA Approvals Are Lowest in Decade*, Washington Post A1 (Nov. 18, 2002).

⁴⁴¹ See Hopkins, *supra* n. 440, at B1.

⁴⁴² *Id.*

determine whether they will, in fact, lead to more rapid generic drug entry.

Here it is worth being reminded of the compromise that led to the creation of the original Hatch-Waxman legislation. This compromise was to facilitate and speed up generic drug entry⁴⁴³ but, at the same time, safeguard innovation incentives.⁴⁴⁴ In this round of Hatch-Waxman reforms, various lawmakers did acknowledge this duality of opposing incentives that shaped the original Hatch-Waxman Act, and also acknowledged the importance of having a vibrant pharmaceutical industry.⁴⁴⁵ Yet, their words in this regard seemed to be spoken without any actual analysis of whether the reforms, together with other changes in the pharmaceutical industry, might dampen innovative incentives for innovative companies. Only the passage of time will show whether all of the changes in the Hatch-Waxman reforms leading to downward pressure on drug prices and monetary transfers away from innovative companies will end up having a negative effect on innovation. However, at this point there is reason to believe that these reforms, especially when taken in the context of the other reforms in the Medicare Reform Legislation, could depress the rate of pharmaceutical innovation.

One question worth asking is how to encourage and support innovation when it comes to pharmaceuticals. It seems that there are at least four factors that one should consider in this regard.

First, since strong patent protection is considered by the pharmaceutical industry to be critical in allowing it to appropriate sufficient returns to cover the costs of its drug development activities,⁴⁴⁶ it is important that our patent laws respect patent exclusivity in the pharmaceutical area. On this point, as the author has discussed in prior articles,⁴⁴⁷ it is important to not

⁴⁴³ See e.g. H.R. Rpt. 98-857(I) at 14-17 (June 21, 1984).

⁴⁴⁴ *Id.* at 15, 17-18.

⁴⁴⁵ See e.g., *supra* nn. 307-10 and accompanying text.

⁴⁴⁶ Edwin Mansfield has found that among twelve different industry groups, only in the drug industry were patents considered essential to developing and marketing most inventions. See generally Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 *Mgt. Sci.* 173 (1986); see also Ronald C. Levin, Alvin K. Klevorick, Richard R. Nelson & Sidney G. Winter, *Appropriating the Returns from Industrial Research and Development*, 3 *Brookings Papers on Econ. Activity* 783, 796 (1987) (describing the results of a survey in which the authors obtained completed questionnaires from high level R&D executives in various industry areas, including the drugs, plastic materials, inorganic and organic chemical areas. In such areas, both product and process patents were rated as very effective in terms of appropriating the returns from industrial research and development).

⁴⁴⁷ See generally Natalie M. Derzko, *In Search of a Compromised Solution to the Problem Arising from Patenting Biomedical Research Tools*, 20 *Santa Clara Computer & High Tech. L.J.* 347 (2004) [hereinafter Derzko I]; Natalie M. Derzko, *A Local and Comparative Analysis of the Experimental Use Exception—Is Harmonization*

allow exceptions to patent infringement to become overly broad so as to vitiate the exclusivity of patent rights.

Second, it is important that patents that are issued are valid and, if they are invalid, that a mechanism be in place by which to get rid of them. By getting rid of such invalid patents, obstacles will be removed for competitors to proceed with the research, development and marketing of new and better products and processes. Although patent law doctrines pertaining to patent validity and patentability are designed to prevent invalid patents from being issued by the U.S. Patent and Trademark Office and allow for invalid patents to be rendered unenforceable pursuant to a court challenge, the Hatch-Waxman provisions, particularly as recently reformed in the Medicare Reform Legislation go even further to ensure that the clutter of invalid patents is promptly removed from the marketplace. In particular, the Hatch-Waxman provisions are set up to provide incentives to generic companies to challenge weak patents by, for example, providing a 180-day period of exclusivity to the first generic patent challenger.⁴⁴⁸ Moreover, as discussed earlier, to provide greater certainty as to a patent, the newly reformed Hatch-Waxman provisions also expressly allow generic companies to launch declaratory judgment actions as to a patent if the patent holder does not launch a patent infringement action against it in response to a paragraph IV certification.⁴⁴⁹ While getting rid of invalid patents is beneficial for a generic drug applicant, it is also beneficial for pharmaceutical companies that are engaged in innovation efforts in areas relating to the invalidated patents. Innovative companies, however, are concerned that speculative litigation can take away precious time and money to use in the innovation enterprise.⁴⁵⁰ Therefore, the amount of litigation over pharmaceutical patents must be kept in check and frivolous lawsuits minimized.

A third way to encourage innovation, which is related to the second point made above, is to provide a venue to resolve patent disputes promptly so that parties can determine their competitive positions and plan their innovation efforts accordingly. An efficient court system is critical to making this happen. Also important is a court system that renders consistent decisions as to patent matters. Theoretically, the Court of Appeals for the Federal Circuit should provide such certainty as to patent matters because it is charged with the primary responsibility of interpreting U.S. patent law.⁴⁵¹

Appropriate?, 44 IDEA 1 (2003) [hereinafter Derzko II].

⁴⁴⁸ 21 U.S.C.A. § 355(j)(5)(B)(iv).

⁴⁴⁹ See e.g. *supra* nn. 391-96 and accompanying text; 21 U.S.C.A. § 355(j)(5)(C).

⁴⁵⁰ See *supra* n. 337 and accompanying text.

⁴⁵¹ This may, however, be less the case now in view of the U.S. Supreme Court decision in *The Holmes Group, Inc. v. Vornado Air Circulation Sys. Inc.*, 535 U.S. 826 (2002),

Also, by creating an artificial notion of patent infringement pursuant to 35 U.S.C. § 271(e)(2) when a generic company files a drug approval application with a paragraph IV certification pursuant to either 21 U.S.C. §§ 355(b)(2) or 355(j), the Hatch-Waxman provisions do their part in streamlining the procedure for resolving patent disputes and providing certainty to the marketplace. Moreover, as discussed in the previous part, now that the recently reformed Hatch-Waxman provisions have eliminated those opportunities for strategic behavior that previously led to protracted patent disputes, such reforms will further streamline dispute resolution in the patent area.

A fourth way to encourage innovation, and perhaps the most important way when it comes to encouraging pharmaceutical innovation, is to ensure that the term of a patent or other form of marketing exclusivity is sufficiently long to allow a company to at least recoup its research and development expenditures. In an economic study of the effects of the Hatch-Waxman Act after one decade (i.e., from 1984-1994), Henry Grabowski and John Vernon “found [based on computer modeling] that the length of patent protection was a very important policy instrument for the pharmaceutical market.”⁴⁵² These economists also found that the patent term restoration provisions introduced in Title II of the Hatch-Waxman Act and now permanently housed in section 156 of the Patent Act⁴⁵³ did extend the effective patent term, in many cases up to the statutory maximum of 14 years.⁴⁵⁴ Nonetheless, Grabowski and Vernon recommended that Congress

which significantly narrowed the Federal Circuit’s jurisdiction in patent appeals. Anne M. Maher, in her article, *The ‘Holmes’ Decision*, 24 Natl. L.J. B11 (July 8, 2002), noted, “Holmes is likely to limit the availability of Federal Circuit review and permit forum shopping, and both results may return the state of patent law to that existing before the Federal Circuit’s creation, a situation in which the diversity in the application of the patent laws reduced the value of patents.” *Id.*

⁴⁵² Henry Grabowski & John Vernon, *Longer Patents for Increased Generic Competition in the US*, 10 Supp. 2 PharmacoEconomics 110, 122 (1996). This quote continues that, although the length of patent protection is very important, it was subject to “significant diminishing returns as one extended patents to [what was at the time of the study] the full nominal life of 17 years [from the date of issuance of a patent].” *Id.* (Now, patent terms expire 20 years from the date of filing. 35 U.S.C. § 154(a)(2)). The authors also found that drug product lifetimes had shortened due to “increased price sensitivity in the pharmaceutical market because of managed care, as well as increased availability of substitute therapies and generic competitors for major brand name products.” *Id.* at 121-22. Nonetheless, these economists’ ultimate recommendation in the paper which is to consider increasing patent term restoration possibilities, effectively extending the patent term. *Id.* at 122.

⁴⁵³ 35 U.S.C. § 156(a).

⁴⁵⁴ As noted by Grabowski & Vernon, *supra* n. 452, at 121: “The Act has clearly led to

consider increasing the term of exclusivity for new drugs:

The European Community recently enacted patent restoration and data exclusivity policies for pharmaceuticals. The new European Community law resembles the US law in many respects. As in the US, patent term restoration is subject to a cap of 5 years. In addition, patents cannot be extended beyond an effective life of 15 years (compared with 14 years in the US). However, in one very important respect the European Community law has a more favorable incentive for drug innovation. Patent time lost during the clinical development period in the European Community is eligible for 100 % restoration versus 50 % in the US. The differential treatment of patent time lost during clinical testing produces unintended distortions in patent term extensions. This is currently a particularly relevant policy issue because clinical development periods have been increasing for recent US drug introductions, while NDA approval times have been declining. Another major difference between the US and the European Community is that the latter has a data exclusivity period of 6 to 10 years.

From the standpoint of societal welfare, it is also especially important that research and development projects capable of producing medical breakthroughs be encouraged. An undesirable feature of the current US rules on patent term restoration is that breakthrough products subject to very high risks and above-average expected development periods will end up with below-average effective patent lives (other factors being equal). This is another undesirable consequence of the fact that patent time lost in the development period is eligible for only 50 percent credit in the US. Hence, this provision of the 1984 Act warrants particular attention by Congress when it considers revisions in the patent restoration law. We believe that US legislators should also consider an increase in the minimum period of protection such new drugs enjoy against generic competition. This should be done in the light of the changing economics of the drug innovation process over the past decade, including those emanating from the generic competition section of the 1984 Waxman-Hatch Act. (Footnotes omitted).⁴⁵⁵

Despite this suggestion of Grabowski and Vernon, the recent Hatch-Waxman reforms made no adjustments to the patent restoration period. On the contrary, when considering the Medicare Reform Legislation reforms in their entirety (i.e., the Hatch-Waxman reforms together with the Medicare prescription drug benefit, and the potential importation provisions), these reforms have put even stronger downward pressure on the price of pharmaceuticals, and thus the revenues available to innovative companies to reinvest in research and development. Even the Hatch-Waxman reforms in

significant patent extensions on recent new drug introductions. For example, the average effective patent life for new drugs coming to the market in the 1991 to 1993 period was 11.8 years, with an average extension of 2.3 years. Moreover, 43% of these NCEs had effective patent lives of 14 years or more (14 years is the upper limit for extensions under the Act)."

⁴⁵⁵ *Id.* at 122. The author has made similar suggestions in a previous article. *See generally* Derzko II, *supra* n. 447.

the Medicare Reform Legislation together with the new FDA patent listing regulations⁴⁵⁶ should lead to faster generic drug entry and lower drug prices by eliminating strategic behavior.

In more recent writing, Grabowski considered “the role and impact of patents and intellectual property protection in the discovery and development of new pharmaceutical and biotechnical products”⁴⁵⁷ and concluded that “[a]n important implication for public policy is that reimbursement, regulatory or patent policies that target the returns to the largest selling pharmaceuticals can have significant adverse consequences for R&D incentives in this industry.”⁴⁵⁸ As to amendments to the Hatch-Waxman scheme, Grabowski suggests “[i]mprovements on the margin,” such as providing “a longer minimum exclusivity period before an ANDA could be filed for new drug introductions” since Europe and Japan have longer exclusivity periods than the 5 years provided in the United States.⁴⁵⁹ Moreover, he discouraged altering or eliminating any patent restoration aspects of the law to accelerate generic competition.⁴⁶⁰ Grabowski’s first recommendation is very interesting given the fact that innovative companies have indicated current exclusivity periods available in the United States (i.e., the periods during which the FDA cannot approve a generic drug) have not proved particularly helpful for them in terms of protection for their innovation investment.⁴⁶¹

The failure of the recent reforms to the Hatch-Waxman Act to address the findings and recommendations of these economists could negatively impact future pharmaceutical innovation. In 2003, prior to the Hatch-Waxman reforms being implemented, Grabowski seemed to think that Hatch-Waxman was well balanced.⁴⁶² However, in the post-reform Hatch-

⁴⁵⁶ 68 Fed. Reg. 36676 (June 18, 2003); see generally *infra* § V.1; 21 U.S.C. § 314.53.

⁴⁵⁷ Henry Grabowski, *Pharmaceuticals: Politics, Policy and Availability: Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 8 Geo. Pub. Policy Rev. 7, 8 (2003).

⁴⁵⁸ *Id.* at 19.

⁴⁵⁹ *Id.* at 20.

⁴⁶⁰ *Id.*

⁴⁶¹ Kuhlik notes that, “[t]he five-year and three-year data exclusivity periods [available under the FDC Act] have proven to be of relatively limited importance as compared to patents. In most cases, the five-year period will expire before the basic composition-of-matter patent.” Kuhlik, *supra* n. 34, at 98.

⁴⁶² That is, in 2003 before the recent changes in the Hatch-Waxman scheme, Grabowski found that “the law has provided a reasonably well structured system of incentives for both innovative and generic firms. Both R&D investments and generic utilization have increased dramatically in the period since the passage, consistent with the objectives of

Waxman universe, there is a legitimate concern whether this balance will remain.

Whether such a balance will remain is particularly questionable when one factors in that research and development costs are increasing.⁴⁶³ In addition, not only must an innovative pharmaceutical company pay for the drug development costs of the drug that ends up finally going to market, but also must pay for all of the failed attempts. As noted by Grabowski, “only the top three deciles of new drug introductions have present values that exceed average R&D costs.”⁴⁶⁴ This means:

[T]he search for blockbuster drugs is what drives the R&D process in pharmaceuticals. The median new drug introduction does not cover average R&D costs (including allocations for the cost of discovery and the candidates that fall by the wayside). A few top-selling drugs are key in terms of achieving economic success in pharmaceutical R&D over the long run. The large fixed costs of pharmaceutical development and the skewed distribution of outcomes help to explain the clustering of biotech firms at the research stage of the R&D process and the large number of alliances between biotech and big pharmaceutical firms at the development and marketing stages.⁴⁶⁵

Recently, “development costs for all drugs, from lab to FDA approval” have been pegged at an average of \$802 million per drug.⁴⁶⁶ Consequently, there is reason to believe that there will be less money available to pharmaceutical companies to invest in research and development, potentially resulting in a slower rate of new drug innovation. This includes less money to invest in partnerships with biotech companies, most of which would require the pharmaceutical company to make a substantial investment to shuttle a potentially promising drug through the clinical development phase of drug research. Moreover, “[a]lthough the term of a patent is twenty years from filing, the effective patent life for pharmaceuticals—the time remaining following FDA approval—is

the [A]ct.” Grabowski, *supra* n. 457, at 20.

⁴⁶³ The Boston Consulting Group, *Sustaining Innovation in U.S. Pharmaceuticals—Intellectual Property Protection and The Role of Patents*, 37-38 (Jan. 1996). Moreover, Grabowski noted that the length of clinical trials for more recent introductions is much greater than for earlier introductions and concluded that “the experience with respect to development times parallels the experience observed with respect to success rates.” Grabowski, *supra* n. 457, at 15. Specifically, “the cohort of 2000-2001 new biopharmaceutical introductions had a total clinical development time (including FDA approval) of 86 months, versus 53.2 months for 1982-1989 biopharmaceutical introductions.” *Id.* Such longer clinical trials can lead to greater R&D costs.

⁴⁶⁴ Grabowski, *supra* n. 457, at 17.

⁴⁶⁵ *Id.* at 17-18.

⁴⁶⁶ See Hopkins, *supra* n. 440; see also Grabowski, *supra* n. 457, at 17-18.

approximately eleven to twelve years in practice.”⁴⁶⁷ However, “[e]ffective patent life for other industries averages approximately 18.5 years.”⁴⁶⁸

Some people might say that the effect of the Hatch-Waxman reforms on pharmaceutical development could be very positive. For example, pharmaceutical industry critics point out that the pharmaceutical industry has historically been found to be the most profitable in the country.⁴⁶⁹ In addition, critics have noted that promotional spending is growing faster than spending on research and development, and have suggested that pharmaceutical companies’ marketing activities are often misleading.⁴⁷⁰ Moreover, an increasing number of court challenges as to unfair pricing strategies undertaken by innovative companies have been commenced.⁴⁷¹ Therefore, such critics might think that the Hatch-Waxman reforms together with other changes in the pharmaceutical industry might finally keep this

⁴⁶⁷ Kuhlik, *supra* n. 34, at 96-97. In this article, Bruce Kuhlik, Senior Vice President and General Counsel of the Pharmaceutical Research and Manufacturers of America (PhRMA), the main trade organization for innovative pharmaceutical companies, offers a stark exposition of the state of the innovative pharmaceutical industry, including an explanation of why the current status of the pharmaceutical patent and pricing schemes make it very difficult to recoup the costs of developing a new drug. *Id.* Kuhlik also expressed words of caution about allowing drug importation from Canada and elsewhere, since drug importation would also effect foreign drug price controls. *Id.* at 108. This, Kuhlik said, would even further “undermine the returns necessary for innovation.” *Id.* According to Pfizer’s chief financial officer, David Shedlarz, the risk of U.S. price controls on prescription drugs is increasing but could be lessened if federal trade officials successfully challenged the protection that Canada and countries in Europe provide to generic drugs. Ransdell Pierson, Yahoo!Business, *Pfizer Urges Trade Fight Versus Protected Generics*, <http://in.news.yahoo.com/040628/137/2eo36.html> ¶ 1 (updated June 28, 2004). Accordingly, Shedlarz has urged the U.S. to raise this point as a trade issue. *Id.* at ¶ 10. Moreover, an Ernst & Young study has noted that price controls are “virtually inevitable within the next few years, unless U.S. drug makers take steps to moderate their prices.” *Id.* at ¶ 4. This Ernst & Young study recommends gradually lowering the prices in the United States and raising them elsewhere in the world since “the current pricing model is simply unsustainable.” Juliann Walsh & Nicole Ostrow, *Drugmakers Should Cut Prices Before Laws, Report Says*, Bloomberg News (June 24, 2004).

⁴⁶⁸ Kuhlik, *supra* n. 34, at 97.

⁴⁶⁹ See e.g. *Pharmaceutical Industry Remains Most Profitable in the Country*, Public Citizen (Apr. 12, 2001) (available at <http://www.citizen.org/pressroom/release.cfm?ID=610>) (accessed Dec. 26, 2004).

⁴⁷⁰ David Pauly, *Drug Companies’ Cost of Pushing Pills Rivals R&D*, Bloomberg Markets (Aug. 26, 2004).

⁴⁷¹ *Id.*; see e.g. Hagens Berman, *Average Wholesale Price Drug Class Action Litigation Filed September 6, 2002*, http://www.hagens-berman.com/average_wholesale_price_drug_litigation (accessed Dec. 26, 2004).

lucrative industry in line.

Scherer suggests, however, that the picture that is painted of the pharmaceutical industry by critics may not be complete. For example, he indicates that “[i]n 2002, Big Pharma companies devoted 18 percent of their sales revenue to research, development, and testing activities.”⁴⁷² Moreover, Scherer responds as follows to the critics noting the extraordinary profitability of the pharmaceutical industry:

Year after year, the pharmaceutical industry has ranked at or near the top of *Fortune* magazine’s annual list of the most profitable American industries, which are rated in terms of accounting returns as a percentage of either stockholders’ equity or total assets. But here, too, there is an element of fallacy. Under standard accounting practice, outlays for research and development are written off in the year they occur. But, in fact, such expenditures are an investment, yielding fruit many years after they are incurred. They ought, in principle, to be included in the company’s assets and then depreciated over an appropriate time period. When they are not, the capital base to which profits are related in standard measures tends to be undervalued, and percentage returns on that capital base are overstated. A government study found that, when appropriate corrections were made, the true returns on investment by the pharmaceutical industry during the 1980s were only 2 to 3 percent higher, on average, than “normal” competitive rates of return, which were estimated to average roughly 10 percent (excluding the effects of inflation). This differential of 2 to 3 percent might have been attributable, at least in part, to technological risks not readily avoided through the portfolio strategies available to financial market investors. Whether the differential has remained within that range in recent years has not been tested by broadly accepted analyses.⁴⁷³

Thirdly, Scherer explains that “as drug prices rise or the difference between drug sales revenues and production costs increases, research-and-development outlay also tend to rise relative to their trend; as drug prices fall, so in tandem do research-and-development outlays.”⁴⁷⁴

Additionally, the Hatch-Waxman reforms may be seen as positive because such reforms (and particularly the inability to obtain multiple 30 month stays) could dampen the incentives that innovative companies have previously had to evergreen their patents.⁴⁷⁵ In theory, this may translate into less interest among innovators in refining existing drugs by improving, for example, the drug delivery, dosage forms, or side-effect profiles of a known drug, such that more effort can be put into research on entirely new drug

⁴⁷² F.M. Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351(9) *New Eng. J. Med.* 927, 927 (Aug. 26, 2004).

⁴⁷³ *Id.* at 929.

⁴⁷⁴ *Id.*; see also F.M. Scherer, *The Link Between Gross Profitability and Pharmaceutical R&D Spending*, 20(5) *Health Affairs* 216 (Sept./Oct. 2001).

⁴⁷⁵ See e.g. Mahn, *supra* nn. 105-109 and accompanying text.

concepts and families.

Yet, it seems undeniable that there will be a smaller pool of revenue available to innovative companies to invest in research and development as a result of the recent reforms to the Hatch-Waxman provisions. This may well lead to a lower rate of drug development. Those critical of innovative companies likely would take the position that the reduction of their revenue streams should not cause problems since it will force the companies to transfer reinvested revenues from marketing (which these critics think, as noted before, innovative companies spend too much money on anyway) to research and development.

Another point of view is that innovative companies' marketing expenditures are necessary to remain competitive in the marketplace and to keep both physicians and consumers informed of the availability of various beneficial drugs. If companies market too much, or if the marketing is misleading, rather than cut revenues for pharmaceutical industries, a more appropriate policy approach may be to impose strict regulations on the type and extent of marketing that a pharmaceutical company may undertake or to otherwise regulate the amount of marketing by such companies. Moreover, if future economic indicators show less research and development investment and fewer new drugs emerging from the R&D pipeline, then Congress may wish to take the earlier-mentioned advice provided by Grabowski and Vernon into consideration and implement some further patent term extension reforms.⁴⁷⁶

A scheme that the author would recommend is one in which the patent could be further extended beyond what the current law allows for a specified additional period of time that would make economic sense. This mechanism would provide further adjustments to the patent term policy lever that was initially adjusted somewhat in the original Hatch-Waxman legislation but also would be sensitive to the need for price reductions on drugs for which patent protection is nearing the end of its term.

For discussion purposes, we might assume an extension of 4 years. However, for every additional year of patent term extension, the price of the pharmaceutical would have to be reduced by a specified amount. This specified amount would be calculated by taking the difference between the price of the drug under patent and the likely price of the drug upon patent expiry, and reducing the price gradually within the extended period so that, by the end of the extension period, the price of the drug reaches the approximate price that it would be sold at upon patent expiry. So, for example, for an additional 4-year extension, the price of the drug would have

⁴⁷⁶ This would seem to be more important than extending the FDA exclusivity provisions, which drug companies seem to rely on less. See Pauly, *supra* n. 470.

to drop by 25 percent of the difference between the patent price and the expired patent price each year. Moreover, to obtain the additional patent term extension, the scheme could require the pharmaceutical company to invest all or most of the monies received from the drug into research and development expenditures. When making an application for such a patent term extension, the innovative drug company applicant could be required to set forth the pricing of the drug over the period of the extension, and certify that a specified percentage of the revenues from the drug would be reinvested into future research and development projects rather than, for example, into marketing. This scheme would allow for drug prices to go down over time but would also give additional money to innovative companies to invest in further research and development efforts. Such a scaled reduction in drug prices might also discourage the fierce battles that have occurred in the past when innovative drugs would go off patent, as we have seen earlier in this article.

Some observers may argue that a price reduction scheme over a patent term extension will not work in practice because it is so difficult to ascertain the price of pharmaceutical drugs.⁴⁷⁷ While this may be true, it is the author's understanding that such a scheme exists in Japan for pharmaceuticals, albeit with the government being the main, if not only, purchaser of drugs, thus making it easier to peg the price at a certain value.⁴⁷⁸ Since direct bargaining between government and pharmaceutical companies is prohibited pursuant to the Medicare Reform Legislation,⁴⁷⁹ the Japanese scheme could not be implemented here. However, the certification method alluded to above could require, under the threat of stiff civil or criminal penalties as with Orange Book patent listings, that pharmaceutical companies establish a fair declining price scheme, with the revenue going into research and development. A fair price might be the average or median price of the various prices under which prescription drugs are sold, from the price of a drug available to the uninsured population to the price of the drug as set by Hospital Management Organizations (HMOs), Pharmaceutical Benefit Managers (PBMs) and the Medicare/Medicaid schemes. Such a certification could be submitted to a special committee formed under the auspices of two government agencies—the U.S. Patent and Trademark Office and the Food and Drug Administration.

⁴⁷⁷ See e.g. Patricia Simms, *Attorney General Sues 20 Drug Firms; Suit Is Over Pricing Practices, and Lautenschlager Says She's Negotiating with Four of the Companies*, Wis. St. J. A1 (June 4, 2004) (describing the AWP litigation).

⁴⁷⁸ Anecdotal evidence provided by Prof. Harold Edgar of Columbia University on Aug. 2, 2004.

⁴⁷⁹ See generally 117 Stat. at 2066.

However, if such a declining pricing scheme over a patent term extension is considered inoperable, another option might be to establish a tax that increases over the time of the extension term, imposed on innovative companies' revenues from the sale of the particular drug covered by the patent being extended. The tax revenue from such a scheme could go into various medical expenditures for society's benefit. The remainder of the pharmaceutical company's revenue could be required to go into research and development. However, this approach is not preferred since the price of the drug will not necessarily decline, which was the whole point of suggesting a declining pricing scheme over an extension period in the first place. Moreover, it is hard to ensure that the tax revenue will, in fact, go into the appropriate expenditures.

Of course, there are other ways that society could address a low rate of drug development. For example, one alternative is to have the government do the research funded through taxation. In this type of scheme, there would not be two categories of pharmaceutical companies (i.e., innovators and generics), since all drug companies would simply be charged with the task of delivering a quality pharmaceutical product based on the research and development conducted by the government. However, the question is whether such a scheme is likely to be effective. It does not seem that the government would have the expertise to engage in the complicated research and development tasks, including developing and administering clinical trials to test new drug candidates that look promising based on laboratory testing results. Moreover, there is no guarantee that the government could conduct such research and development activities more cheaply and honestly than an innovative drug company.

Kenneth Dam indicates that another alternative to the competitive innovation that occurs pursuant to the patent system might be for a "government agency [to] simply contract, after competitive bidding, for delivery of a yet-to-be-discovered drug with specified desirable medicinal properties."⁴⁸⁰ However, Dam noted that:

[C]ompetitive bidding suffers from two possible infirmities in innovation situations: the difficulty of defining exactly what it is that is to be allocated exclusively (since we cannot easily define an invention before it has occurred), and the likelihood of a great deal of rent seeking in the form of efforts to influence governmental choice (witness defense contracting in the United States). Hence, when we consider the alternatives, it seems unwise to condemn competitive R & D as undesirable rent seeking.⁴⁸¹

⁴⁸⁰ Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. Leg. Stud. 247, 263 (1994).

⁴⁸¹ *Id.* at 264. In his article, Kenneth Dam explained that, although a patent should not be

There is another approach that society may decide to take if the Hatch-Waxman reforms do lead to a lower rate of drug development. That approach would be to simply accept a lower rate of drug development and accept that not all of humankind's ailments should be treated by drugs. However, it is hard to imagine a society that would think this way since it is so foreign to our current expectations. For example, when the world was faced with a Severe Acute Respiratory Syndrome (SARS) outbreak in early 2003, the first question that all people had in their minds was whether there was a drug that could fight this infectious disease and, if there was no such drug, how long it might take to develop an antimicrobial drug or a vaccine to combat this deadly disease. Consequently, particularly in the field of infectious disease, a complacent approach could be devastating. The following words, which appeared in the popular press at the turn of the twenty-first century, are telling: "We're in the midst of an escalating arms race within the microbe, and we may be losing."⁴⁸²

Given the importance of developing new antimicrobials and vaccines, an additional option for stimulating beneficial innovation might be to develop specific incentives for this kind of pharmaceutical development.⁴⁸³ Such incentives could be either in the form of patent term extension provisions, or specific exclusivity provisions.⁴⁸⁴ For example, the Orphan

said to create a monopoly since it does not cover significant market power, "many patents, especially those that achieve commercial success, do result in the patentee enjoying economic rent," which is "measured by the difference between the patentee's per-unit costs and competitors' per-unit costs (to the extent attributable to the patented innovation) multiplied by the patentee's volume." *Id.* at 250. Dam further notes that some scholars have described the exercise of seeking economic rents (i.e., rent seeking) as wasteful since such parallel activity among competitors can lead to a waste of scarce resources. *Id.* at 250-52. In the patent context, rent seeking involves "invest[ing] resources to obtain patents (not just in the process of obtaining a patent but also in the research and development to make the invention)." *Id.* at 251. However, Dam does not believe that such patent-related rent seeking should be seen so negatively. *Id.* at 252.

⁴⁸² J. Madeleine Nash, *The Antibiotic Crisis*, 157 TIME 90, 91 (Jan. 15, 2001).

⁴⁸³ For a scientific perspective on the problem, see e.g. Richard P. Wenzel, *The Antibiotic Pipeline—Challenges, Costs, and Values*, 351 New Eng. J. Med. 523-26 (Aug. 5, 2004).

⁴⁸⁴ Such exclusivity provisions may not necessarily be pursuant to the Food, Drug & Cosmetic Act (FDCA). See generally 21 U.S.C. § 301 (2000). Although many antibiotics are regulated as drugs pursuant to the FDCA, vaccines and some antibiotics are regulated as biologics under a completely different statutory scheme, namely, the Biologics Act or the Public Health Service Act § 351. See 42 U.S.C. § 262 (2000); Hutt & Merrill, *supra* n. 7, at 521-22, 663-64; see also *FDA Action on Applications and Abbreviated Applications*, 21 C.F.R. § 314.101 (2004); see generally 59 Fed. Reg. 50338 (Oct. 3, 1994) (distinguishing between antibiotics regulated as drugs and those regulated as biologics). To date, there is no generic system for biologics since it has been thought

Drug Act does provide a 7-year marketing exclusivity period to pharmaceutical companies that develop orphan drugs.⁴⁸⁵ A drug is “an ‘orphan drug’ if it is for a ‘rare disease or condition’ that affects fewer than 200,000 patients in the United States or for which there is no reasonable expectation that the cost of developing the drug for a disease will be recovered from sales in the United States.”⁴⁸⁶

Other similar exclusivity provisions also exist in the Food, Drug and Cosmetic Act. For example, Congress introduced the 180-day period of exclusivity⁴⁸⁷ for ANDA applicants, as well a 5-year new chemical entity exclusivity period,⁴⁸⁸ and a 3-year new data exclusivity period⁴⁸⁹ for NDA applicants pursuant to the Hatch-Waxman Act in 1984. Each of these exclusivity period runs concurrently with any available patent term.⁴⁹⁰ A company may also obtain a pediatric exclusivity period.⁴⁹¹ This is a 6-month marketing exclusivity period that is “granted to all dosage forms and all indications with the same active moiety as the drug studied.”⁴⁹² Unlike the Hatch-Waxman exclusivity periods and the orphan drug exclusivity period, “pediatric exclusivity attaches to the end of all existing marketing exclusivity and patent periods.”⁴⁹³ The pediatric exclusivity periods exists “[a]s an incentive to industry to conduct [pediatric] studies requested by the

impossible to develop bioequivalent generic biologics. See Hutt & Merrill, *supra* n. 7, at 664-65. However, development of a generic scheme for biologics is likely to become the next battleground between innovative companies and generic companies. See e.g. FDA, *Generic Pharmaceutical Association Materials for January 30, 2002*, http://www.fda.gov/cder/ogd/GPHA_Jan_21.htm (accessed October 28, 2004) (describing a meeting in which this association urged the FDA to approve generic biologics NDAs).

⁴⁸⁵ This is provided in the *Orphan Drug Act*, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended in various sections of 21 U.S.C. and 42 U.S.C.). The 7-year Orphan Drug Exclusivity is specifically provided at 21 U.S.C. § 360cc (1994 and Supp. III. 1997).

⁴⁸⁶ Robert A. Bohrer & John T. Prince, *A Tale of Two Proteins: The FDA's Uncertain Interpretation of the Orphan Drug Act*, 12 Harv. J.L. & Tech. 365, 369 (1999).

⁴⁸⁷ 21 U.S.C.A. § 355(j)(5)(b)(iv).

⁴⁸⁸ *Id.* at §§ 355(c)(3)(D)(ii), (j)(F)(ii).

⁴⁸⁹ *Id.* at §§ 355(c)(3)(D)(iii-iv), (j)(F)(iii)-(iv).

⁴⁹⁰ See U.S. Food & Drug Administration Center for Drug Evaluation & Research, *Frequently Asked Questions on Pediatric Exclusivity (505A), The Pediatric “Rule,” and Their Interaction*, Answer to Question 10, <http://www.fda.gov/cder/pediatric/faqs.htm> (accessed Dec. 29, 2004).

⁴⁹¹ 21 U.S.C.A. § 355(a).

⁴⁹² *Id.*

⁴⁹³ *Id.*

[FDA].”⁴⁹⁴

An exclusivity period similar to any of the exclusivity periods discussed above might be introduced to encourage innovative companies to develop new antimicrobials and vaccines. For example, an exclusivity period for this purpose could be established that would not extend any patent terms, but would provide marketing exclusivity to the innovative company by preventing the FDA from approving any generic drug that is a copy of the drug during the exclusivity period. The exclusivity period could run concurrently with the patent term and would not commence until the FDA were to approve the new antimicrobial or vaccine. Such an exclusivity period would provide a further means by which to introduce fine structure in the United States’ innovation incentives regime to encourage particularly desirable innovation activities that may be difficult to introduce in the context of the U.S. Patent Act.⁴⁹⁵

VII. CONCLUDING REMARKS

After laying out the Hatch-Waxman scheme that defines the pharmaceutical industry and particularly the interactions between innovative and generic companies, this article chronicled the various examples of strategic behavior that have arisen under that scheme, and the consequences resulting therefrom. Thereafter, this article reviewed and analyzed the reforms that have arisen as a result of such strategic and sometimes anticompetitive behavior, both in terms of their ability to curtail this undesirable behavior in the future and accelerate or at least facilitate generic drug entry, as well as in terms of the impact of such reforms on another important consideration pursuant to the Hatch-Waxman scheme, namely, the rate of future pharmaceutical innovation.

In conclusion, when evaluating the intended consequences of the Hatch-Waxman reforms, this article finds that the reforms are generally positive in that they remove possibilities for wasteful gamesmanship in the system and facilitate the processes allowing for generic drug entry, true to

⁴⁹⁴ *Id.* (under the heading “Exclusivity”).

⁴⁹⁵ The importance of implementing patent law in a nuanced fashion to further technology policy in specific areas of technology is discussed more broadly in Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575 (2003). One of the reasons that such fine structure might be hard to introduce in the Patent Act is that Article 27(1) of the overarching international intellectual property law agreement called the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) does not allow discrimination in patent protection amongst different technologies. *Agreement on Trade-Related Aspects of Intellectual Property Rights* art. 27, 108 Stat. 4809 (Apr. 15, 1994).

the spirit of the original Hatch-Waxman scheme. However, this article provides a more negative evaluation of the unintended consequences of the reformed Hatch-Waxman scheme, from the perspective of encouraging innovation. True, the reformed scheme may move innovative resources away from improvements of existing drugs into completely new areas of pharmaceutical research, and should help clear the marketplace of invalid patents that are hampering pharmaceutical innovation. However, the continued downward pressure on the prices of innovative pharmaceuticals will lead to fewer resources for drug development, which may further dampen the pharmaceutical innovation drought that is already being experienced.

As a remedy, this article suggests a system for extending patent exclusivity for a specified additional period of time that makes economic sense. However, the price of the pharmaceutical would have to be reduced gradually within the extended period so that, by the end of the extension period, the price of the drug reaches the approximate price at which it would be sold upon patent expiry. Moreover, to obtain the additional patent term extension, the scheme could require the pharmaceutical company to invest all, or most, of the monies received from the drug into research and development expenditures. In addition, pharmaceutical innovation in the important areas of antimicrobial and vaccine development could be encouraged by introducing an exclusivity period as has been done for pharmaceuticals that are developed to treat orphan diseases. Such transparent innovation incentives are clearly better than the “backdoor” ways of extending exclusivity that became the practice of innovative companies, namely, obtaining multiple 30-month stays on generic drug entry pursuant to extensive Orange Book listings, and filing invalid evergreen patents. Of course, establishing such innovation incentives for yielding an uncertain future benefit does entail an immediate cost for society. This cost comes in the form of higher prices for pharmaceuticals sold exclusively and often under patents by innovative companies. The alternative, however, may be that society will have to accept a substantially slower rate of pharmaceutical innovation.