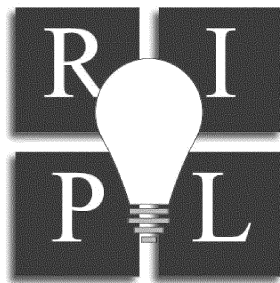


# THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



## DEADLY DELAY / POSTPONED PILLS

CHRISTOPHER R. WALKER

### ABSTRACT

Since 1984, generic pharmaceuticals have continued to grow, and are an important element in our national struggle to increase affordable health care options in the United States. The Hatch-Waxman Act has played a pivotal role in helping to create a regulatory environment that fosters the development of generic pharmaceuticals, thereby increasing access to lower-cost alternatives to more expensive drugs. An important part of balancing the interests of the generic manufacturers against those of the primary pharmaceutical makers is the thirty-month stay provision of the Hatch-Waxman Act. This comment begins by taking a look at the history of the Hatch-Waxman Act and recent reforms to the Hatch-Waxman Act. The comment explores the policy goals of the Act, and some of the abuses that developed once the Act was passed, with a particular focus on the evolution of the thirty-month stay provision of the Hatch-Waxman Act. The comment analyzes recent cases, paying particular attention to the equitable approach taken by the court when lengthening or shortening the stay in response to the various interests the court is seeking to protect. Next, this comment analysis whether or not the Hatch-Waxman Act has met the policy goals it was intended to meet. The comment evaluates the effect the Hatch-Waxman Act had in its general form as contrasted to the current state of affairs in the court, framed within the regulatory duties of the FDA to determine the appropriate direction for future legislation. Additionally, the comment proposes reforms to reestablish balance so that the thirty-month stay provision of the Hatch-Waxman Act is used to maintain patent rights without abusing the rights of others.

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## DEADLY DELAY / POSTPONED PILLS

CHRISTOPHER R. WALKER\*

## INTRODUCTION

The Drug Price Competition and Patent Term Restoration Act of 1984<sup>1</sup> (“the Hatch-Waxman Act” or “the Act”) attempts to strike a balance between the competing policy interests of inducing pioneering research and development of new drugs and enabling production of low-cost, generic copies of those drugs. The Act was a response to the high cost of pharmaceuticals with few lower-costing generic alternatives, and the decision of the Court of Appeals for the Federal Circuit (“Federal Circuit”) decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*<sup>2</sup> Before the enactment of the Hatch-Waxman Act in 1984, a generic pharmaceuticals manufacturer could not begin to make, use, or sell a drug until all of the patents covering the drug had expired, even if that use was related to expediting the availability of generic drugs after the date of the patent’s expiration.<sup>3</sup>

The law functionally lengthened the period of exclusivity of the patent holder, as generic manufacturing and testing were not legal until the actual date of the patent’s expiration.<sup>4</sup> The Pharmaceutical Manufacturers Association (“PMA”) and the Generic Pharmaceutical Industry Association (“GPIA”) had already begun to strike compromises that would incorporate both patent term restoration and expedited generic approval.<sup>5</sup> The Hatch-Waxman Act comprised a series of amendments to the Federal Food, Drug, and Cosmetic Act<sup>6</sup> (“FDCA”) and the Patent Act<sup>7</sup> which

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<sup>1</sup> Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b, 68c, 70b; 21 U.S.C. §§ 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282 (2006)).

<sup>2</sup> 733 F.2d 858, 860 (Fed. Cir. 1984), *superseded by statute*, 21 U.S.C. § 355. The burden placed upon the generic generally discouraged generics from being produced. In this case, in 1983 Bolar became interested in marketing, after the ’053 patent expired, a generic drug equivalent. *Id.* at 860. Since a generic drug’s commercial success is tied to how quickly it is brought on the market after a patent expires, and because approval for an equivalent of an established drug can take more than 2 years, Bolar, did not immediately wait for the ’053 patent to expire. *Id.* Bolar immediately began to obtain federal approval to market its generic version, and Roche filed a complaint to prevent the use of any drug precursor during the life of the ’053 patent. *Id.* Bolar argued that its intended use of the patented product should be excepted from the use prohibition, based on a liberal interpretation of the traditional experimental use exception and/or that public policy favors generic drugs and thus mandates the creation of a new exception in order to allow FDA required drug testing. *Id.* at 862. The court rejected this, and proposed that the legislature should step in. *Id.* at 864.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> Alan D. Lourie, *Patent Term Restoration*, 66 J. PAT. & TRADEMARK OFF. SOC’Y. 526, 533 (1984).

<sup>6</sup> 21 U.S.C. §§ 301, 321, 331–337, 341–363, 371–384, 391–399.

<sup>7</sup> 35 U.S.C. §§ 1–135.

addressed these differences between the PMA and the GPIA.<sup>8</sup> The outlook for pioneer drug manufactures was an increasing concern for PMA, since many popular drugs were losing patent protection.<sup>9</sup> For example, in recent years:

An additional \$24 billion of branded products, . . . will lose their market exclusivity in the top eight markets in 2009, according to IMS Health. This loss of patent protection will contribute to generics sales of more than \$68 billion in 2009, and a 5–7% growth rate, which is similar to the rates in 2008 but lower than the levels experienced in 2006 and 2007.<sup>10</sup>

Since 1984, generics have continued to build market share, and are important factors in increasing affordable health care options.<sup>11</sup> In this comment, Part I provides background information regarding the provisions of the Hatch-Waxman Act, the policy goals of the Act, and some of the abuses that have developed. Part II analyses whether the policy goals of the Hatch-Waxman Act are being met. Part III proposes a modified structure, or ways the courts can seek to reestablish balance so that the thirty-month stay is used to maintain patent rights without abusing the rights of others.

## I. BACKGROUND

### *A. Balancing Interests*

Pioneer drug makers, represented by the PMA, are the drug makers that research and develop drugs for the marketplace.<sup>12</sup> Generic drug makers, represented by the GPIA, develop lower-cost alternatives for existing drugs.<sup>13</sup> In attempting to strike a balance between pioneer drug makers and generics, the Hatch-Waxman Act gives pioneer drug makers an extension to the patent term equal to one-half of the time spent in human clinical trials and the drug application period, for a maximum extension of 5 years.<sup>14</sup> The patent must be listed by the Food and Drug

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<sup>8</sup> 21 U.S.C. § 355; 35 U.S.C. § 271.

<sup>9</sup> See *Global Pharmaceutical Growth Tempered by Lagging US Market*, PHARMATECH.COM, <http://pharmtech.findpharma.com/pharmtech/Global-Pharmaceutical-Growth-Tempered-by-Lagging-U/ArticleStandard/Article/detail/562151> (last visited Sept. 29 2010). While the overall U.S. pharmaceutical field is projected to grow only 1–2% to \$287–297 billion, down from the 2–3%, generics continue to grow, and many blockbuster patents are losing protection. *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> Lourie, *supra* note 5, at 533.

<sup>13</sup> *Id.*

<sup>14</sup> Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 188–90 (1999). For the patent term restoration period, a pioneer receives an extension term equal to one-half of the time of the investigational new drug (“IND”) period—running from the time in which a pioneer can begin human clinical trials—plus the NDA period—the period during the NDA review. *Id.* The maximum extension is five years and the total market exclusivity time cannot exceed fourteen years. *Id.* The length of the exclusivity periods are arbitrary legislative numbers that were not based on any particular

Administration (“FDA”) in its “Approved Drug Products with Therapeutic Equivalence” publication, commonly known as the “Orange Book”.<sup>15</sup> The pioneer manufacturer of a new drug must file a New Drug Application (“NDA”), which requires extensive scientific and clinical proof of the safety and efficacy of that drug prior to approval.<sup>16</sup>

For the generic drug makers, the Hatch-Waxman Act created a regime by which manufacturers who wished to bring a generic version of a drug listed in the Orange Book to market could take advantage of safety and efficacy studies of the listed drug.<sup>17</sup> A generic drug is one that is the “bioequivalent” of the brand-name drug.<sup>18</sup> Before the Hatch-Waxman Act, generic drug makers had to repeat scientific and clinical studies in order to bring the drug to market.<sup>19</sup>

After the Hatch-Waxman Act, the generic drug development process begins by targeting a brand name drug whose patent is going to expire within three to five years.<sup>20</sup> According to the “safe harbor” provision of the Hatch-Waxman Act, a generic manufacturer can make and use pharmaceuticals in violation of a pioneer company’s patent on a drug, as long as that use is reasonably related to obtaining federal approval to market pharmaceutical or veterinary products.<sup>21</sup> The generic

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measuring reference. *Id.* Additionally, Pipeline drugs, which are drug applications pending at the time the Act was passed, received two years or less of exclusivity. *Id.* This was based on the assumption that if they were in a pipeline already, they would be approved in a year or two, so there was no perceived need to give more time. *Id.* Some pipeline drugs have taken eight years for approval. *Id.*

<sup>15</sup> 21 U.S.C. § 355(j)(7)(A) (2006). Approved drugs are listed by the Food and Drug Administration (“FDA”) in its “Approved Drug Products with Therapeutic Equivalence” publication, commonly known as the “Orange Book.” The Orange Book is the industry standard, and is referred to by all parties involved. The Orange Book is produced annually by the FDA, published by the U.S. Government Printing Office. FOOD & DRUG ADMINISTRATION, U.S. DEP’T OF HEALTH & HUMAN SERVS., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (30th ed. 2010), available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>. The Orange Book contains a list of: (1) approved prescription drugs; (2) approved over-the-counter drugs; (3) approved biologics; and (4) products that were approved but had the approval revoked. *Id.*

<sup>16</sup> 21 U.S.C. § 355(b) (requiring that the filing must include “full reports of investigations” regarding safety, efficacy, composition, methods, facilities, packaging, and samples).

<sup>17</sup> Mossinghoff, *supra* note 14, at 190. This reflects one of the major assumptions underlying the Hatch-Waxman Act, which was that duplicates of pioneer drugs would be the same as the pioneer drugs themselves. *Id.*

<sup>18</sup> *Id.* A drug is considered bioequivalent under the Hatch-Waxman Act where:

- (i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same . . . dose . . . ; or
- (ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same . . . dose . . . and the difference from the listed drug in the rate of absorption of the drug is intentional.

21 U.S.C. § 355(j)(8)(B)(i)–(ii).

<sup>19</sup> Roche Products, Inc v. Bolar Pharm. Co., 733 F.2d 858, 860 (Fed. Cir. 1984).

<sup>20</sup> See Richard J. Findlay, *Originator Drug Development*, 54 FOOD & DRUG L.J. 227, 227 (1999).

<sup>21</sup> 35 U.S.C. § 271(e)(1) (protecting uses that are objectively reasonably related to gathering information for FDA submission). This issue has been quite contentious. See *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1280–81 (N.D. Cal. 1991), *aff’d*, 991 F.2d 808 (Fed. Cir. 1993)

manufacturer may develop its version of a drug under the auspices of a “safe harbor,” without fear of being sued by the pioneer company for patent infringement.<sup>22</sup> A generic drug company may then submit an Abbreviated New Drug Application (“ANDA”) to the FDA as long as it has met the statutory criteria.<sup>23</sup>

Some of the statutory criteria an ANDA applicant must demonstrate are that its generic drug has the same active ingredient, its generic drug has the same basic pharmacokinetics, and its generic drug is bioequivalent to the pioneer drug.<sup>24</sup> Importantly, the applicant must certify that “to the best of his knowledge,” (1) there has been no patent filed for the drug; (2) that a patent has expired; (3) that the patent will expire on a certain date; or (4) that the patent is invalid or will not be infringed by the new drug for which the application has been submitted.<sup>25</sup> The four types of certifications have different windows for activation.<sup>26</sup> A paragraph I or II certification is effective immediately.<sup>27</sup> A paragraph III certification is effective when the other patent expires.<sup>28</sup> Similar to the paragraph I and II certifications, a paragraph IV certification is effective immediately.<sup>29</sup> Once the ANDA is approved, the generic manufacturer may begin commercially marketing its generic equivalent.<sup>30</sup>

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(inferring that the phrase “reasonably related” as used in § 271(e)(1) reflects Congress’ acknowledgement that it will often be unclear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, will be required to win that agency’s approval). Therefore, “Congress used this phrase to communicate its intention that the courts give parties some latitude in making judgments about the nature and extent of the otherwise infringing activities they would engage in as they sought to develop information to satisfy the FDA.” *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *See* 21 U.S.C. § 355(j)(2)(A)(ii)-(iv) (recognizing that any person may file with the Secretary an abbreviated application for the approval of a new drug, and the application must adhere to all statutory regulations and requirements). Some of the more important requirements relate to the nature of the active ingredient, the number of active ingredients, the route of administration, the dosage form, and the strength of the drug. *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.* § 355(j)(2)(A)(vii)-(viii).

[A] certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug . . . is required to be filed . . .

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . or . . . for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

*Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Id.* § 355(j)(5)(B)(i).

<sup>28</sup> *Id.* § 355(j)(5)(B)(ii).

<sup>29</sup> *Id.* § 355(j)(5)(B)(iii).

<sup>30</sup> *See* 21 U.S.C. § 355(a).

A major issue during negotiations of the Hatch-Waxman legislation involved paragraph IV certifications.<sup>31</sup> A paragraph IV certification is considered an infringement against the patented drug if the patent is valid.<sup>32</sup> If the patent holder chooses to bring an infringement action, the ANDA is immediately suspended.<sup>33</sup> There was a question as to how long the FDA would issue a stay before approving the generics for marketing if a generic company said the patent was invalid or not infringed.<sup>34</sup> The purpose of the stay, which is a delay in granting the ANDA, is to protect NDA holders with valid drug patents.<sup>35</sup> The stay was determined to be

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<sup>31</sup> Mossinghoff, *supra* note 14, at 190. The court wanted to emphasize the fact that the ANDA could not be approved, but the court could approve the times when an ANDA may be made effective if the FDA approved the ANDA. *Id.*

<sup>32</sup> 35 U.S.C. § 271(e)(2)(A) (2006).

It shall be an act of infringement to submit . . . an application under section 505(j) . . . or described in section 505(b)(2) of [21 U.S.C. § 355(b)(2)] for a drug claimed in a patent or the use of which is claimed in a patent . . . .

...  
 [I]f the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

*Id.* § 271(e)(2).

<sup>33</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>34</sup> Mossinghoff, *supra* note 14, at 190. Throughout much of the debate, the stay was eighteen months. H.R. REP. NO. 98-857, pt. 1, at 27 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2660. However, through the work of the research industry, that time period was changed to thirty months. *Id.* This is due to the nature of the give and take on the part of both the Pharmaceutical Manufacturers Association (“PMA”) and the Generic Pharmaceutical Industry Association (“GPIA”). *Id.* Congress did believe that it was important to promote the creation of new drugs, therefore the desires of the PMA were very important. *Id.* The provision for a stay was added by the Committee on Energy and Commerce to accommodate the competing interests, where PMA was willing to compromise on sections of the bill relating to ANDAs in exchange for “greater protection of existing human pharmaceutical patents,” while GPIA was originally willing to “live with an eighteen-month rule because of other provisions of the bill.” *Id.* at 10; *see also* Mylan Pharm., Inc. v. Shalala, 81 F. Supp. 2d 30, 40 (D.D.C. 2000) (“In introducing the amendment on the Senate floor, Senator Hatch stated in like terms that extending the stay period from 18 to 30 months ‘increases the likelihood that the litigation will be concluded within the time period during which ANDA’s are not allowed.’”).

The legislative history reveals that the stay was extended from 18 to 30 months not at the request of the generic drug companies who feared losing their 180-day exclusivity, but at the urging of the brand-name drug companies who sought to protect their own market share. As Congressman Waxman explained in greater detail:

What the 18-month or thirty-month issue deals with is, should not the litigation be resolved, at what point would we allow the generic manufacturer to go on the market with the generic product anyway. The thirty-month period is one that gave further assurance to the brand-name drug manufacturer that the generic drug manufacturer would not put his competitor on the market until that court decision came through.

*Id.* at 41. (citation omitted).

<sup>35</sup> H.R. REP. NO. 98-857, pt. 1, at 28. The stay protects the pioneer patent holder, or NDA, by allowing the patent holder to sue the ANDA applicant for infringement before the generic enters the market. *Id.* The congressional committee reported that this procedure fairly balances the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights



thirty-months to allow for litigation.<sup>36</sup> After a generic company files for an ANDA after determining that the patent is invalid or not infringed, it has to immediately notify the patent owner, who has forty-five days in which to file an infringement action and then another thirty-months of exclusivity before an ANDA can be approved.<sup>37</sup> The thirty-month stay continues until: (1) the court determines that there is no infringement; (2) the court determines that there is infringement, in which case the suspension ends when the patent expires; or (3) the passing of thirty-months after the date the patent owner received notice, subject to the court's discretion.<sup>38</sup> It is highly unusual to receive a decision earlier than the thirty-month period.<sup>39</sup>

If no legal challenges are presented, the generic drug approval process would take approximately three to five years.<sup>40</sup> Once the FDA has approved an ANDA, the generic drug company has a 180-day period of exclusivity whereby no other generic company can market the generic version of the drug.<sup>41</sup> This 180 day period of exclusivity is triggered by the earlier of either: (1) the day the applicant commences marketing the drug ("the commercial marketing trigger") or (2) the date of "a decision of a court" in a patent infringement suit holding that the patent which is the subject of the certification is invalid or not infringed.<sup>42</sup> This grants market exclusivity to the first applicant to file a paragraph IV ANDA on a particular drug listed in the Orange Book.<sup>43</sup>

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of third parties to contest the validity of a patent or to market a product which they believe is not claimed by the patent. *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>38</sup> *Id.* § 355(j)(5)(B)(iii)(I)-(III).

<sup>39</sup> Mossinghoff, *supra* note 12, at 189–90.

<sup>40</sup> Richard J. Findlay, *Symposium Issue—Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act: Originator Drug Development*, 54 FOOD & DRUG L.J. 227, 229 (1999). The timeline for a generic company is much shorter for two reasons: (1) the company is targeting a defined product that has been on the market for some time, (2) the dynamics of the compound under study are well known. *Id.* To say that it only takes three to five years is "understating the case," because generic companies often begin preparations to produce a drug about seven years before the patent expires or exclusivity ends. *Id.* Once the period ends, the generic company would then be free to market the product without concern of infringement. *Id.*

<sup>41</sup> 21 U.S.C. § 355(j)(5)(B)(iv); *see also* Mylan Pharm., Inc. v. Shalala, 81 F. Supp. 2d 30, 32–33 (D.D.C. 2000) (holding that the 180-day exclusivity period was not contingent on the existence of litigation with the NDA holder).

Clause (iv) of *section 355(j)(5)(B)(iv)* states that the first ANDA applicant's 180-day exclusivity is triggered on the earlier of the date that the Secretary receives notice of the first commercial marketing of the drug or 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."

*Id.* at 36 (quoting 21 U.S.C. § 355(j)(5)(B)(iv)). The essential question is "whether an appealed district court decision finding the patent at issue to be invalid or not infringed unambiguously qualifies as 'a decision of a court' under the statute." *Id.* The court found that it was 'a decision of the court,' and based on this finding, granted a declaratory judgment. *Id.* at 47. Based on the equities of the case, however, the court denied a preliminary injunction. *Id.*

<sup>42</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>43</sup> 21 U.S.C. § 355(j)(5)(B)(iv). *See* Representative Henry Waxman, Speech at the Generic Pharmaceutical Association's First Annual Policy Conference: Securing the Future of Affordable Medicine (Sept. 20, 2005), *available at* <http://www.waxman.house.gov/News/DocumentSingle.aspx?DocumentID=116533>. The simple purpose of the exclusivity period is to

### *B. Becoming Unbalanced Again*

The automatic thirty-month stay can be a powerful tool for pioneer drug companies because a pioneer drug company only needs to state a cause of action for infringement for the stay to take effect.<sup>44</sup> The true power of the thirty-month stay is the fact that the patentee can be granted an automatic injunction for any claim, no matter the strength of the claim, which can be abusive to the ANDA filer.<sup>45</sup> The fact that there could be multiple consecutive thirty-month stays automatically imposed on an ANDA was a source of even more abuse.<sup>46</sup> In July 2002, the Federal Trade Commission (“FTC”) issued a study of the pharmaceutical industry (“FTC Study”) in which it recommended, among other things, that the Hatch-Waxman laws be amended so that only one automatic thirty-month stay be provided to pioneer pharmaceutical companies.<sup>47</sup> The FTC opined that “permitting only one thirty-month stay per drug product per ANDA should eliminate most of the potential for improper Orange Book listings to generate unwarranted thirty-month stays.”<sup>48</sup> As a result, the FDA adopted new patent listing regulations.<sup>49</sup> Accordingly, the final rule also states that there is only one opportunity for a thirty-month stay in the approval date of each ANDA application.<sup>50</sup> The final rule will make the patent submission and listing process more efficient as well as enhance the ANDA application approval processes.<sup>51</sup>

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encourage Paragraph IV challenges by rewarding the first filing applicant—“in exchange for undertaking the costs and risks of patent litigation, the successful challenger is given [six] months of marketing without any other generic competition.” *Id.* The purpose of the legislation is to encourage generic drug manufactures to challenge patents. *Id.* The exclusivity period is very valuable to generic manufacturers because they can sell their product at a price significantly higher than they could if multiple generics were on the market. Joseph H. Meltzer, Terence S. Ziegler, & Casandra A. Murphy, *Fighting the High Cost of Health Care*, TRIAL, Oct. 2007, at 55. Studies have found that the first generic competitor enters the market at seventy to eighty percent of the pioneer drug company’s price. *Id.*

<sup>44</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>45</sup> Natalie Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165, 176 (2005). This was one of the major problems generic companies had with the original Hatch-Waxman Act. *Id.* Additionally, because the thirty-month stay was so easy to get, there was a large incentive for pioneer drug manufactures to list any patent at all. *Id.*

<sup>46</sup> *Id.* An example is *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003), where Apotex filed an ANDA pertaining to SmithKline Beecham Corporation’s antidepressant drug, Paxil. Due to three patent listings by SmithKline, three consecutive thirty-month stays were automatically imposed on FDA approval of Apotex’s ANDA. *Id.*

<sup>47</sup> FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, at i (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

<sup>48</sup> *Id.* at v.

<sup>49</sup> 21 C.F.R. § 314 (2010). In issuing these regulations, the FDA was motivated by the fact that prior FDA regulations led to multiple thirty-month stays which delayed generic drug entry—a consequence not intended either by Congress or the FDA. Notice of Adoption of Final Rule on Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,676 (June 18, 2003). Additionally, 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. *Id.* Permitted listings would include patents on active ingredients, drug formulations, and uses of a drug. *Id.*

<sup>50</sup> 21 C.F.R. § 314.

<sup>51</sup> Notice of Adoption of Final Rule on Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. at 36,676.

The new rules are prospective and apply only to patents listed after August 18, 2003.<sup>52</sup> Also, there has been recent judicial recognition of antitrust liability for pioneer companies who abuse the thirty-month stay.<sup>53</sup> Finally, with the passage of the Medicare Reform Legislation,<sup>54</sup> the thirty-month stay provision has been bound against these obvious abuses by legislation.<sup>55</sup> Even though new regulations have passed that deal with the egregious violations of the policy motivating the thirty-month stay, the court must work to maintain the benefits of the thirty-month stay and promote policy adherence on the side of both the pioneer and generic drug producers.

### *C. Pursuing Purpose*

The purpose of the thirty-month stay, like that of the preliminary injunction, is to protect the patentee's rights and preserve the status quo during the pendency of the infringement suit.<sup>56</sup>

Unlike a preliminary injunction, however, the thirty-month stay is automatically granted.<sup>57</sup> The court has discretion to shorten or extend the length of

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The final rule maintains a balance between the innovator companies' intellectual property rights and the desire to get generic drugs on the market in a timely fashion. 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. . . . 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.

*Id.*

<sup>52</sup> Derzko, *supra* note 45, at 214–15.

<sup>53</sup> Stephanie E. Piatt, *Regaining the Balance of Hatch-Waxman in the FDA Generic Approval Process: An Equitable Remedy to the Thirty-Month Stay*, 59 N.Y.U. ANN. SURV. AM. L. 163, 191 (2003) (stating that an antitrust plaintiff may demonstrate that the patent infringement suit filed by the pioneer patent holder was "a mere sham to cover what is actually no more than an attempt to interfere directly with the business relationships of a competitor"). However, the hurdle for such a suit is extremely high. *Id.* The plaintiff must prove an exception to § 217(d)(3) and a violation of section two of the Sherman Act in order to establish a claim. *Id.*

<sup>54</sup> Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified at 26 U.S.C. §§ 139A, 223, 4980G; 42 U.S.C. §§ 299b, 1395b, 1395w, 1395cc, 1395kk, 1395zz, 1395hhh, 1396u).

<sup>55</sup> *Id.* In pertinent part, the amendment affected the thirty-month stay provision by limiting the number of stays that could be granted for one ANDA, and limiting the applicable Orange Book listings to those already listed before an ANDA was filed. *Id.*

<sup>56</sup> Piatt, *supra* note 53, at 200.

<sup>57</sup> 21 U.S.C. § 355(j)(5)(B)(iii) ("[T]he 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 . . .") (emphasis added). This has been important in a number of cases. See, e.g., *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002). In *Andrx*, the generic producer moved to have the district court shorten the thirty-month stay of the pioneer patent holder because it had already been granted one thirty-month stay (involving the '791 patent) and was not entitled to a second one (involving the '463 patent). *Id.* at 1371. *Andrx* also stated that after the pioneer company licensed the '463 patent, it deliberately changed its formulation of its drug product to fall within the claims of the '463 patent specifically so

time of the thirty-month stay, if the court determines that either party has failed to expedite the process, or acted to delay or hinder prompt resolution of the ANDA filing.<sup>58</sup> A preliminary injunction requires the court to examine the traditional four-factor test to determine whether or not to issue the injunction.<sup>59</sup> The test requires a plaintiff to demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law are inadequate to compensate for that injury; (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.<sup>60</sup> The issue is one of equity.<sup>61</sup>

The thirty-month stay requires no such test.<sup>62</sup> It is automatic, and is limited only by court discretion.<sup>63</sup> The court must ensure that the thirty-month stay is equitably enforced.<sup>64</sup>

## II. ANALYSIS

### A. Seeking Policy

Next, it is important to take a look at the policy goals of the reforms to the Hatch-Waxman Act, followed by analysis of the equitable approach to lengthening

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that it could claim an additional stay period. *Id.* at 1373. The court did not reach the question of whether the district court's authority to shorten the thirty-month statutory stay would be limited to those cases in which there was a failure to expedite the infringement action once it has been filed or whether the authority extends as well to situations in which the infringement action was not commenced expeditiously, for example, because of delay in the prosecution and/or issuance of the patent or in the filing of the infringement action. *Id.* at 1379. The court did, however, conclude that it could not shorten the period because of a delay in the resolution of the overall patent dispute between the pioneer and the generic company. *Id.* In another instance, where a generic was seen to behave poorly, the thirty-month stay was extended. *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 557 F.3d 1346 (2009). Here, the court held that the trial court did not abuse its discretion under 21 U.S.C. § 355(j)(5)(B)(iii) when it granted pioneer drug company's motion to extend the statutory stay because generic ANDA filer recast its product more than 18 months after it provided the original sample to the pioneer company and only 8 months before trial was set to commence. *Id.* at 1350. The court held that by altering its proposed drug late in the litigation by changing the particle size manufacturing specification of its active pharmaceutical ingredient past the discovery deadline, the generic company did not cooperate in expediting the patent litigation in the court. *Id.*

<sup>58</sup> *Id.* at 1355.

<sup>59</sup> *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 392 (2006). This case overturned a long-standing presumption in favor of granting permanent injunctions against patent infringers. Now, to have an injunction granted is not a matter of course, but requires a showing of the four elements. *Id.* at 391.

<sup>60</sup> *eBay*, 547 U.S. at 392.

<sup>61</sup> *Id.* at 392. The court found that a permanent injunction should not automatically be issued upon a finding of infringement, and the injunction should not be denied solely because the patent holder does not practice the patented invention. *Id.* The court was attempting to restore parity between the patent laws and other areas of the law, while maintaining the interests and rights of patent holders. *Id.* at 393.

<sup>62</sup> Piatt, *supra* note 53, at 201.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

and shortening the thirty-month stay in recent notable cases. Such analysis will reveal the efficacy of the policy changes. Also, a general look at the effect the Hatch-Waxman Act had in its general form as contrasted to the current state of affairs in the court and the regulatory duties of the FDA will be beneficial in determining the appropriate direction for future legislation.

After the reforms of the Hatch-Waxman Act, as embodied in the Medicare Prescription Drug, Improvement and Modernization Act of 2003<sup>65</sup> (“MMA”), the pioneer drug manufactures can no longer abuse the thirty-month stay, and the number of stays has effectively been limited to one.<sup>66</sup> Additionally, the act made it easier for the generic drug manufacturer to bring a civil action under 28 U.S.C. § 2201 for a declaratory judgment that the listed patent is invalid or will not be infringed by the ANDA, if the pioneer patent holder has not brought an infringement action within the 45-day notice period.<sup>67</sup> The court has always had the ability to alter the length of the stay, and the stay would end after thirty-months, but the court has simply been too mechanistic in granting the stay.<sup>68</sup> This mechanistic application of the law allowed pioneer drug makers to get multiple stays, with no regard to the effect upon generic drug makers, and essentially defeated the purpose of the act by allowing pioneer drug makers to subvert the process in order to delay the production of generics.<sup>69</sup> After reform, the patent submission and listing process is more efficient and has enhanced the ANDA and 505(b)(2) application approval processes.<sup>70</sup> The number of stays has effectively been limited to one, because the thirty-month stay can apply only to patents listed in the Orange Book at the time the ANDA was filed.<sup>71</sup> Any later filed patents will not trigger a new thirty-month stay, unless the ANDA is amended to assert that it does not infringe a new patent that has been listed in the Orange Book. This is in keeping with the original intent of Congress, which was to allow the pioneer patent holder to maintain its protection, while allowing a generic manufacturer to produce a generic drug sooner.<sup>72</sup> In order to protect against an ANDA that has already been filed, a pioneer patent holder would need to seek injunctive relief through the courts as it would for any infringement activity, without the benefit of the regulatory body of the FDA.<sup>73</sup> Once again, Congress has attempted to induce pioneering research and development of new drugs

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<sup>65</sup> Pub. L. No. 108-173, § 1102(a), 117 Stat. 2066, 2457 (codified at 21 U.S.C. § 355 (2006)).

<sup>66</sup> See 21 U.S.C. § 355.

<sup>67</sup> See *id.* § 355(j)(5)(C); 28 U.S.C. § 2201.

<sup>68</sup> See FTC STUDY, *supra* note 47, at ii (“The data suggest that cases involving multiple patents take longer than those involving fewer patents.”) Regarding past examples examined by the study, the findings revealed that “[a]s of June 1, 2002, for 6 out of the 7 cases that have been pending for more than 30 months before a decision from a district court, the brand-name company has alleged infringement of 3 or more patents.” *Id.* at 48. The study concluded that the time required for resolving patent infringement litigation between the pioneer drug maker and the generic drug manufacturer was trending upwards, exceeding 30 months. *Id.* at 47.

<sup>69</sup> *Id.*

<sup>70</sup> Notice of Adoption of Final Rule on Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,676 (June 18, 2003).

<sup>71</sup> *Id.*

<sup>72</sup> H.R. REP. NO. 98-857, pt. 1, at 17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650. Congress opined that this measure would save all purchasers of drugs a substantial amount of money, as well as getting generic drugs to the market between eighteen months and two years before they would reach the market without such a provision. *Id.*

<sup>73</sup> See 21 U.S.C. § 355(j)(5)(C) (2006).

while enabling production of low-cost, generic copies of those drugs by working to maintain the benefits of the thirty-month stay while limiting any abuses.

### *B. Expediting Action*

In examining the activities of the drug manufacturers to determine possibly inequitable activity, the courts have asserted that the activities of both parties should work to expedite the process.<sup>74</sup> When the pioneer drug manufactures use the FDA's citizen petition process in a way that effectively delays the approval of the generic drug manufacturer's drug, the nature of the claims becomes very important.<sup>75</sup> Ultimately, a closer look at the history of litigation between the pioneer drug manufacturers and the generic manufacturers will reveal the ongoing tension between the parties, and the approaches taken to mitigate the effects of that tension and any abuses that may occur. The courts have not sought to use equitable means to correct the behavior of pioneer drug manufactures and generic drug manufacturers who engage in questionable conduct.<sup>76</sup>

### *C. Examining Policy*

Since the passage of the Hatch-Waxman Act, the court has adjudicated claims that related to enforcing the policy goals outlined by the Hatch-Waxman Act. One example relating to the proper granting of the thirty-month stay is *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*<sup>77</sup> Although Biovail lost the infringement action in a ruling affirmed by the Federal Circuit in 2001, while the suit was pending, Biovail obtained rights to a patent for an extended release form of the drug, and listed this in the Orange Book as covering the patent subject to the ANDA filed by Andrx.<sup>78</sup> Although the district court found this action was "done to impede or

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<sup>74</sup> See 21 U.S.C. § 355(j)(5)(B)(iii). Each party must "reasonably cooperate in expediting the action." *Id.*

<sup>75</sup> See Henry A. Waxman, Congressman, Remarks at the Generic Pharmaceutical Association's 2007 Annual Policy Conference: Generics: Prescription for Affordable Healthcare (Sept. 6, 2007), [http://waxman.house.gov/UploadedFiles/Generic\\_Pharmaceutical\\_Associations\\_2007\\_Annual\\_Policy\\_Conference.pdf](http://waxman.house.gov/UploadedFiles/Generic_Pharmaceutical_Associations_2007_Annual_Policy_Conference.pdf) (listing several tactics used to delay generic manufacturers' attempts to bring generics to market). Congressman Waxman asserts that, despite the enhancements to the law, the pioneer drug companies will find "[a] new method of evergreening their patents; A new spate of petitions to delay FDA approval of generics; A new scheme to undermine incentives to challenge patents; or Another misleading campaign to cast doubt on the safety and effectiveness of generics." *Id.*

<sup>76</sup> Andrew A. Caffrey, II & 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, 35 (2004). The pioneer drug manufactures and the generic drug manufactures can often work hand in hand to delay the process of producing generic drugs. *Id.* Often, this would occur by misuse of the 180 day exclusivity period granted to the ANDA filer. *Id.* The court curtailed some of this abuse in the ruling of *In Mova Pharmaceutical Corp. v. Shalala*, where the D.C. Circuit held that the 180-day exclusivity period was not contingent on the existence of litigation with the NDA holder. *Id.*

<sup>77</sup> 276 F.3d 1368 (2002).

<sup>78</sup> *Id.* at 1373. Andrx pharmaceuticals wanted to manufacture a generic to Biovail Corporation's Tiazac (an angina and hypertension medication), filed an ANDA with a paragraph IV

delay the expeditious resolution of the patent actions between Biovail and Andrx over approval of Andrx's generic equivalent to Tiazac" and in accordance with the Hatch-Waxman Act determined that the thirty-month stay should be shortened, the Federal Circuit vacated the order.<sup>79</sup> The court determined that the district court exceeded its authority by shortening the statutory thirty-month stay in an infringement action.<sup>80</sup> The court emphasized the fact that the action was undertaken pursuant to the administrative proceedings of Biovail before the FDA, and thus was not an appropriate determination before the courts, but the court ignored the arguably inequitable conduct of Biovail.<sup>81</sup>

The situation here would not be likely to occur under the new statute, because the second patent was issued and listed after the ANDA was filed, but the court still has not made a point of augmenting the length of the statutory stay based on the conduct of the pioneer patent holder, whether that conduct is before the FDA or the

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clarification in 1998, and was sued for infringement by Biovail. *Id.* This triggered the thirty-month stay, and the FDA could not approve the ANDA until the thirty months concluded, or the litigation regarding infringement produced a determination of non-infringement. *Id.* After the second patent was listed in the Orange Book, Andrx attempted to get a declaratory judgment that newly filed patent was not infringed and that the newly filed patent was invalid, and requested delisting of the patent from the Orange Book and shortening of the thirty-month period. *Id.* Because the district court ruled that Biovail's assertion of the new patent was "done to impede or delay the expeditious resolution of the patent actions between Biovail and Andrx over approval of Andrx's generic equivalent to Tiazac," the court ordered the thirty-month stay shortened. *Id.* at 1374. Upon review by the Federal Circuit, the district court's order was vacated, holding that the district court did not have the power to shorten the statutory thirty-month stay period in an action for infringement. *Id.* 1380.

<sup>79</sup> *Id.* at 1374. The Hatch-Waxman Act addresses this issue head on. 21 U.S.C. § 355(j)(5)(B)(iii). The statute states that:

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.

*Id.* However, the court did not examine whether "the district court's authority to shorten the thirty-month statutory stay is limited to those cases in which there was a failure to expedite the infringement action once it is filed or whether the authority extends as well to situations in which the infringement action was not commenced expeditiously" and did not address whether or not a delay in the prosecution or issuance of the patent, or in the filing of the infringement action, could qualify as a failure to act expeditiously. *Andrx*, 276 F.3d at 1376.

<sup>80</sup> *Andrx*, 276 F.3d at 1376. The court emphasized that under its decision in *Mylan*, the district court "has no authority in the infringement action, as opposed to an action under the Administrative Procedure Act, to shorten the thirty-month stay because of allegedly improper conduct before the FDA." *Id.* The court went on to assert that there was no statutory support for the proposition by the district court that it could shorten the thirty-month stay because of a delay in the resolution of the overall patent dispute between the two parties. *Id.*

<sup>81</sup> *See id.*; Caffrey, *supra* note 76, at 11.

The court . . . ought not have been confused about the potential for the use of confusion [by a pioneer drug manufacturer] in achieving favorable and unwarranted outcomes at the FDA. The court noted that "Biovail's changing of its manufacturing process could not have been designed to justify the listing of the [new] patent in the Orange Book," which is indeed a correct statement of the law, but overlooks the fact that through misapplication of complex regulatory schemes, the FDA process is subject to abuse by parties claiming protections to which they are not legally entitled, and which are, technically, legally impossible.

*Id.* at 12 (footnote omitted).

court.<sup>82</sup> The court left open the option of bringing a claim against the FDA to approve an ANDA under the Administrative Procedure Act (“APA”),<sup>83</sup> and asserted that “we did not hold or suggest that an ANDA applicant may not sue the FDA directly under the APA to compel the FDA to approve the ANDA if the FDA’s action in denying the ANDA is arbitrary, capricious, or not in accordance with law”, even though the FDA generally declines to consider such issues.<sup>84</sup>

In the case of *Apotex, Inc. v. Thompson*,<sup>85</sup> the court went even further, and suggested that the legislature should address this fault.<sup>86</sup> The generic drug manufacturer, Apotex, filed a citizen’s petition with the FDA challenging its refusal to grant final approval of its ANDA and sought removal of its patents from the Orange Book because they failed to claim the subject of the NDA.<sup>87</sup> Ultimately, the

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<sup>82</sup> 21 U.S.C. § 355(j)(5)(B)(iii)(I)-(IV). Pioneer drug manufacturers “can only obtain one thirty-month stay, but still require that notice be provided whenever a paragraph IV certification is made.” Derzko *supra* note 45, at 219. “The rules set forth for patent listing, however, are still effective.” *Id.* The unresolved issues of patent listing remain. *Id.*

<sup>83</sup> 5 U.S.C. §§ 551–559, 701–706, 1305, 3344, 4301, 5335, 5372, 7521.

<sup>84</sup> *Andrx*, 276 F.3d at 1378.

<sup>85</sup> 347 F.3d 1335 (Fed. Cir. 2003).

<sup>86</sup> *Id.* at 1353–54. In a concurrence, Judge Plager opined:

[i]t 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 requirement that the NDA holder file required patent information. 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 Pharmaceuticals, Inc. v. Thompson*, 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.

*Id.* at 1353–54 (Plager, J., concurring) (citations omitted). However, the FDA has been consistent in maintaining that it should not be making determinations regarding the validity of patents listed in the Orange Book. *Id.* at 1349.

<sup>87</sup> *Apotex*, 347 F.3d at 1338. In this case, Appellee SmithKline held the NDA for Paxil (paroxetine hydrochloride hemihydrate) and listed the patent for the crystalline form of paroxetine hydrochloride hemihydrate in the Orange Book. *Id.* In 1998, Apotex filed an ANDA for a generic bioequivalent of Paxil. After receiving notice of the paragraph IV certification, SmithKline filed suit, triggering the automatic thirty-month stay, which expired in November 2000. In February and May of 1999, SmithKline was issued patent number 5,872,132 and patent number 5,900,423, which are forms of paroxetine hydrochloride anhydrate. *Id.* Apotex filed paragraph IV certifications for the ’132 and ’423 patents, and SmithKline sued Apotex for allegedly infringing the 5,900,423 patent. The FDA treated that lawsuit as triggering a second thirty-month stay of approval of Apotex’s ANDA, a stay that expired in January 2002. The court found “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.”



court held that “nothing in the Hatch-Waxman Act . . . 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,” and “the Hatch-Waxman Act does not require the FDA to review patents substantively before listing them in the Orange Book.” Again, this ruling would not occur under the reformed Hatch-Waxman Act, since the subsequent patents in question were issued and listed after the ANDA was filed, but the court once again missed an opportunity to apply equitable principles in the application of the thirty-month stay and the overall application of the Hatch-Waxman legislation.

However, in *Eli Lilly & Co. v. Teva Pharmaceuticals*,<sup>88</sup> the Federal Circuit held that the trial court did not abuse its discretion under 21 U.S.C. § 355(j)(5)(B)(iii) when it granted pioneer drug company Eli Lilly’s motion to extend the statutory stay because generic ANDA filer Teva recast its product more than eighteen months after it provided the original sample to the pioneer company and only eight months before trial was set to commence.<sup>89</sup> The court held that by altering its proposed drug late in the litigation by changing the particle size manufacturing specification of its active pharmaceutical ingredient past the discovery deadline, the generic company did not cooperate in expediting the patent litigation in the court.<sup>90</sup> The court distinguished this case from the *Andrx* decision by emphasizing that “the district court extended the statutory thirty-month stay [of Teva’s ANDA] based on its findings of Teva’s lack of cooperation in expediting the patent litigation in its court.”<sup>91</sup> The court’s findings were not based on Teva’s filing with the FDA.<sup>92</sup> However, the court went on to assert that its “decision was supported by the record, its factual findings, and proper application of the law.”<sup>93</sup>

This decision hints at a new willingness by the court to actively exercise its discretion to alter the length of the thirty-month stay according to principles of equity, as outlined before in terms of altering the thirty-month stay if it finds that a party “failed to reasonably cooperate in expediting the action.”<sup>94</sup> Although the court again makes a point of distinguishing between a proceeding before the court and a proceeding before the FDA, the court in *Eli* and in *Andrx* admit that the effect, the delay of “the expeditious resolution of the patent action,” is the same, regardless of

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<sup>88</sup> 557 F.3d 1346 (2009).

<sup>89</sup> *Id.* at 1349. Teva filed an ANDA in 2006, seeking approval to manufacture and market a generic version of raloxifene. *Id.* Lilly sued Teva on June 29, 2006, alleging that Teva’s ANDA infringed four method patents of the twelve listed Orange Book patents for raloxifene: patent number RE38,968, patent number RE39,049, patent number RE39,050, and patent number 6,906,086. *Id.* The FDA issued the thirty-month stay on Teva’s ANDA from the date that Lilly received Teva’s paragraph IV notifications, expiring on November 16, 2008. *Id.* On September 25, 2006, the district court set a trial date four months after expiration of the thirty-month statutory stay. *Id.* In February 2007, Lilly amended its complaint, asserting that Teva infringed three additional Evista patents covering raloxifene particle size and formulation. *Id.* On July 8, 2008, Teva amended its ANDA in order to “include a new particle-size measuring methodology for the active pharmaceutical ingredient in its proposed raloxifene tablets.” *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.* at 1351.

<sup>92</sup> *Id.* In *Andrx*, the court thought that it could shorten the thirty-month stay due to a delay in the resolution of patent disputes between the pioneer drug manufacturer and the generic drug manufacturer. *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1376 (Fed. Cir. 2002).

<sup>93</sup> *Lilly*, 557 F.3d at 1351.

<sup>94</sup> 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

the forum. The barrier is the decision in *Mylan*, where the court determined that the district court has no authority in the infringement action, as opposed to an action under the APA, to shorten the thirty-month stay because of allegedly improper conduct before the FDA.<sup>95</sup> This decision occurred before the passage of the new amendments to the Hatch-Waxman Act, and recent activity by the court, as shown in *Eli*, suggests that the direction of the court is shifting on this issue.<sup>96</sup>

#### *D. Promoting Policy*

After the FTC Study, the new patent listing regulations of the FDA, and the passage of the MMA, the thirty-month stay has been corrected of obvious past abuses. Additionally, the patent submission and listing process is ostensibly more efficient, and the ANDA application approval processes is enhanced.<sup>97</sup> However, the new rules are prospective and apply only to patents listed after August 18, 2003.<sup>98</sup> There have been few cases before the court that have applied the new statute, but the intent of Congress remains the same: to allow the pioneer patent holder to maintain its protection, while allowing a generic manufacturer to produce a generic drug sooner.<sup>99</sup> Even though new regulations have passed that deal with the egregious

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<sup>95</sup> *Andrx*, 276 F.3d at 1376. See also *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (D.D.C. 2001). In this case, the court asserts that the Hatch-Waxman Act “shows no explicit provisions allowing an accused infringer to defend against infringement by challenging the propriety of the Orange Book listing of the patent.” *Id.* at 1332. The court went further to express that “Congress only envisioned that recognized defenses could be raised in declaratory judgments in patent infringement actions.” *Id.* at 1333.

<sup>96</sup> *Eli Lilly & Co. v. Teva Pharm.*, 557 F.3d 1346, 1351 (Fed. Cir. 2009). See also *Connetics Corp. v. Pentech Pharm., Inc.*, No. 07-6297, 2009 U.S. Dist. LEXIS 33694 (N.D. Ill. Apr. 16, 2009) (balancing the interests of the parties and the prejudice to either party that could accrue due to allowing an amended answer to be submitted by the defendant). The court states that since the plaintiffs, the pioneer drug manufacturers, could not be prejudiced by any delay (which would result in delaying the defendant’s ANDA), and the fact that the plaintiffs themselves have already sought a discovery extension, the extension by the defendants would not violate the equity of the proceedings. *Id.* at \*17.

<sup>97</sup> See FTC STUDY, at i; Notice of Adoption of Final Rule on Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,676 (June 18, 2003) (“The final rule maintains a balance between the innovator companies’ intellectual property rights and the desire to get generic drugs on the market in a timely fashion.”)

The final rule maintains a balance between the innovator companies’ intellectual property rights and the desire to get generic drugs on the market in a timely fashion. 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. . . . 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.

*Id.*

<sup>98</sup> *Derzko*, *supra* note 43, at 214–15.

<sup>99</sup> H.R. REP. NO. 98-857, pt. 1, at 28 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2660, Congress opined that this measure would save all purchasers of drugs a substantial amount of money, as well as getting generic drugs to the market between eighteen months and two years before they would reach the market without such a provision. *Id.*

violations of the policy motivating the thirty-month stay, the court must work to maintain the benefits of the thirty-month stay and promote policy adherence on the side of both the pioneer and generic drug producers while furthering legislation against abuses.<sup>100</sup>

### III. PROPOSAL

#### *A. New Outlook*

In order for the court to (1) maintain the benefits of the thirty-month stay and (2) promote policy adherence on the side of both the pioneer and generic drug producers, reforms are necessary.<sup>101</sup>

The reforms may take the shape of a new statutory provision to challenge Orange Book listings, new statutory provisions that provide an evidentiary threshold for the NDA holder, or a reduction in the amount of time granted for the automatic stay, with a mandatory review of the progress of the pending litigation against the ANDA filer. The reasons for such options vary, and each option has different possible effects on the ability to strike a balance between the two divergent interests of the pioneer drug manufacturer and the generic manufacturer. This section will address the positives and negatives of each proposal, and will also provide possible legislative language to accomplish each suggested goal. In so doing, the proposal will yield a number of alternatives to consider.

#### *B. A New Statutory Provision to Challenge Orange Book Listings.*

The reason to provide a new statutory provision to challenge the current process of listing patents with the Orange Book can be found by analyzing the case of AAIPharma, Inc. v. Thompson.<sup>102</sup> In this case, the FDA claimed to have no right to challenge the listing of a patent on anything more than administrative grounds.<sup>103</sup>

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<sup>100</sup> H.R. Res. 1, 108th Cong. (2003). In pertinent part, the amendment affected the thirty-month stay provision by limiting the number of stays that could be granted for one ANDA, and limiting the applicable Orange Book listings to those already listed before an ANDA was filed. *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> 296 F.3d 227 (4th Cir. 2002). In this case, AAIPharma owned U.S. Patent No. 6,258,853 (filed Jan. 31, 2001) for a polymorphic variant of the active ingredient in Prozac, Eli Lilly & Company's antidepressant drug. *Id.* at 233. When the patent on Prozac expired on August 2, 2001, generic manufacturers were prepared to market their versions of Prozac. *Id.* AAIPharma sought to list the '853 patent in the Orange Book. This would claim Prozac, thus requiring manufacturers of generic versions of Prozac to certify to AAIPharma that their products did not infringe the '853 patent. Despite not having a marketable drug ready to market that used this patent, AAIPharma plead before the court. *Id.* at 234. The Court recognized that a third party patent holder of an approved drug is entitled to the protection of the Hatch-Waxman Act, including the granting of the thirty-month stay. *Id.* at 242.

<sup>103</sup> *Id.* When AAIPharma asked the FDA to intervene regarding the listing of the new patent for prozac, the FDA maintained that its role in Orange Book listings was purely ministerial. *Id.* at

The court affirmed, and even though this was a clear case of a patent holder abusing the listing of the Orange Book to achieve additional patent protection, the FDA claimed to be powerless to stop such abuse.<sup>104</sup> The remedy to prevent such occurrences in the future is clear statutory language that grants the FDA additional power.<sup>105</sup> The statute currently reads as “the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.”<sup>106</sup> One change to the statute should be an alteration of the procedure to challenge Orange Book listings.<sup>107</sup> The relevant section of the statute should read as “the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary may publish it, subject to review and/or challenge.”<sup>108</sup> This change in statutory provision will help reinforce the balance between the ANDA filer and the NDA holder by allowing some review of the listing of a patent in the Orange Book, to verify its relevance to the ANDA filing. The NDA holder will no longer have the ability to submit Orange Book listings that are not supported by relevance to the ANDA application.<sup>109</sup> If the listing is not relevant to the ANDA certifications, then there should be no delay in approval of the filing. The delay caused by a thirty-month stay granted due to an unrelated or un infringed patent listed in the Orange Book is in direct opposition to the goals of the Hatch-Waxman Act.<sup>110</sup> Changing the statute to prohibit this behavior would assist in achieving policy adherence on the side of both the pioneer and generic drug producers.

Additionally, the proposed change in the statute would also help to maintain the benefits of the thirty-month stay provision. Congress expressly intended to use the thirty-month stay as a mechanism for respecting the presumption of validity of a patent.<sup>111</sup> This proposed change in the statute would still allow an NDA holder to maintain his rights when those rights have been properly gained.<sup>112</sup> The adverse

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234. Regulations promulgated by the FDA state that if the accuracy of a listing is challenged, the affected party must notify the FDA and the FDA. *See* 21 C.F.R. § 314.53(f) (2010).

<sup>104</sup> 296 F.3d at 234. The court reinforced the administrative role of the FDA, and presented the alternative route of suing under the APA. *Id.* This is an unsatisfying remedy for the reasons stated above.

<sup>105</sup> *See* 21 U.S.C. § 355(c)(2) (2006).

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> *See* 21 U.S.C. § 355(c)(2). Changing this section will directly impact the ability of an ANDA filer to correct any errors with Orange Book listings, because it will force the ANDA holder to justify the listing with the Orange Book as it related to the application of the ANDA filer.

<sup>109</sup> *See* Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 IOWA J. CORP. L. 309, 333 (2005).

<sup>110</sup> H.R. REP. NO. 98-857, pt. 1, at 28 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2661. Congress believed “this procedure fairly balanced the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights of third parties to contest the validity of a patent to market a product which they believe is not claimed by the patent.” *Id.*

<sup>111</sup> *Id.*

<sup>112</sup> *See* Derzko, *supra* note 45, at 220. Patents for improvement are likely to still be sought, but the administration of infringement proceedings will proceed along normal lines. *Id.* The article goes on to state that “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

effect will only be triggered when a patent right is improperly gained or an attempt is made to subvert the system through outright fraud. The statutory change would not affect the forty-five day period that commences with the provision of notice regarding the certification from the ANDA filer. This forty-five day period would become even more critical, because this would be the time for evidentiary proceedings and assertions of validity for the opposed Orange Book listing. Once the NDA holder has made a showing of relevance and validity, the burden of proof then would shift back to the ANDA filer, and the proceedings would follow along the same judicial path as was requisite before the statutory change.

The precedent for administration of hearings related to ANDA certifications can serve as a model. Already, Congress has determined that the FDA will give an ANDA filer notice of disapproval when an ANDA is rejected.<sup>113</sup> Once rejected, the ANDA filer has the opportunity to have a hearing on the approvability of the ANDA.<sup>114</sup> The hearing is constrained by time and scope.<sup>115</sup> Similarly, a hearing regarding the validity of the Orange Book listing should be tightly constrained, in order to provide the greatest amount of protection to the NDA holder, the greatest degree of expediency for all parties, and the greatest degree of assurance possible for the ANDA filer.

Because Congress has already limited the applicable Orange Book listings for ANDA applications to those already listed when the application is filed, the ANDA filer will have knowledge of all applicable Orange Book listings, and can immediately challenge any that appear to be irrelevant or incorrect.<sup>116</sup> If the statute is changed to allow review and removal of inapplicable or erroneous Orange Book listings, the possible delays for generic drug manufacturers would be lessened.

### *C. New Statutory Provisions that Provide an Evidentiary Threshold for the NDA Holder.*

In addition to the ability to review the listings found in the Orange Book, the Hatch-Waxman Act should be reformed by demanding greater evidence of proper

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nonetheless still be pursued via regular channels for patent infringement.” *Id.* at 219. Similarly, the NDA holder will have to be concerned about the problems that may occur regarding Orange Book listings that should have occurred but did not. *Id.* “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.” *Id.* at 221.

<sup>113</sup> 21 U.S.C. § 355(c)(1)(B). The applicant is given notice of an opportunity for a hearing before the Secretary on whether the application is approvable. *Id.* If the applicant “elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree.” *Id.* The hearing is then conducted on an expedited basis. *Id.*

<sup>114</sup> See Greene, *supra* note 109, at 328–29 (“As the regulations provide, the FDA merely notifies the NDA holder that an ANDA has raised questions about an Orange Book listing, accepts the response from the NDA holder, and lists the patent.”) This is insufficient, because the patent holder has no obligation to do anything more than assert validity. *Id.* at 329. There is no accountability for the patent holder, who receives the grant of the thirty-month stay without review. *Id.* at 351.

<sup>115</sup> *Id.* at 328.

<sup>116</sup> H.R. Res. 1, 108th Cong. (2003). In pertinent part, the amendment affected the thirty-month stay provision by limiting the number of stays that could be granted for one ANDA, and limiting the applicable Orange Book listings to those already listed before an ANDA was filed. *Id.*

conduct and relevancy regarding the relationship between the ANDA certification and the NDA charges of infringement.<sup>117</sup> This includes the applicability and validity of the Orange Book listings, as mentioned above, as well as the proof provided via any proceedings or hearings, and the conduct of the NDA holder during the hearings and subsequent trial.<sup>118</sup>

Currently, the ANDA filer can make a challenge to the FDA if the ANDA has been disapproved.<sup>119</sup> The limitations for such a challenge are great, and the FDA does not make an effort to determine which of the parties has made a better showing of fact. The only concern of the FDA is that the NDA holder has responded in a timely manner, and has either made a correction, amendment or assertion of validity.<sup>120</sup>

The FDA often refers to its role as nothing more than “purely ministerial,” leaving the ANDA filer to seek relief elsewhere<sup>121</sup> This is not in keeping with the real role of the FDA as the body that acts *de facto* as a court to grant the thirty-month stay.<sup>122</sup> More should be required of the FDA to make sure that the process is meeting the policy goals outlined by the statute.

#### *D. Court Action*

The Hatch-Waxman Act allows a court to shorten or lengthen the thirty-month stay of FDA approval if either party fails “to reasonably cooperate in expediting the action.” The Federal Circuit interpreted this provision to apply only to conduct relating to the overall patent litigation.<sup>123</sup>

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<sup>117</sup> 21 U.S.C. § 355(j)(5)(B)(iii). The statute states that:  
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.*

*Id.* (emphasis added).

<sup>118</sup> See Greene, *supra* note 109, at 332. Many unresolved issues of patent listing remain, some of which are “the increase in the number of patents listed in the Orange Book, particularly for blockbuster drugs.” *Id.* Also, “the increased number of patents filed leads to litigation involving multiple patents and a longer period of time required for resolution. Moreover, in analyzing late-listed patents, the FTC recognized that several categories of patents raised significant issues concerning whether they were properly listed within the meaning of the statute.” *Id.*

<sup>119</sup> 21 U.S.C. § 355(c)(1)(B).

<sup>120</sup> *Id.*

<sup>121</sup> See, e.g., *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002); *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001). In these cases, the court gave no relief to an ANDA filer seeking to challenge an Orange Book listing. The court in *Mylan* asserted that the Hatch-Waxman Act “shows no explicit provisions allowing an accused infringer to defend against infringement by challenging the propriety of the Orange Book listing of the patent.” *Mylan*, 276 F.3d at 1331.

<sup>122</sup> See *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1353–54 (Fed. Cir. 2003).

<sup>123</sup> See *Andrx*, 276 F.3d at 1376. In *Andrx*, the court thought that it could shorten the thirty-month stay due to a delay in the resolution of patent disputes between the pioneer drug manufacturer and the generic drug manufacturer. The district court was concerned about the actions of a party slowing the proceedings before the FDA, and shortened the thirty-month stay accordingly. *Id.*

This is not a limitation provided by the statute itself, as the court stated that the statute left room for interpretation, and the court specifically left open the question of

whether the district court's authority to shorten the thirty-month statutory stay is limited to those cases in which there was a failure to expedite the infringement action once it is filed or whether the authority extends as well to situations in which the infringement action was not commenced expeditiously, for example, because of delay in the prosecution and/or issuance of the patent or in the filing of the infringement action.<sup>124</sup>

This open question could be answered by legislative action.<sup>125</sup>

*E. Reduction in the Amount of Time Granted for the Automatic Stay, with a Mandatory Review of the Progress of the Pending Litigation Against the ANDA Filer.*

Throughout much of the discussion on the ratification of the Hatch-Waxman Act, the length of the stay was eighteen months.<sup>126</sup> However, through the work of the research industry, that time period was changed to thirty months.<sup>127</sup> The provision for a stay was added by the Committee on Energy and Commerce to accommodate the competing interests, where the PMA was willing to compromise on sections of the bill relating to ANDAs in exchange for "greater protection of existing human pharmaceutical patents," while the GPIA was originally willing to "live with an eighteen-month rule because of other provisions of the bill."<sup>128</sup> From the beginning, the length of the stay was contentious.<sup>129</sup>

If the legislators changed the length of the stay to fit actual average time to resolve cases for patent infringement, the length would be much shorter.<sup>130</sup> The

<sup>124</sup> *Andrx*, 276 F.3d at 1376.

<sup>125</sup> *See* *Eli Lilly & Co. v. Teva Pharm.*, 557 F.3d 1346.

<sup>126</sup> H.R. REP. NO. 98-857, pt. 1, at 27 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2660. Congress was concerned that permitting an applicant to market a drug at the conclusion of eighteen months would mean that the marketing would occur before the resolution of the infringement suit. *Id.* at 28. this would mean that the ANDA filer would have overturned the statutory presumption of a patent's validity. *Id.* Congress intended to maintain the presumption of validity, and to give all current protections available under the then current laws. *Id.*

<sup>127</sup> *Id.* This is due to the nature of the give and take on the part of both the PMA and the GPIA. *Id.*

<sup>128</sup> H.R. Rep. No. 98-857, pt. 2, at 10 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2694; *see* *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 40 (D.D.C. 2000).

<sup>129</sup> *See* *Mossinghoff*, *supra* note 14, at 190. In introducing the amendment on the Senate floor, Senator Hatch stated in like terms that extending the stay period from 18 to 30 months "increases the likelihood that the litigation will be concluded within the time period during which ANDA's are not allowed." *Id.*

<sup>130</sup> Kimberly A. Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?*, 79 N.C. L. REV. 889, 908 (2001) (providing calculations and statistics that show the average time to resolution of patent cases filed in district courts from 1995 to 1999 was 1.12 years). The number of patents before district courts has steadily increased since that time. *See* Adam Shartzner, *Patent Litigation 101: Empirical Support for the Patent Pilot Program's Solution to Increase Judicial Experience in Patent Law*, 18 FED. CIR. B.J. 191, 210 (2009) ("In 2007, 2,914

actual length would be closer to half of the current length of the stay, which suggests that NDA holders are getting an unfair increase in the monopoly granted by their patent.<sup>131</sup> Congress should amend the Hatch-Waxman Act to provide a closer assessment of the time actually required to initially receive a court ruling.<sup>132</sup> Additionally, Congress should provide language that would make the granting of the stay renewable after the passage of an initial fraction of the over-all time. This would insure that both parties fulfill the obligation to expedite the proceedings.

Upon changing the length of the statutory stay and making the continuation of the stay contingent upon the behavior of both parties, Congress would make the process more fair for both the generic manufacturer and the pioneer drug maker. The generic drug maker could produce generics sooner, and the pioneer drug maker would get only the just benefit of the patent received for the drug covered by the ANDA application.

#### CONCLUSION

Reforms are necessary for the court to (1) maintain the benefits of the thirty-month stay and (2) promote policy adherence on the side of both the pioneer and generic drug producers.<sup>133</sup>

Congress should provide a new statutory provision to challenge Orange Book listings, new statutory provisions that provide an evidentiary threshold for the NDA holder, and/ or a reduction in the amount of time granted for the automatic stay, with a mandatory review of the progress of the pending litigation against the ANDA filer. These reforms would help to achieve the policy goals of the reforms to the Hatch-Waxman Act, and would strengthen the recent trend of using an equitable approach to lengthening and shortening the thirty-month stay.

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patent cases were filed. This is an increase of 18.3% over the number of patent cases filed in 2000. The increase in patent litigation burdens district court dockets and contributes to delays in resolution.”) (footnotes omitted).

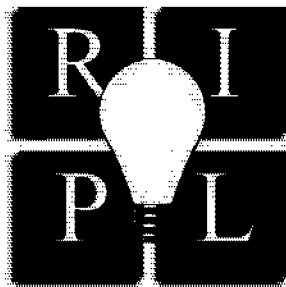
<sup>131</sup> Shartzler, *supra* note 130, at 209 (“The increase in importance of intellectual property, and more specifically, patents, to a corporation’s revenue stream has led to a rise in patent litigation.”). As the income from intellectual property becomes more important, companies have more incentive to litigate, and to delay any reduction in the monopoly period. *Id.* at 209.

<sup>132</sup> Moore, *supra* note 130, at 908 (providing calculations and statistics that show the average time to resolution of patent cases filed in district courts from 1995 to 1999 was 1.12 years).

<sup>133</sup> H.R. REP. NO. 98-857, pt. 1, at 28 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2661. Congress believed “this procedure fairly balances the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights of third parties to contest the validity of a patent to market a product which they believe is not claimed by the patent.” *Id.*



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