

**WILL THE FEDERAL CIRCUIT’S *ELI LILLY v. TEVA* DECISION
LEAD TO EFFORTS TO ABUSE THE MODIFICATION PROVISION
OF THE HATCH-WAXMAN ACT?**

By Claire K. Comfort*

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INTRODUCTION

[1] The Hatch-Waxman Act provides a mandatory thirty-month stay on the Food and Drug Administration’s (FDA) approval of an Abbreviated New Drug Application (ANDA) when a patent infringement suit is filed.¹ The Act includes a provision for a district court to shorten or extend the Act’s thirty-month stay on FDA approval if “either party to the action failed to reasonably cooperate in expediting the action”² (hereinafter “the modification provision”). The federal district courts have on the whole been very conservative in their interpretation of the modification provision.³ The district courts have, to date, seldom exercised their power

* J.D., Columbia University School of Law, 2009; B.S., Georgetown University, 2006.

¹ See 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

² *Id.*

³ See, e.g., *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1354 (Fed. Cir. 2009) (Prost, J., dissenting); Gerald Sobel et al., *Hatch-Waxman Litigation from the Perspective of Pioneer Pharmaceutical Companies*, in PATENT LITIGATION STRATEGIES HANDBOOK 183, 197 (Barry L. Grossman & Gary M. Hoffman eds., 2d ed. 2005).

to alter the obligatory thirty-month stay.⁴ In a recent case, *Eli Lilly v. Teva*, the Federal Circuit held that a district court's decision to modify the statutory thirty-month stay is within the discretionary powers of that particular district court, may be based on a party's uncooperative discovery practices before the court, and will only be reviewed for an abuse of discretion.⁵ In the wake of the *Eli Lilly* decision, it is now likely that the modification provision will become more liberally interpreted and frequently invoked by some of the district courts.

[2] Part I of this article provides an introduction to the Hatch-Waxman Act, the legislative history of the modification provision, and some discussion on the market incentives that pioneer pharmaceutical companies have to extend the statutory thirty-month stay. Part II covers the facts of the *Eli Lilly v. Teva* decision, a case in which the Southern District of Indiana used the modification provision to prevent the generic defendant Teva from launching its ANDA product to compete with Eli Lilly's Evista product before the start of the parties' trial. Part III of this article surveys other district court decisions concerning the modification provision. The goal of Part III is to provide a foundational understanding of the prior judicial understanding of the modification provision. Accordingly, all of the decisions in Part III were made prior to the Federal Circuit's *Eli Lilly v. Teva* decision. Part IV of this article discusses the legal significance of the *Eli Lilly v. Teva* decision and argues that the Federal Circuit's decision was inadequate. Part V of this article concludes that the Federal Circuit's deceptively simple *Eli Lilly v. Teva* decision is a harbinger with substantial ramifications for Hatch-Waxman jurisprudence.

I. INTRODUCTION TO THE HATCH-WAXMAN ACT

[3] In 1984 Congress passed the Drug Price Competition and Patent Term Restoration Act (commonly known as the "Hatch-Waxman Act").⁶

⁴ *See id.*

⁵ *Eli Lilly*, 557 F.3d at 1348–51.

⁶ Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 21 U.S.C. and 35 U.S.C.).

The goal of the Hatch-Waxman Act was to balance protections for patented pharmaceutical drugs with improved market access for less expensive generic drugs.⁷

[4] Prior to enactment of the Hatch-Waxman Act, generic pharmaceutical manufacturers had to file full New Drug Applications (NDA), which required the generic manufacturer to perform the same intensive clinical trials that pioneer pharmaceutical manufacturers complete, in order to receive FDA approval to market a new generic drug.⁸ Generic drug manufacturers also had to wait until the pioneer drug patents expired before they could begin the time-consuming NDA approval process.⁹ Under the Hatch-Waxman Act, generic pharmaceutical manufacturers instead file an Abbreviated New Drug Application (ANDA) certifying that the generic drug candidate is “bioequivalent” to the FDA approved pioneer drug product.¹⁰ The ANDA process allows a generic manufacturer to use the drug safety and effectiveness studies that the pioneer manufacturer submitted for its NDA.¹¹ A generic manufacturer is

⁷ See H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48; WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., *THE HATCH-WAXMAN ACT: PROPOSED LEGISLATIVE CHANGES AFFECTING PHARMACEUTICAL PATENTS* (2004); *see also* Frederick Tong, Comment, *Widening the Bottleneck of Pharmaceutical Patent Exclusivity*, 24 WHITTIER L. REV. 775, 804 (2003) (“Although this compromise has been an uneasy partnership for all parties involved, both sides have profited enormously.”).

⁸ See H.R. REP. NO. 98-857, pt. 1, at 16, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649 (“Prior to 1962, . . . all drugs [must have been] approved as safe before they could be marketed.”).

⁹ See, e.g., Holly Soehnge, Note, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 51 (2003) (citing H.R. REP. NO. 98-857, pt. 1, at 14–15, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48).

¹⁰ U.S. Food & Drug Admin., *What are Generic Drugs?* (2009), <http://www.fda.gov/Drugs/ResearchForYou/Consumers/BuyingMedicineSafely/UnderstandingGenericDrugs/ucml44456.htm>.

¹¹ See *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1348 (Fed. Cir. 2009) (citing 21 U.S.C. § 355(j)(2)(A)).

also permitted to file an ANDA before the patents for a pioneer drug expire and to receive FDA approval to market its generic drug upon either the expiration of all applicable pioneer drug patents or upon a judicial determination that the pioneer drug's patents are invalid or not infringed by the generic's "bioequivalent" product.¹²

[5] Upon filing an NDA, a pioneer drug manufacturer is required to list the patents that claim its drug product.¹³ If the NDA receives approval, the FDA publishes a listing of the drug and its applicable patents in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").¹⁴ In an ANDA, the generic manufacturer is required to include a statement with one of four different certifications (known as "paragraph certifications") with respect to each patent listed in the Orange Book for the "bioequivalent" NDA product.¹⁵ The four possible paragraph certifications are:

- (i) that such patent information has not been filed,
- (ii) that such patent has expired,
- (iii) [that the generic does not seek to enter the market until] the date on which such patent will expire, or

¹² See generally *id.* at 1348–49; Sobel et al., *supra* note 3, at 184–85.

¹³ 21 C.F.R. §§ 314.53(a)–(b)(1) (2009); see also Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman To Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309, 316 (2005).

¹⁴ U.S. FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS iv (2009), available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>. The FDA does not evaluate the strength or validity of patents in the Orange Book. See *id.*

¹⁵ See, e.g., Steven J. Lee et al., *Waxman-Hatch Litigation from the Perspective of the Generic Pharmaceutical Industry*, in PATENT LITIGATION STRATEGIES HANDBOOK, *supra* note 3, at 149, 152–53.

(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.¹⁶

When an ANDA includes a paragraph IV certification that a patent is invalid or will not be infringed by the ANDA product, the ANDA filer must notify the NDA holder to provide the NDA holder with an opportunity to file a patent infringement action.¹⁷

[6] A paragraph IV certification creates an artificial act of patent infringement.¹⁸ Under the Hatch-Waxman Act, a pioneer pharmaceutical company has forty-five days from the receipt of a paragraph IV notice in which to file an infringement suit.¹⁹ If the pioneer manufacturer brings a patent infringement action against the ANDA filer within the forty-five day window, the statutory thirty-month stay on the FDA's approval of the ANDA product immediately takes effect.²⁰ The statutory stay lasts for either thirty months or until the date that the infringement suit is resolved, whichever occurs first.²¹ The generic ANDA filer is barred from bringing a declaratory judgment action against the patent holders, typically the pioneer manufacturer, during the forty-five day notice window.²² If the pioneer manufacturer does not file an infringement action within forty-five days of receipt, the FDA may approve the ANDA.²³ A pioneer manufacturer may still bring an infringement action against the ANDA

¹⁶ 21 U.S.C. § 355(b)(2)(A) (2006).

¹⁷ *Id.* § 355(b)(3)(C).

¹⁸ *See id.* § 355(j)(5)(B)(iii); *cf.* *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004) (discussing 35 U.S.C. § 271(e)(2)).

¹⁹ 21 U.S.C. § 355(j)(5)(B)(iii).

²⁰ *See id.* §§ 355(c)(3)(C), (j)(5)(B)(iii).

²¹ *Id.* § 355(j)(5)(B)(iii).

²² *Id.* § 355(c)(3)(D)(i)(I)(aa).

²³ *See id.* § 355(c)(3)(C).

filer after the forty-five day period has elapsed, but filing suit at that time will no longer impose a stay on the FDA's approval or prevent the market entry of the ANDA product.²⁴ Suffice it to say, it is very rare that an NDA holder will not file an infringement action within the forty-five day window in order to secure the automatic thirty-month stay.²⁵

1. LEGISLATIVE HISTORY OF THE THIRTY-MONTH STAY

[7] The reason Congress chose to make thirty months the length of the statutory Hatch-Waxman stay remains unknown.²⁶ The Hatch-Waxman Act and its subsequent amendments were heavily lobbied.²⁷ “The legislative history indicates that the thirty-month stay was a hard-won compromise between brand-name manufacturers, generics manufacturers, and other stakeholders.”²⁸ On the one hand, because the provisions of the Hatch-Waxman Act were so heavily disputed, the legislative intent behind

²⁴ See *id.* § 355(j)(5)(B)(iii).

²⁵ See Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 177–78 (2008) (“The purpose of the thirty-month stay is to protect NDA holders with valid drug patents.”).

²⁶ See, e.g., Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999) (“There is a paucity of legislative history on the Hatch-Waxman Act.”).

²⁷ See Medicare Prescription Drug, Improvement, and Modernization Act of 2003 tit. XI, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended at 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)). The pioneer pharmaceutical industry was the leading industry campaign contributor in the 2002 election year, prior to the enactment of the 2003 Amendments to the Hatch-Waxman Act. The generic drug industry, which did not lag far behind, was one of the top ten industry campaign contributors that year. See, e.g., Center for Responsive Politics, *Pharmaceuticals/Health Products: Long-Term Contribution Trends*, <http://www.opensecrets.org/industries/indus.php?ind=H04> (last visited Nov. 10, 2009).

²⁸ *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1354 n.3 (Fed. Cir. 2009) (Prost, J., dissenting).

specific provisions of the Act is often unclear.²⁹ On the other hand, there is strong evidence in the legislative history that, in creating a thirty-month stay, Congress intended for generic drug manufacturers to have the opportunity to launch their product at-risk in the later stages of most infringement trials.³⁰

[8] The only legislative history on the modification provision is a statement in the House Report: “Each party to a patent infringement suit is charged to reasonably cooperate in expediting the action. Failure by either party to cooperate in a reasonable manner may be used by the court to reduce or lengthen the time, as appropriate, before an ANDA approval becomes effective.”³¹ The House version of the bill originally provided for an FDA stay of only eighteen months.³² The House Report cites findings that the median time between filing and disposition of a patent suit was thirty-six months, and that ten percent of cases take more than seventy-seven months.³³ The House Report contains language that a proposed amendment that would stay FDA approval until after a court

²⁹ For example, the Supreme Court has stated: “No interpretation we have been able to imagine could transform § 271(e)(1) into an elegant piece of statutory draftsmanship. To construe it as the Court of Appeals decided, one must posit a good deal of legislative imprecision . . .” *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 679 (1990) (deciding that the Court of Appeals for the Federal Circuit’s decision, which assumed legislative imprecision, was the best statutory interpretation available); *see also* Mossinghoff, *supra* note 27.

³⁰ *See* H.R. REP. NO. 98-857, pt. 2, at 10 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2694. An at-risk launch means that the generic manufacturer will be liable for damages if it proceeds to market its product and the court subsequently finds the patent valid and infringed. *See generally* Sobel et al., *supra* note 3, at 198–99.

³¹ *Id.* at 16, *reprinted in* 1984 U.S.C.C.A.N. 2686, 2700.

³² Drug Price Competition and Patent Term Restoration Act of 1984, H.R. 3605, 98th Cong. § 101 (1984); H.R. REP. NO. 98-857, pt. 2, at 9–10 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2693-94 (“This [eighteen-month] provision was added by the Committee on Energy and Commerce to accommodate the competing concerns of the PMA and the generic manufacturers. . . . The generic manufacturers . . . were willing to live with an eighteen-month rule because of other provisions of the bill.”).

³³ H.R. REP. NO. 98-857, pt. 2, at 10, *reprinted in* 1984 U.S.C.C.A.N. 2686, 2694.

verdict of invalidity was inadvisable because it would “substantially delay generics from getting onto the market” and potentially discourage generics from challenging the validity of a pioneer drug patent.³⁴ The House Report further states that such an amendment was unnecessary because a patent holder can recover damages if the generic manufacturer launches an infringing product after the FDA stay expires.³⁵

[9] The House Report strongly suggests that provision of the statutory stay was not done solely to delay generic market entry and that the stay was not intended to last through most infringement trials.³⁶ The House arguably designed the stay to encourage pioneer manufacturers to pursue a speedy trial resolution.

[10] In the end, it was the Senate’s proposal for a thirty-month stay that triumphed.³⁷ But it is important to note that even the thirty-month stay was still six months less than the congressional finding for the median length of a patent infringement suit.³⁸ The takeaway message is that:

It is important to remember that the purpose of the thirty-month stay is not necessarily to extend the patent holder’s monopoly, but to create an adequate window of time during which to litigate the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market.³⁹

³⁴ *Id.*

³⁵ *Id.*

³⁶ *See id.* at 9–10, *reprinted in* 1984 U.S.C.C.A.N. 2686, 2693–94.

³⁷ *See, e.g.*, Drug Price Competition and Patent Term Restoration Act of 1984, S. 2926, 98th Cong. § 101 (1984).

³⁸ H.R. REP. NO. 98-857, pt. 2, at 10, *reprinted in* 1984 U.S.C.C.A.N. 2686, 2694.

³⁹ *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001) (citing to Senator Hatch’s and Representative Waxman’s statements in the Congressional Record).

While it is not fully clear why Congress chose a period of thirty months or why it included the modification provision in the Hatch-Waxman Act, the legislative history reveals that the thirty-month stay was not intended to function purely as a mechanism for preventing generic market entry during an infringement lawsuit, but rather was created as an integral part of a larger statutory scheme aimed at promoting generic market entry.⁴⁰ In settling on a thirty-month stay and including the modification provision, Congress most likely sought to balance a fair period of time for conducting a trial without the risk of generic market entry against an appreciation of the risk that too long of a statutory stay period would create incentives for parties to unnecessarily delay the trial date until the end of the stay period.⁴¹

2. PIONEER MANUFACTURER INCENTIVES FOR DELAY

[11] The statutory thirty-month stay is of tremendous financial value to pioneer pharmaceutical companies.⁴² During the statutory stay period, a pioneer manufacturer remains in complete control of the product market regardless of the strength of its patents.⁴³ Because there is always some risk of losing at trial, a pioneer manufacturer does not want to hold trial until the end of the thirty-month statutory stay period. A pioneer pharmaceutical company has strong market incentives to extend the thirty-

⁴⁰ See Narinder S. Banait, *Antitrust Issues and the Hatch-Waxman Act*, IPFRONTLINE, Nov. 11, 2005, <http://www.ipfrontline.com/depts/article.asp?id=7181&deptid=4>.

⁴¹ Because the statutory stay period also terminates on the date that a court finds the patent invalid or not infringed, generic manufacturers (usually) have strong interests in pursuing quick lawsuits. See, e.g., Lee et al., *supra* note 16, at 162.

⁴² See Robert E. Colletti, *The Role of the Food and Drug Attorney in Hatch-Waxman Lawsuits*, in *Inside the Minds: Food and Drug Law Settlements and Negotiations* (2006), available at <http://www.flhlaw.com/files/Publication/bcc5610d-419a-4ee2-b46a-293235ebd8e5/Preview/PublicationAttachment/dd3abe66-7e12-4c62-8e23-2a9ef2bb3503/CollettiBookChapter.pdf>.

⁴³ See FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 14* (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

month statutory stay, or further delay generic market entry by any means possible.⁴⁴

[12] Prior to the 2003 Hatch-Waxman Amendments, pioneer pharmaceutical companies were able to secure more than one statutory stay for the same drug product.⁴⁵ Companies accomplished this by listing a new patent in the Orange Book after the first thirty-month stay against the generic defendant became effective.⁴⁶ One example of this type of behavior occurred in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*⁴⁷ In *Andrx*, the pioneer manufacturer Biovail licensed a new patent, reformulated its drug product to fall within this new patent, and listed the new patent in the Orange Book for its drug after the generic defendant Andrx was successful at trial against the pioneer's primary drug patent.⁴⁸ This newly listed patent resulted in a second infringement trial with another thirty-month statutory stay against the defendant's ANDA product.⁴⁹ The second trial was assigned to the same district court judge, William P. Dimitrouleas, who had heard the first trial.⁵⁰ Dimitrouleas used the modification provision to shorten the second statutory stay.⁵¹ On appeal, the Federal Circuit reversed, holding that the district court's

⁴⁴ See Sarah E. Eurek, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 DUKE L. & TECH. REV. 18, ¶¶ 4–5, <http://www.law.duke.edu/journals/dltr/articles/pdf/2003DLTR0018.pdf>.

⁴⁵ See FED. TRADE COMM'N, *supra* note 44, at iii.

⁴⁶ *Id.*

⁴⁷ 175 F. Supp. 2d 1362 (S.D. Fla. 2001), *vacated*, 276 F.3d 1368 (Fed. Cir. 2002). *Andrx* is the only case other than *Eli Lilly v. Teva* in which the Federal Circuit has considered the modification provision.

⁴⁸ See *id.* at 1365–66.

⁴⁹ See *id.* at 1365, 1367.

⁵⁰ See *id.* at 1365; *Biovail Corp. Int'l v. Andrx Pharms., Inc.*, 158 F. Supp. 2d 1318, 1320 (S.D. Fla. 2000).

⁵¹ See *Andrx*, 276 F.3d at 1375–76.

decision to use the modification provision must be based on behavior before the court, not on behavior before the FDA.⁵²

[13] The outcome in *Andrx* provided a strong stimulus for the 2003 Amendments. Under the 2003 Amendments, a pioneer manufacturer is now limited to only one statutory thirty-month stay per ANDA.⁵³ While a pioneer pharmaceutical manufacturer may sue a generic manufacturer under a later listed patent, the pioneer manufacturer is not eligible to receive any additional stay on the FDA approval of an ANDA for patents listed after the ANDA is first filed.⁵⁴

[14] The additional statutory stay in *Andrx* is but one example of the ways in which pioneer pharmaceutical companies have become very skillful at advantageously using the provisions of the Hatch-Waxman Act to keep generic competition off the market.⁵⁵ As one commenter has stated: “The Hatch-Waxman Amendments increased generic drug entry in the market, but they were also vulnerable to abuse by brand-name manufacturers. The terms of the original Hatch-Waxman Amendments

⁵² *See id.*

⁵³ *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1101, 117 Stat. 2066, 2448–57 (codified as amended at 21 U.S.C. § 355(j)(5)(B)(iv) (2006)).

⁵⁴ *See id.*

⁵⁵ *See, e.g.,* Yana Pechersky, Note, *To Achieve Closure of the Hatch-Waxman Act’s Loopholes, Legislative Action Is Unnecessary: Generic Manufacturers Are Able To Hold Their Own*, 25 CARDOZO ARTS & ENT. L.J. 775, 777 (2007) (“While this amendment eliminated the practice by brand name manufacturers of using a string of thirty-month stays to keep generic entrants off the market, it did not address the remaining loopholes.”); Beth Understahl, Note, *Authorized Generics: Careful Balance Undone*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 355, 378 (2005) (“The history of the Hatch-Waxman Amendments clearly demonstrates that innovators will exploit loopholes in the statutory language to squeeze out as much market share as possible when faced with generic competition.”); *see also* Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165, 175–203 (2005).

created incentives for anticompetitive behavior.”⁵⁶ Current examples of pioneer manufacturer tactics to delay generic market entry include frivolous claims of patent infringement,⁵⁷ authorized generics,⁵⁸ and collusive settlements between pioneers and generic companies.⁵⁹

[15] According to another commenter: “The goals of the Act . . . are threatened by clever market players who find ways to avoid the give-and-take required to make the Act work.”⁶⁰ With its current broad and highly deferential reading of the modification provision, the Federal Circuit has created a new area of uncertainty in the Act that pioneer companies can exploit to their advantage in delaying generic market entry.

⁵⁶ Understahl, *supra* note 55, at 367–68.

⁵⁷ When the primary patent(s) are set to expire, a manufacturer will often list, and then file suit under, new patents that have little to do with the basic functioning of the drug product. “Evergreening” is the practice of extending a patent monopoly by means of a later more peripheral patent. *See, e.g.,* Tong, *supra* note 6, at 788 (“While the practice of evergreening itself is legitimate, pioneer drug companies can abuse the system by patenting virtually every aspect of their drug, including product, process, use, formulation and even tablet shape. By staggering every possible patentable aspect of the drug down to formulation and tablet size, the lifetime of a pioneer drug’s exclusive marketing can be significantly extended.”).

⁵⁸ An authorized generic is a “generic” product manufactured by the pioneer manufacturer or its authorized licensee. Authorized generics are legal, and entitled to share the market during the first ANDA filer’s 180-day exclusivity period. Authorized generics may work to deter the market entry of generic ANDA products. *See generally* Christopher S. Ponder, Comment, *The Dubious Value of Hatch-Waxman Exclusivity*, 45 HOUS. L. REV. 555, 571–79 (2008) (assessing whether authorized generics are anticompetitive).

⁵⁹ *See, e.g.,* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1568 (2006).

⁶⁰ Kristin E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?*, 57 FOOD & DRUG L.J. 247, 270 (2002).

II. THE FACTS OF *ELI LILLY & CO. v. TEVA PHARMACEUTICALS USA, INC.*⁶¹

[16] Eli Lilly and Company sells raloxifene hydrochloride under the brand name Evista.⁶² Evista is approved for treatment of postmenopausal osteoporosis and prevention of breast cancer.⁶³ On May 16, 2006, Teva Pharmaceuticals USA notified Eli Lilly that it had filed an ANDA with paragraph IV certifications for raloxifene.⁶⁴ Eli Lilly subsequently filed suit on June 29, 2006, in the Southern District of Indiana, alleging that Teva infringed four of the twelve patents listed in the Orange Book for Evista.⁶⁵ The statutory thirty-month stay against approval of Teva's ANDA was immediately effective and would expire on November 16, 2008.⁶⁶ The district court entered a scheduling order with a discovery deadline of August 18, 2008, and a trial date of March 9, 2009.⁶⁷ During discovery, Teva first provided Eli Lilly with samples of its proposed ANDA product.⁶⁸ In February 2007, Eli Lilly amended its complaint to

⁶¹ See Case History Timeline *infra* Addendum (supplementing facts of *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, No. 1:06-CV-1017, 2008 WL 4809963, at *1 (S.D. Ind. Oct. 29, 2008)) [hereinafter Case History Timeline for *Eli Lilly v. Teva*].

⁶² See *id.*

⁶³ U.S. Food and Drug Administration, Electronic Orange Book, <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> (last visited Nov. 10, 2009) (searching by proprietary name "Evista").

⁶⁴ See Case History Timeline for *Eli Lilly v. Teva*, *supra* note 61.

⁶⁵ See *id.* By the date of the infringement trial, there were sixteen patents listed in the Orange Book for Evista. See U.S. Food and Drug Administration, Electronic Orange Book, <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> (last visited Nov. 10, 2009) (searching by proprietary name "Evista").

⁶⁶ See *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, No. 1:06-CV-1017, 2008 WL 4809963, at *1 (S.D. Ind. Oct. 29, 2008).

⁶⁷ See *id.* at *1 & n.2.

⁶⁸ See Corrected Non-Confidential Brief of Plaintiff-Appellee *Eli Lilly & Co.* at 3–6, *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, No. 2009-1071 (Fed. Cir. Dec. 22, 2008), 2008 WL 5550616 [hereinafter *Brief of Plaintiff-Appellee*].

assert Teva infringed three additional patents covering Evista's particle size and formulation.⁶⁹

[17] On July 8, 2008, Teva amended its ANDA with the FDA to include a new particle size measuring methodology for the active pharmaceutical ingredient in its proposed raloxifene tablets.⁷⁰ Two days later, Teva informed Eli Lilly of this amendment.⁷¹ Teva provided three batch samples of its amended ANDA product to Eli Lilly, the first on July 28, 2008, the second on August 19, 2008, and the third on September 17, 2008.⁷² From July through September 2008, Teva provided Eli Lilly with 27,000 pages of documentation related to its new particle size measuring methodology.⁷³ It is important to note that Teva delivered two of the batch sample products and produced some of the related documents after the August 18, 2008 discovery deadline, which was set almost two years earlier, in September 2006.⁷⁴

[18] Eli Lilly subsequently filed a motion in September 2008 requesting that the Southern District of Indiana extend the statutory thirty-month FDA stay on approval of Teva's ANDA.⁷⁵ Judge Sarah Evans Barker granted Eli Lilly's motion to extend the stay until the start of trial on March 9, 2009, a period of approximately four months after the scheduled thirty-month expiration date of the stay.⁷⁶ Evista had \$1.076 billion in

⁶⁹ See *id.*; see generally Complaint, *Eli Lilly*, 2009 WL 3060227 (No. 1:06-CV-1017).

⁷⁰ Brief of Plaintiff-Appellee, *supra* note 68, at 6–13.

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ See *id.* at 6–13, 25–29.

⁷⁵ *Id.* at 13–17.

⁷⁶ *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, No. 1:06-CV-1017, 2008 WL 4809963, at *2 (S.D. Ind. Oct. 29, 2008). On October 6, 2008, Eli Lilly also filed motions for a

sales for 2008.⁷⁷ Accordingly, the decision to extend the FDA stay approximately four months was potentially worth hundreds of millions of dollars to Eli Lilly.

[19] The basis for the decision by Judge Barker to extend the statutory FDA stay against Teva deserves attention for a couple of reasons. First, under the 2003 Hatch-Waxman Amendments, Eli Lilly was not entitled to a second statutory stay for the four patents it added to its complaint in February 2007.⁷⁸ Teva's FDA amendment and belated product and document production all related to these later added patents. Second, under *Andrx*, the district court could not consider Teva's ANDA amendment—legitimate conduct before the FDA—in its determination of whether Teva “failed to reasonably cooperate in expediting the action.”⁷⁹ Therefore, the fact that Teva engaged in discovery production after the discovery deadline is the only logical basis the district court could use to support a finding that Teva had “failed to reasonably cooperate in expediting the action” and, consequently, extend the statutory FDA stay against Teva's ANDA.⁸⁰ The district court's opinion prominently relied on Eli Lilly's arguments that Teva had “failed to reasonably cooperate in the action” by submitting some of its new product samples and related documentation after the August 18, 2008 discovery deadline.⁸¹ But the

temporary restraining order (TRO) and a preliminary injunction to prevent Teva from launching its product on or after the November 16, 2008 expiration of the stay. *See id.* at *2 n.5.

⁷⁷ Press Release, Eli Lilly & Co., Lilly Reports Fourth-Quarter and Full-Year 2008 Results (Jan. 29, 2009), available at http://files.shareholder.com/downloads/LLY/589013876x0x268802/086c5a30-2bfb-4353-8e81-be50b8f17b19/LLY_News_2009_1_29_Financial.pdf.

⁷⁸ Non-Confidential Reply Brief of Defendant-Appellant Teva Pharms. USA, Inc. at 1–4, *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, No. 2009-1071 (Fed. Cir. Dec. 30, 2008), 2008 WL 5550617 [hereinafter *Brief of Defendant-Appellant*].

⁷⁹ *See Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370–80 (Fed. Cir. 2002).

⁸⁰ *Eli Lilly*, 2008 WL 4809963, at *1–2.

⁸¹ *See id.*

district court never stated that Teva's discovery delays were severe enough to satisfy the statutory requirement: "fail[ure] to reasonably cooperate in expediting the action."⁸² Instead, the district court's conclusions supporting its ruling relied on evidence that Teva's behavior related to recasting its product caused Eli Lilly to need more time to prepare for the trial.⁸³

[20] The most interesting fact of the case is that the originally scheduled March 9, 2009 trial date never moved.⁸⁴ It is hard to connect a finding that the defendant's behavior caused the pioneer plaintiff to need more time to prepare for trial with the solution of a stay on FDA approval—effectively a preliminary injunction—in the absence of a corresponding stay on the litigation. While it is not necessary to alter the trial date to warrant use of the modification provision by the district court, there should have at least been a finding that the defendant's behavior was on a level that would warrant staying the litigation. Otherwise, the fact that there was no delay in the litigation suggests that the court was using the modification provision as a "punishment" mechanism for a discovery delay, instead of for its intended purpose.⁸⁵

[21] Because the statutory stay is equivalent to injunctive relief, the Federal Circuit took the *Eli Lilly v. Teva* case on interlocutory appeal pursuant to 28 U.S.C. § 1292(a)(1).⁸⁶ On February 24, 2009, the Federal Circuit affirmed the Southern District of Indiana's decision to use the

⁸² Brief of Defendant-Appellant, *supra* note 78, at 1–4.

⁸³ *See Eli Lilly*, 2008 WL 4809963, at *2.

⁸⁴ *See id.*

⁸⁵ Henry Lebowitz, Remarks at Columbia Law School Advanced Patents Seminar (Apr. 16, 2009).

⁸⁶ *See Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1349–50 (Fed. Cir. 2009).

modification provision to extend the FDA stay against Teva's ANDA until the start of the infringement trial.⁸⁷

III. DISTRICT COURT DECISIONS CONCERNING THE MODIFICATION PROVISION PRIOR TO THE FEDERAL CIRCUIT'S RULING IN *ELI LILLY v. TEVA*

[22] Prior to the Federal Circuit's recent ruling, there have been nine district court decisions—other than *Eli Lilly v. Teva*—related to the modification provision.⁸⁸ Moreover, excluding the Southern District of Indiana and the Southern District of Florida's decision, which was overturned by the Federal Circuit in *Andrx*, only two district courts have been willing to exercise their power to modify the statutory thirty-month

⁸⁷ *Id.* at 1351. Interestingly, on April 22, 2009, Judge Barker granted a renewed motion for preliminary injunction in favor of Eli Lilly. The April 2009 preliminary injunction prevented Teva from launching its generic product until there was a final trial ruling on the merits of the infringement suit. *See Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 609 F.Supp.2d 786, 790-812 (S.D. Ind. 2009); *see also* Press Release, Eli Lilly & Co., Lilly Granted Preliminary Injunction to Prevent Launch of Generic Raloxifene (Apr. 22, 2009), available at http://files.shareholder.com/downloads/LLY/784741347x0x289245/8d085039-0f56-4397-823a-45ad2ee83dc2/LLY_News_2009_4_22_Corporate.pdf. The fact that Judge Barker later granted Eli Lilly a preliminary injunction supports this article's argument that a preliminary injunction, and not the modification provision, was the more appropriate legal analysis for determining whether or not to prevent Teva from launching its generic raloxifene product at the time the original thirty-month FDA stay expired.

⁸⁸ Based on an extensive search of Westlaw, LexisNexis, and the Stanford IP Litigation Clearinghouse website (available at <http://lexmachina.stanford.edu>). *See generally* *Glaxo, Inc. v. TorPharm, Inc.*, No. 95 C 4686, 1997 U.S. Dist. LEXIS 12816 (N.D. Ill. Aug. 20, 1997); *Zeneca Ltd. v. Pharmachemie B.V.*, 16 F. Supp. 2d 112 (D. Mass. 1998); *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, No. IP 99-38-C H/G, 2001 U.S. Dist. LEXIS 2728 (S.D. Ind. Mar. 8, 2001); *Minn. Mining & Mfg. Co. v. Alphapharm Party Ltd.*, No. Civ. 99-13 MJDLGL, 2002 WL 1299996 (D. Minn. Mar. 8, 2002); *Andrx Pharms., Inc. v. Biovail Corp.*, 175 F. Supp. 2d 1362 (S.D. Fla. 2001); *Novartis Corp. v. Dr. Reddy's Labs., Ltd.*, No. 04 Civ. 0757 (SAS), 2004 U.S. Dist. LEXIS 21094 (S.D.N.Y. Oct. 21, 2004); *Eli Lilly & Co. v. Barr Labs., Inc.*, Cause No. 1:02-CV-1844-SEB-VSS (S.D. Ind. May 27, 2005); *Dey, L.P. v. Ivax Pharms., Inc.*, 233 F.R.D. 567 (C.D. Cal. 2005); *In re Brimonidine Patent Litig.*, No. 07-MD-1866, 2008 U.S. Dist. LEXIS 92405 (D. Del. Oct. 31, 2008).

stay under the modification provision.⁸⁹ The Southern District of New York granted an extension of the thirty-month FDA stay against a generic defendant in conjunction with the generic defendant's motion for a stay on the litigation.⁹⁰ The Central District of California granted a request to shorten the thirty-month stay due to a pioneer plaintiff's failure to identify and disclose the inventors of its patent.⁹¹

[23] For the most part, the district courts have been reluctant to exercise their discretionary power under the modification provision.⁹² The Northern District of Illinois, the District of Massachusetts, the District of Minnesota, and the District of Delaware have each denied a motion to modify the statutory thirty-month FDA stay as not warranted.⁹³ These courts have tended to recognize that some natural give-and-take exists in the discovery process, and have each concluded that the fact that a party has committed some delay does not mean that the party has necessarily "failed to reasonably cooperate in expediting the action."⁹⁴

[24] The Southern District of Indiana is currently an outlier in how liberally it interprets the modification provision and how frequently it grants requests for modification of the statutory FDA stay.⁹⁵ The Southern

⁸⁹ See *Novartis Corp.*, 2004 U.S. Dist. LEXIS 21094; *Dey, L.P. v. Eon Labs, Inc.*, No. SACV 04-00243 CJC (FMOx), 2005 U.S. Dist. LEXIS 39475 (C.D. Cal. Dec. 22, 2005).

⁹⁰ *Novartis Corp.*, 2004 U.S. Dist. LEXIS 21094, at *14–15.

⁹¹ *Eon Labs, Inc.*, 2005 U.S. Dist. LEXIS 39475, at *2–3.

⁹² As one commenter notes, this is "perhaps because courts have been unwilling to blame one party exclusively for failure to cooperate." David Bickart, *The Hatch-Waxman Act*, in *DEVELOPMENTS IN PHARMACEUTICAL AND BIOTECH PATENT LAW* 205, 247 (2008).

⁹³ *Glaxo, Inc.*, 1997 U.S. Dist. LEXIS 12816, at *23; *Zeneca Ltd.*, 16 F. Supp. 2d at 113; *Minn. Mining*, 2002 WL 1299996, at *6; *In re Brimonidine Patent Litig.*, 2008 U.S. Dist. LEXIS 92405, at *13.

⁹⁴ *Minn. Mining*, 2002 WL 1299996, at *2.

⁹⁵ See generally *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, No. IP 99-38-C H/G, 2001 U.S. Dist. LEXIS 2728 (S.D. Ind. Mar. 8, 2001).

District of Indiana has now granted motions to extend the statutory thirty-month stay in three different cases, all of which have involved Eli Lilly and Company as the plaintiff and an alleged discovery failure against (what is now) three different generic defendants.⁹⁶

1. *GLAXO, INC. v. TORPHARM, INC.*

[25] In 1997, the Northern District of Illinois was the first court to rule on 21 U.S.C. § 355(j)(4)(B)(iii)'s modification provision.⁹⁷ In the case, the generic defendant TorPharm sought to shorten the thirty-month statutory stay by five months.⁹⁸ The Northern District of Illinois found that TorPharm's contentions that pioneer manufacturer plaintiff Glaxo was still delivering requested discovery documents two months after the close of discovery and that TorPharm had needed to file four motions to compel in order to obtain documents that Glaxo had promised to produce in discovery responses were both true.⁹⁹ The court nevertheless denied TorPharm's request to shorten the stay.¹⁰⁰

[26] The Northern District of Illinois concluded that Glaxo's discovery delays were not sufficient behavior to warrant shortening the statutory thirty-month stay.¹⁰¹ The district court's "overall impression of this case during the discovery phase [was] that both parties conducted a tremendous amount of discovery within a relatively short period of time."¹⁰² The court

⁹⁶ See generally *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346 (Fed. Cir. 2009); *Eli Lilly & Co. v. Barr Labs., Inc.*, Cause No. 1:02-CV-1844-SEB-JMS (S.D. Ind. May 27, 2005); *Zenith Goldline Pharms.*, 2001 U.S. Dist. LEXIS 2728.

⁹⁷ See generally *Glaxo, Inc.*, 1997 U.S. Dist. LEXIS 12816.

⁹⁸ *Id.* at *5.

⁹⁹ *Id.* at *9.

¹⁰⁰ *Id.* at *10.

¹⁰¹ *Id.* at *7–10.

¹⁰² *Id.* at *8.

concluded that, even though “Glaxo was untimely in its document productions,” modification of the statutory stay was not appropriate because Glaxo had “nonetheless cooperated in moving along this litigation.”¹⁰³ The Northern District of Illinois’s decision in *Glaxo* is interesting because, while failure to reasonably cooperate is admittedly a very factual determination, the decision is contrary to the conclusion reached by the district court in *Eli Lilly v. Teva*.

2. *ZENECA LTD. v. PHARMACHEMIE B.V.*

[27] In 1998, the District of Massachusetts first considered a motion to extend the statutory thirty-month FDA stay.¹⁰⁴ The court denied the motion.¹⁰⁵ The opinion simply states that 21 U.S.C. § 335(j)(5)(B)(iii) imposes an “affirmative duty [on the parties] to ‘reasonably cooperate in expediting the action’” and that “the record shows that the defendant has cooperated reasonably in expediting this action.”¹⁰⁶ This decision is one of the only officially published district court decisions regarding the modification provision, but the opinion is too pithy to provide much in terms of worthwhile precedent.

3. *ELI LILLY & Co. v. ZENITH GOLDLINE PHARMACEUTICALS, INC.*

[28] In 2001, the Southern District of Indiana was the first court to exercise its power under the modification provision.¹⁰⁷ The court extended the statutory stay until entry of a final judgment in the infringement action.¹⁰⁸ Interestingly, the case plaintiff, who filed for

¹⁰³ *Id.* at *9–10.

¹⁰⁴ *See generally* *Zeneca Ltd. v. Pharmachemie B.V.*, 16 F. Supp. 2d 112 (D. Mass. 1998).

¹⁰⁵ *Id.* at 113.

¹⁰⁶ *Id.*

¹⁰⁷ *See generally* *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, No. IP 99-38-C H/G, 2001 U.S. Dist. LEXIS 2728 (S.D. Ind. Mar. 8, 2001).

¹⁰⁸ *Id.* at *2.

extension of the stay, was Eli Lilly and Company.¹⁰⁹ The court found that generic defendant Zenith Goldline “failed to reasonably cooperate in expediting this action by failing to meet the case management deadline for serving its expert witness reports on the central issue of the case—invalidity.”¹¹⁰ Under the case management plan, the expert reports were due ninety days before trial.¹¹¹ Zenith Goldline was unable to produce the reports at that time, stating that the reports would be available approximately thirty days before trial.¹¹² The court held that Zenith Goldline’s failure to meet the discovery deadline for the expert reports was sufficient to trigger an extension of the statutory FDA stay because the reports were “on the critical path of this trial schedule.”¹¹³

[29] In *Eli Lilly v. Zenith Goldline*, the Southern District of Indiana was the first court to hold that the modification provision of the Hatch-Waxman Act applied to dilatory discovery tactics.¹¹⁴ The plaintiff, jurisdiction, and facts in *Eli Lilly v. Zenith Goldline* parallel the circumstances in the *Eli Lilly v. Teva* case. A key difference between the cases, however, is that the *Zenith Goldline* court had previously granted Eli Lilly a motion based on Zenith Goldline’s discovery delays to continue the trial by approximately four months.¹¹⁵ Arguably, Zenith Goldline’s behavior was more severe, and its discovery delay was less excusable than Teva’s behavior in the more recent *Eli Lilly v. Teva* case.

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.* at *3.

¹¹² *Id.*

¹¹³ *Id.* at *4.

¹¹⁴ *Id.* at *2–3.

¹¹⁵ *See id.* at *2.

4. *MINNESOTA MINING & MANUFACTURING CO. V. ALPHAPHARM PARTY LTD.*

[30] *Minnesota Mining* was another case where the generic defendant made evidentiary submissions after the deadlines for expert reports and discovery set forth in the scheduling order.¹¹⁶ The thirty-month stay had expired and the generic defendant Alphapharm was preparing to make an at-risk launch of its product.¹¹⁷ The pioneer plaintiff 3M filed motions both to extend the statutory thirty-month stay and for a preliminary injunction.¹¹⁸ The District of Minnesota denied both motions.¹¹⁹ The court held that Alphapharm's submissions were "not untimely" due to "the complexity of the issues involved."¹²⁰ The court determined that, if 3M wanted to extend the statutory stay, 3M would have to seek and secure a preliminary injunction.¹²¹ 3M's motion for a preliminary injunction was denied because it could not establish irreparable harm.¹²² The court stated that any potential injury could be easily measured in monetary terms and remedied with money damages.¹²³

5. *ANDRX PHARMACEUTICALS, INC. V. BIOVAIL CORP.*

[31] In 2000, the Southern District of Florida ruled that generic defendant Andrx's ANDA for a generic version of pioneer plaintiff Biovail's drug Tiazac did not infringe Biovail's patents.¹²⁴ However,

¹¹⁶ *Minn. Mining & Mfg. Co. v. Alphapharm Party Ltd.*, No. Civ. 99-13 MJDLGL, 2002 WL 1299996, at *3 (D. Minn. Mar. 8, 2002).

¹¹⁷ *Id.* at *2.

¹¹⁸ *Id.*

¹¹⁹ *Id.* at *6.

¹²⁰ *Id.* at *3.

¹²¹ *Id.*

¹²² *Id.* at *3-5.

¹²³ *Id.*

¹²⁴ *Andrx Pharms., Inc. v. Biovail Corp.*, 175 F. Supp. 2d 1362, 1365 (S.D. Fla. 2001).

before Andrx could market its drug, Biovail licensed a patent for an extended release formulation of the active ingredient in Tiazac and listed this new patent with the FDA.¹²⁵ Biovail then filed suit against Andrx under the new patent, triggering a second thirty-month stay against Andrx's ANDA.¹²⁶ There was strong suspicion that Biovail's second lawsuit was frivolous and that Biovail's listing of the extended release formulation patent was a sham designed solely to use the thirty-month stay provision of the Hatch-Waxman Act to keep Andrx off the market.¹²⁷

[32] The Southern District of Florida transferred the second case as a related case to the same judge who had heard the first case.¹²⁸ The district court decided that Biovail's actions in listing the new patent were clearly "done to impede or delay the expeditious resolution of the patent actions," and the court exercised its power under the modification provision to terminate Biovail's second thirty-month statutory stay against Andrx's ANDA.¹²⁹ The court justified its authority under the modification provision stating, "[I]t is clear that this Court was given express authority in the Hatch-Waxman Act to police the Congressional compromise between patent protections for the pioneer drug maker and the public's need for speedy approval of safe lower-cost generic equivalents to those drugs."¹³⁰ The Federal Circuit reversed,¹³¹ holding that the modification

¹²⁵ See *Biovail Corp. Int'l v. Andrx Pharms., Inc.*, 158 F. Supp. 2d 1318, 1330 (S.D. Fla. 2000), *aff'd*, 239 F.3d 1297 (Fed. Cir. 2001).

¹²⁶ *Id.* at 1328.

¹²⁷ *See id.*

¹²⁸ *See id.* at 1320; *Andrx*, 175 F. Supp. 2d at 1365.

¹²⁹ *Andrx*, 175 F. Supp. 2d at 1375.

¹³⁰ *Id.*

¹³¹ *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370–80 (Fed. Cir. 2002).

provision of the Hatch-Waxman Act did not allow the district court to consider behavior before the FDA.¹³²

6. *NOVARTIS CORP. V. DR. REDDY'S LABS., LTD.*

[33] In *Novartis v. Dr. Reddy's Laboratories*, the Southern District of New York extended the thirty-month stay in conjunction with granting a motion by the generic defendant Dr. Reddy's Laboratories to stay the litigation.¹³³ The litigation involved the FDA's stay of approval of one of the ingredients in an application for combination capsules with two drug ingredients that worked synergistically.¹³⁴ The court found the defendant's request to stay the litigation was warranted because it would simplify the issues and promote judicial economy, but that extension of the thirty-month stay on FDA approval of the combination drug product was necessary to ensure that pioneer plaintiff Novartis would not be disadvantaged by the delay in the litigation proceedings.¹³⁵ The district court supported its determination to invoke the modification provision stating: "[Dr. Reddy's Laboratories] cannot feasibly argue that it is reasonably cooperating in expediting the action when it has asked the court to stay the proceedings."¹³⁶ The decision was non-controversial. While the plaintiff objected to staying the litigation, the defendant did not object to tolling the thirty-month FDA stay while the infringement litigation was on hold.¹³⁷

¹³² *Id.* The final case outcome in *Biovail v. Andrx* is credited as being a major driver behind the 2003 Hatch-Waxman Amendments, which limited the pioneer manufacturer to only one thirty-month stay per ANDA.

¹³³ See generally *Novartis Corp. v. Dr. Reddy's Labs., Ltd.*, No. 04 Civ. 0757 (SAS), 2004 U.S. Dist. LEXIS 21094 (S.D.N.Y. Oct. 21, 2004).

¹³⁴ *Id.* at *7-8.

¹³⁵ *Id.* at *11-13.

¹³⁶ *Id.* at *13.

¹³⁷ See *id.* at *12-13.

7. *ELI LILLY & CO. v. BARR LABORATORIES, INC.*¹³⁸

[34] The Southern District of Indiana also granted Eli Lilly a limited extension of the statutory stay in *Eli Lilly v. Barr Laboratories*.¹³⁹ In that case, the generic defendant Barr had failed to provide plaintiff Eli Lilly with a sample of its product.¹⁴⁰ In its order, the court stated that it is “important, perhaps essential, that the composition of the generic drug product for which FDA approval is being sought . . . and which Lilly alleges to be the infringing product should be definitely established.”¹⁴¹ The “order provided that, after the defendant produced the sample, the stay would extend through *a reasonably expeditious time period for preparing for trial.*”¹⁴² Most interestingly, Judge Sarah Evans Barker, the same judge who presided over and issued the statutory extension in *Eli Lilly v. Teva*, also issued the extension order in the *Eli Lilly v. Barr* case.¹⁴³

8. *DEY, L.P. v. IVAX PHARMS., INC.*

[35] The Central District of California is the only court, excluding the Southern District of Florida’s decision which was reversed by the Federal Circuit in *Andrx*, to grant a generic defendant’s motion to shorten the statutory thirty-month stay and to facilitate generic market entry.¹⁴⁴ In

¹³⁸ *Eli Lilly & Co. v. Barr Labs., Inc.*, Cause No. 1:02-CV-1844-SEB-JMS (S.D. Ind. May 27, 2005). This Order Granting Limited Extension of Statutory Stay was unpublished, but nevertheless cited in the district court’s order in *Eli Lilly v. Teva*.

¹³⁹ *Id.*

¹⁴⁰ *Id.* at 1.

¹⁴¹ *Id.* at 2.

¹⁴² *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, No. 1:06-CV-1017, 2008 WL 4809963, at *2 (S.D. Ind. Oct. 29, 2008) (emphasis added).

¹⁴³ *See id.* at *1; *Eli Lilly*, Cause No. 1:02-CV-1844-SEB-VSS, at 3.

¹⁴⁴ *Dey, L.P. v. Ivax Pharms., Inc.*, 233 F.R.D. 567 (C.D. Cal. 2005), *aff’d on reh’g sub nom.* *Dey, L.P. v. Eon Labs, Inc.*, No. SACV 04-00243 CJC (FMOx), 2005 U.S. Dist. LEXIS 39475 (C.D. Cal. Dec. 22, 2005).

Dey v. Ivax, the Central District of California granted a motion to terminate the thirty-month stay¹⁴⁵ based upon a finding that the pioneer plaintiff Dey, L.P. had failed to cooperate in expediting the litigation.¹⁴⁶ The court found that Dey had concealed studies comparing its product to a prior art drug and delayed its disclosure of the proper inventor of the patent at issue by repeatedly changing its position on inventorship.¹⁴⁷ The court concluded that this behavior evidenced Dey's failure to cooperate.¹⁴⁸ The district court later confirmed and further clarified its decision to terminate the statutory stay when it subsequently denied Dey's motion for reconsideration.¹⁴⁹ The court held that pioneer plaintiffs have a duty to form a good faith opinion on the issue of inventorship at the outset of litigation.¹⁵⁰

There is nothing inconsistent about holding both (1) that Dey may seek to correct inventorship if new facts demonstrate a need to do so, and also (2) that Dey nevertheless should be required to inform itself of the facts underlying its claims of inventorship early in the action rather than waiting until the close of evidence at trial to discover the role played by each of its own current and former employees in the development of the patented material.¹⁵¹

¹⁴⁵ This was a consolidated motion because Ivax Pharmaceuticals and Eon Labs, Inc. were both defendants litigating suits against pioneer manufacturer Dey, L.P. relating to the same pioneer drug. Generic defendant Eon Labs was the party who brought and succeeded in the motion to shorten the statutory stay on its ANDA product. *Id.* at 567.

¹⁴⁶ *Id.* at 569–71.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Dey*, 2005 U.S. Dist. LEXIS 39475, at *2–3.

¹⁵⁰ *Id.* at *3.

¹⁵¹ *Id.* at *33–34.

In the opinion of the Central District of California, a pioneer plaintiff's failure to take a solid position on inventorship is alone sufficient grounds for terminating the thirty-month statutory stay under the modification provision.¹⁵²

9. *IN RE BRIMONIDINE PATENT LITIGATION*

[36] The District of Delaware is a frequent venue for Hatch-Waxman litigations, but it has still never exercised its power to modify the statutory thirty-month stay. Further, the District of Delaware has considered the modification provision only once.¹⁵³ In that suit, pioneer plaintiff Allergan requested both to stay the litigation against generic defendant Exela PharmSci and to toll the thirty-month stay on FDA approval of Exela's ANDA.¹⁵⁴ Early in the litigation, Exela had joined Paddock and PharmaForce, two intended partners who were expected to manufacture Exela's ANDA product, as defendants to the suit.¹⁵⁵ Allergan brought its motion to stay the action without knowing Exela's partnership with Paddock and PharmaForce had dissolved.¹⁵⁶ Allergan argued that the litigation should be stayed because Exela's ANDA designated Paddock as the manufacturer and PharmaForce had supplied most of the product bioequivalence information to the FDA.¹⁵⁷ With respect to the thirty-month FDA stay, Allergan argued that "Exela has: (1) failed to respond promptly to the FDA's call for bioequivalence data; (2) suppressed relevant information; and (3) engaged in dilatory discovery tactics, all in

¹⁵² *See id.* at *1-36.

¹⁵³ *See In re Brimonidine Patent Litig.*, No. 07-MD-1866, 2008 U.S. Dist. LEXIS 92405 (D. Del. Oct. 31, 2008).

¹⁵⁴ *See id.* at *1.

¹⁵⁵ *See id.* at *2-3.

¹⁵⁶ *See id.* at *4.

¹⁵⁷ *See id.* at *4 n.3.

an effort to try to run the clock on Allergan.”¹⁵⁸ The district court denied all of Allergan’s requests.¹⁵⁹

[37] The court stated that granting Allegan’s motion to stay the litigation would be “unduly prejudicial to Exela.”¹⁶⁰ The court denied Allergan’s motion on the grounds that a stay would risk Exela’s first ANDA filer status (which entitled Exela to a 180-day market exclusivity period) and delay market entry of the generic product at issue in the litigation, rather than simplify any issues because the case was relatively far along.¹⁶¹ With respect to Allergan’s request to toll the thirty-month stay, the court was “not persuaded” that there was a “sufficient showing to support a finding that Exela [was] not reasonably cooperating in expediting this litigation” because the record did not “reflect the type of dilatory conduct and discovery antics that necessitate such a finding.”¹⁶² The district court concluded that the problems associated with “Exela’s need to identify a new manufacturer, or conduct certain bioequivalence studies, or submit supplemental product information to the FDA” did not indicate failure to cooperate with expediting the litigation.¹⁶³ The District of Delaware went on to add that “these types of issues are, and should be, a normal part of the give-and-take associated with the drug approval process,” before concluding that tolling the stay was not warranted based on the evidence before the court.¹⁶⁴ This decision is particularly

¹⁵⁸ *Id.* at *10.

¹⁵⁹ *Id.* at *12–13. Allergan made a third request that the court grant it leave to use information produced by the generic defendants in the case in a citizen’s petition before the FDA. The district court also denied this third request. *Id.* at *12 (“It is just not apparent to this court why use of Exela’s confidential information is necessary.”).

¹⁶⁰ *Id.* at *5.

¹⁶¹ *Id.* *6, 8–9.

¹⁶² *Id.* at *10.

¹⁶³ *Id.* at *11.

¹⁶⁴ *Id.*

interesting because it occurred during the same week that the Southern District of Indiana reached its conflicting interpretation of the modification provision of the Hatch-Waxman Act in *Eli Lilly v. Teva*.

IV. THE FEDERAL CIRCUIT'S *ELI LILLY V. TEVA* DECISION

[38] The Federal Circuit's holding in *Eli Lilly v. Teva* is potentially problematic precedent. Currently, *Eli Lilly v. Teva* is only the second Federal Circuit decision concerning the modification provision of the Hatch-Waxman Act.¹⁶⁵ In *Eli Lilly*, the Federal Circuit also confined *Andrx v. Biovail*, its prior decision concerning the modification provision, to *Andrx*'s unique procedural stance.¹⁶⁶ The *Eli Lilly* decision is now the *de facto* case that parties will cite and to which the district courts will look when they consider motions under the Hatch-Waxman Act's modification provision. However, the Federal Circuit's *Eli Lilly v. Teva* decision was unduly deferential to the district court. The Federal Circuit's decision fails to provide the district courts with guidance on how to conduct the "fail[ure] to reasonably cooperate in expediting the action" analysis required by the Act.¹⁶⁷

1. THE MAJORITY HOLDING

[39] The Federal Circuit's *Eli Lilly v. Teva* decision was highly deferential to the district court.¹⁶⁸ The court stated that trial courts may adjust the statutory thirty-month FDA stay based upon the uncooperative discovery practices of parties before the court.¹⁶⁹ The Federal Circuit held

¹⁶⁵ See *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1347 (Fed. Cir. 2009); see also *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002).

¹⁶⁶ See *Teva*, 557 F.3d at 1350–51; see also *Andrx*, 276 F.3d at 1368.

¹⁶⁷ *Teva*, 557 F.3d at 1348.

¹⁶⁸ See *id.* at 1350.

¹⁶⁹ *Id.*

that it would only review district court decisions pursuant to the modification provision for an abuse of discretion.¹⁷⁰

[40] The Federal Circuit affirmed *Andrx*, holding that district courts may not extend the statutory stay based on filings before the FDA.¹⁷¹ But it also distinguished *Andrx* as a case in which the district court considered behavior wholly unrelated to the issue at hand, and as a situation that could no longer arise subsequent to the passage of the Hatch-Waxman Amendments.¹⁷² The Federal Circuit determined that the district court's decision to extend the stay was not based on Teva's filing with the FDA but rather "Teva's lack of cooperation in expediting the patent litigation in its court."¹⁷³ As such, the decision to extend the thirty-month FDA stay was a "proper application of the law."¹⁷⁴

2. JUDGE PROST'S DISSENT

[41] In her dissent, Judge Prost argued that the majority both misapprehended the facts and misapplied the law.¹⁷⁵ Prost argued that, because the issue was one of statutory construction, the court should have applied a de novo standard of review.¹⁷⁶ However, Prost concluded that the district court's decision needed to be overturned "even under an abuse of discretion standard."¹⁷⁷ Prost pointed out that the district court never made the necessary statutory finding:

¹⁷⁰ *Id.*

¹⁷¹ *Id.* at 1351.

¹⁷² *Id.* at 1351 & n.1.

¹⁷³ *Id.* at 1351.

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* at 1352 (Prost, J., dissenting).

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

Not once in this order did the court indicate, much less unambiguously state, that it found Teva had failed to reasonably cooperate in expediting this action. The court provided at most two justifications for extending the stay: (1) to provide Lilly a “sufficient opportunity to identify the nature and composition of the raloxifene product as Teva intends for it to be sold,” and (2) to give Lilly “a reasonable amount of time to allow its expert to test and report on the altered raloxifene samples provided by Teva and for Lilly to assess and utilize that information and analysis in preparation for trial.” Neither of these reasons remotely resembles the statutorily required finding.¹⁷⁸

According to Prost, district court findings should clearly “relate[] [the party’s] conduct to the statutory standard,” and district court opinion’s must explain these findings with sufficient reasoning to provide for meaningful appellate review.¹⁷⁹

[42] Prost mentioned the consequences likely to arise from the majority’s opinion. She reasoned that affirming the district court in this case would “effectively eliminate the statutorily required finding” and “prematurely terminate the development of appropriate standards governing modification under 21 U.S.C. § 355(j)(5)(B)(iii).”¹⁸⁰

3. THE MAJORITY OPINION PROVIDES INADEQUATE GUIDANCE TO THE DISTRICT COURTS

[43] While the final outcome in *Eli Lilly v. Teva* is not necessarily incorrect, the majority opinion is highly problematic because it does not provide clear guidance on how to apply the modification provision of the Hatch-Waxman Act. The majority opinion was most likely correct to

¹⁷⁸ *Id.* at 1353 (quoting *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, No. 1:06-CV-1017, 2008 WL 4809963, at *2 (S.D. Ind. Oct. 29, 2008)).

¹⁷⁹ *Id.*

¹⁸⁰ *Id.* at 1355.

conclude that the proper standard of review was abuse of discretion.¹⁸¹ Further, it is not unthinkable that one might conclude, based on the evidence of Teva's late discovery production, that Teva's behavior met the statutory standard of failing to reasonably cooperate in expediting the action. The problem with the Federal Circuit's majority opinion is that it glossed over the fact that the district court never explicitly found that Teva failed to reasonably cooperate in expediting the action.

[44] The Federal Circuit decision creates a risk that district courts will apply the modification provision to a wide variety of discovery failures, instead of only to severe discovery failures that meet the statutory standard. The decision also creates the risk that future court modifications to the statutory stay period will lack significant correlation between the length of modification and the amount of delay caused.

[45] The legislative history indicates that Congress had a reason for setting thirty months as the time length for the stay; Congress did not intend for the stay to remain in effect throughout the duration of every infringement trial.¹⁸² Congress wanted to provide generic manufacturers with the opportunity to launch at-risk following expiration of the stay.¹⁸³ In the absence of legislation clarifying the modification provision, the Federal Circuit has a duty to ensure that district court applications of the modification provision adhere to the terms of the statute. The Federal Circuit should set precedent that, when faced with a motion under the modification provision, a district court must first evaluate whether a party's behavior constitutes a failure to reasonably cooperate. The district court must then determine whether this behavior resulted, or is likely to result, in delaying the trial. Finally, upon satisfaction of both conditions, the district court must consider what length of modification is appropriate

¹⁸¹ Abuse of discretion is the accepted standard for a preliminary injunction, which is effectively the same form of relief. *See generally* *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009).

¹⁸² *See* H.R. REP. NO. 98-857, pt. 2, at 10 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2694.

¹⁸³ *Id.*

to remedy the delay caused. To allow modification of the thirty-month statutory stay using a more cursory analysis (such as the one used by the district court in *Eli Lilly v. Teva*) is dangerous because of the substantial real-world repercussions associated with the timing of the FDA's approval of an ANDA.

V. CONCLUSION

[46] The Federal Circuit's decision in *Eli Lilly v. Teva* is problematic because it fails to provide the district courts with clear guidance on how to interpret and apply the modification provision of the Hatch-Waxman Act. Because it both affirmed the extension of a statutory FDA stay for a relatively minimal discovery delay and failed to delineate clear boundaries for the allowable use of the modification provision, the Federal Circuit's *Eli Lilly v. Teva* decision is likely to result in a significant increase in the number of motions for modification of the statutory thirty-month stay on FDA approval of an ANDA. Pioneer pharmaceutical plaintiffs, in particular, will now file greater numbers of motions to extend the statutory stay. This increase in motions will spark a corollary increase in court decisions to shorten or extend the statutory thirty-month stay.

[47] In the wake of *Eli Lilly v. Teva*, the district courts are likely to vary in their interpretations and applications of the modification provision. Some districts will be more liberal both in the frequency that they decide to modify statutory FDA stays and in the time durations for the FDA stay adjustments that they make. Because of the large, real-world monetary value associated with the extension of a thirty-month FDA stay on ANDA approval, a lack of standardization amongst the district courts relating to their understanding and application of the modification provision could lead to significant forum shopping by pioneer pharmaceutical plaintiffs.

ADDENDUM

Timeline of the Case History for
Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.

2006

May

Teva Pharmaceuticals USA, Inc. filed an ANDA with the FDA to manufacture and market generic raloxifene hydrochloride (which is sold by Eli Lilly under the brand name Evista).

May 16

Teva notified Eli Lilly of its paragraph IV certification.

June 29

Eli Lilly and Company filed a lawsuit against Teva in the Southern District of Indiana alleging that Teva's ANDA product infringed four Evista patents.

The statutory thirty-month stay on FDA approval of Teva's ANDA took effect.

September 25

The district court entered a scheduling order, setting a discovery deadline of August 18, 2008 and a trial date of March 9, 2009.

December

Teva first provided Eli Lilly with a sample of its proposed ANDA product.

2007

February

Eli Lilly amended its complaint to assert that Teva infringed three additional patents related to raloxifene particle size and formulation.

2008

July 8

Teva amended its ANDA with the FDA to include a new particle size measuring methodology for the active ingredient in its proposed raloxifene tablets.

July 10

Teva informed Eli Lilly that it had amended its ANDA.

July 28

Teva provided Eli Lilly with the first batch sample of its amended ANDA product.

August 18

Original scheduled deadline for discovery.

August 19

Teva provided Eli Lilly with the second batch sample of its amended ANDA product.

September 5

Teva provided Eli Lilly with the last of 27,000 pages of documentation related to its new particle size measuring methodology.

September 17

Teva provided Eli Lilly with the third batch sample of its amended ANDA product.

Eli Lilly filed a motion requesting the extension of the statutory thirty-month stay prohibiting Teva from entering the market with its generic raloxifene product.

October 6

Eli Lilly filed motions for a temporary restraining order and a preliminary injunction (both motions were denied as moot).

October 29

The Southern District of Indiana granted Eli Lilly's motion to extend the statutory FDA stay. The stay on FDA approval was extended until the start of trial (March 9, 2009).

November 16

The original statutory thirty-month stay on FDA approval was set to expire. Teva planned to launch at-risk on this date.

2009

February 24

The Federal Circuit affirmed the district court's decision to extend the statutory stay until the start of trial.

March 4

The district court denied Eli Lilly's request for an additional extension of the statutory stay on FDA approval.

March 9

Trial began.

The district court entered a temporary restraining order against Teva. (Teva was planning at-risk launch even on the eve of trial.)

April 22

The Southern District of Indiana granted a preliminary injunction in favor of Eli Lilly until a final trial determination is made.