United States Court of Appeals for the Federal Circuit

2009-1071

ELI LILLY AND COMPANY,

Plaintiff-Appellee,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellant.

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Appealed from: United States District Court for the Southern District of Indiana

Judge Sarah Evans Barker

United States Court of Appeals for the Federal Circuit

2009-1071

ELI LILLY AND COMPANY,

Plaintiff-Appellee,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellant.

Appeal from the United States District Court for the Southern District of Indiana in case no. 1:06-CV-1017, Judge Sarah Evans Barker.

DECIDED: February 24, 2009

Before MICHEL, Chief Judge, RADER and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge RADER. Dissenting opinion filed by Circuit Judge PROST.

RADER, Circuit Judge.

Finding that Teva Pharmaceuticals USA, Inc., ("Teva") "recast its product more than eighteen months after it provided the original sample to Lilly and only eight months before trial is set to commence," the United States District Court for the Southern District of Indiana extended the statutory thirty-month stay of 21 U.S.C. § 355(j)(5)(B)(iii) (2003), preventing the U.S. Food and Drug Administration ("FDA") from finally approving Teva's Abbreviated New Drug Application ("ANDA"). Eli Lilly & Co. v. Teva Pharms. USA, Inc., No. 1:06-cv-1017, 2008 WL 4809963, at *4-5 (S.D. Ind. Dec. 29, 2008)

("Extension Order"). Because the trial court did not abuse its discretion, this court affirms.

I

This case arises under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc (2003); 35 U.S.C. §§ 156 (2002), 271 (2003) (collectively, the "Hatch-Waxman Act"). Plaintiff-Appellee Eli Lilly & Company ("Lilly") sued Teva for patent infringement under 35 U.S.C. § 1 et. seq. and 28 U.S.C. §§ 2201-02.

The Hatch-Waxman Act strikes a balance between the sometimes-competing policy interests of inducing pioneering research and development of new drugs and enabling production of low-cost, generic copies of those drugs. A manufacturer that seeks to market a generic drug may submit an ANDA for approval by the United States Food and Drug Administration ("FDA"), rather than submitting a full New Drug Application ("NDA") showing the safety and efficacy of the generic drug. Thus, the generic manufacturer may rely on safety and efficacy studies of the pioneer manufacturer upon showing the generic drug's bioequivalence with the previously approved drug product. 21 U.S.C. § 355(j)(2)(A) (2003).

The Hatch-Waxman Act also requires a pioneer drug manufacturer to notify the FDA of all patents that "claim[ ] the drug for which the [NDA] applicant submitted the application." 21 U.S.C. §§ 355(b)(1) & (c)(2) (2003). The FDA lists such patents in its Approved Drug Products With Therapeutic Equivalence Evaluations, known as the "Orange Book". Under 35 U.S.C. § 271(e)(2), a generic manufacturer infringes a patent

by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent.

As part of the approval process, an ANDA applicant must make a certification addressing each patent listed in the Orange Book that claims the drug. 21 U.S.C. § 355(j)(2)(A)(vii). The Hatch-Waxman Act specifies the certification alternatives, (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV) (2003). These are commonly referred to as paragraph I, II, III, and IV certifications.

When an ANDA certifies under paragraph IV, the applicant must provide the patentee a detailed basis for its belief that the patent is not infringed, that it is invalid, or that it is unenforceable. 21 U.S.C. § 355(j)(2)(B) (2003). The patentee then has forty-five days to sue the ANDA applicant for patent infringement. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee does not sue, the FDA may proceed to approve the ANDA. If the patentee does file suit, the FDA may not approve the ANDA until expiration of the patent, resolution of the suit, or thirty months after the patentee's receipt of notice, whichever is earlier. Id. The court entertaining the suit has discretion under the statute to order a shorter or longer stay if "either party to the action fail[s] to reasonably cooperate in expediting the action." Id.

In this case, Lilly holds the approved NDA for raloxifene hydrochloride ("raloxifene") tablets. This product is marketed under the brand name Evista® for the

treatment and prevention of postmenopausal osteoporosis. Lilly lists twelve patents that claim Evista® in the Orange Book.

Teva filed an ANDA with the FDA in early 2006, seeking approval to manufacture and market generic raloxifene. As part of its ANDA, Teva filed paragraph IV certifications. On May 16, 2006, Teva notified Lilly of its paragraph IV certifications.

Lilly sued Teva on June 29, 2006, alleging that Teva's ANDA infringed four method patents of its twelve listed Orange Book patents for using raloxifene to prevent or treat postmenopausal osteoporosis: U.S. Patent Nos. RE38,968 ("the '968 patent"), RE39,049 ("the '049 patent"), RE39,050 ("the '050 patent"), and 6,906,086 ("the '086 patent"). The FDA then stayed approval of Teva's ANDA for thirty months, from the date that Lilly received Teva's paragraph IV notifications, expiring on November 16, 2008. Extension Order, 2008 WL 4809963 at *1.

On September 25, 2006, the district court entered a scheduling order, setting a trial date of March 9, 2009—four months after expiration of the thirty-month statutory stay. In February 2007, Lilly amended its complaint to assert that Teva infringed three additional Evista® patents—U.S. Patent Nos. 6,458,811 ("the '811 patent"), 6,797,719 ("the '719 patent"), and 6,894,064 ("the '064 patent")—covering raloxifene particle size and formulation.

On July 8, 2008, Teva amended its ANDA to include a new particle-size measuring methodology for the active pharmaceutical ingredient in its proposed raloxifene tablets. Extension Order, 2008 WL 4809963 at *2. Teva disclosed this amendment to Lilly on July 10, 2008, and provided it three batch samples on July 28, August 19, and September 17, 2008. The district court, however, previously set a

discovery deadline of August 18, 2008. Id. at *4 n.2. By September 5, 2008, Teva also provided Lilly with 27,000 pages of related documentation. Moreover, the district court ordered Teva to produce additional raloxifene samples to Lilly by December 15, 2008, in response to Lilly's motion to compel discovery.

On September 17, 2008, Lilly moved the district court under 21 U.S.C. § 355(j)(5)(B)(iii) to extend the statutory thirty-month stay due to Teva's alleged discovery violations, prejudicing Lilly's preparations for trial. Extension Order, 2008 WL 4809963 at *1. Lilly alleged that Teva "fail[ed] to 'reasonably cooperate in expediting the action' . . . as evidenced by Teva's last-minute alteration of its proposed drug product and its 'multiple delays in producing critical discovery . . . [which have] adversely affected Lilly's infringement case and trial preparation.'" Extension Order, 2008 WL 4809963 at *2 (citing Lilly Mot. for Ext. of Stat. Stay at I-2) (second alteration in the original). Lilly also alleged that Teva prejudiced its preparations for trial by not timely disclosing its plans to alter the particle-size measuring methodology of its proposed raloxifene tablets. Id. Teva allegedly began changing its particle-size measuring methodology as early as November 2007 with the goal of avoiding infringement of Lilly's asserted patents.

On October 6, 2008, Lilly moved the district court for a temporary restraining order ("TRO") and preliminary injunction to prevent Teva from launching its product on November 16, 2008, after expiration of the statutory thirty-month stay. The court granted Lilly's motion on October 29, 2008, to extend the statutory thirty-month stay until the beginning of trial on March 9, 2009. Extension Order, 2008 WL 4809963 at *6.

Lilly's motions for a TRO and preliminary injunction were thus denied as moot. Id. at *6 n.5.

Given the urgency of Teva's situation, just weeks before trial, it filed a motion in this court for an expedited appeal from the district court's order. Because the district court continued the injunction against the FDA, preventing it from finally approving Teva's ANDA until March 9, 2009, this court has jurisdiction over this appeal under 28 U.S.C. § 1292(a)(1).

II

The standard of review in this case is abuse of discretion in both the United States Courts of Appeals for the Federal and Seventh Circuits. See Rick's Mushroom Serv., Inc. v. United States, 521 F.3d 1338, 1342 (Fed. Cir. 2008) ("We review a denial of a request for additional discovery for abuse of discretion."); Gile v. United Airlines, 95 F.3d 492, 495 (7th Cir. 1996) ("[W]e review a district court's discovery determinations for an abuse of discretion."). Therefore, this court need not decide the question of which jurisdiction's law applies and will apply an abuse of discretion standard to its analysis.

"A district court would necessarily abuse its discretion if it based its ruling on an erroneous view of the law or on a clearly erroneous assessment of the evidence." Cooter & Gell v. Hartmarx Corp., 496 U.S. 384, 405 (1990). While extending the thirty-month statutory stay, the district court found,

> In light of the fact that Teva has recast its product more than eighteen months after it provided the original sample to Lilly and only eight months before trial is set to commence, we find that, in preparation for trial, Lilly is entitled to have sufficient opportunity to identify the nature and composition of the raloxifene product as Teva intends for it to be sold.

Extension Order, 2008 WL 4809963 at *4-5. In making this determination, the record contained sufficient evidence, not based on clearly erroneous factual findings, upon which the district court rationally based its decision. The court relied on the evidence in the record that Teva altered its proposed generic raloxifene hydrochloride tablets late in the litigation. Specifically, Teva changed the particle size manufacturing specification of its active pharmaceutical ingredient and the method of measuring the particle size. Id. at *2. Teva then delivered its changed samples to Lilly past the court's August 18, 2008, discovery deadline.

In making these findings, the district court acted within its discretion in this area. 21 U.S.C. § 355(j)(5)(B)(iii) grants district courts the discretion to adjust the statutory thirty-month stay of ANDAs if "either party to the action failed to reasonably cooperate in expediting the action." Trial courts, thus, may shorten or extend the thirty-month statutory period based on the parties' uncooperative discovery practices before the court. Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1337 n.5 (Fed. Cir. 2003) (Schall, J., concurring).

In explaining the statutory language, the House Committee report specified, "[f]ailure 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." H.R. Rep. No. 98-857, at 16 (1984), as reprinted in 1984 U.S.C.C.A.N. 2686, 2700. Because Teva provided Lilly with its altered raloxifene samples just eight months before trial, the district court extended the stay "to provide Lilly with 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." Extension Order, 2008 WL 4809963 at *6.

Teva argues that this court's opinion in Andrx Pharmaceuticals, Inc. v. Biovail Corporation, 276 F.3d 1368 (Fed. Cir. 2002), shows that the district court erred in extending the thirty-month stay. In Andrx, Biovail and Andrx were embroiled in patent litigation over both infringement and validity. Id. at 1372. The filing of the action triggered an automatic thirty-month stay of Andrx's ANDA from the date Biovail received Andrx's paragraph IV certifications on February 20, 2001. Id. Before the expiration of the thirty-month stay, Biovail acquired an exclusive license to a second patent in January 2001 that allegedly claimed the subject matter of its NDA. Id. Biovail changed its manufacturing process to fall within the claims of the second patent, which it submitted to the FDA on January 8, 2001, for listing in the Orange Book. Id. at 1372-73. In a February 2, 2001, letter to Andrx, the FDA stated that because of the listing of Biovail's second patent, it no longer intended to approve Andrx's ANDA upon the expiration of the thirty-month stay. Id. at 1372.

Andrx filed paragraph IV certifications with the FDA on February 16, 2001, that it did not infringe the second patent and that the patent was invalid. Andrx, 276 F.3d at 1373. On April 5, 2001, forty-four days after it received the paragraph IV certifications on February 20, 2001, Biovail filed a second suit against Andrx under 35 U.S.C. § 271(e)(2) for infringement of the second patent. Id. The second suit triggered a second thirty-month statutory stay ending August 8, 2003.[*] Id.

[*] In June 2003, the FDA amended its regulations so that an NDA holder could not obtain additional thirty-month stays based on patents added to the Orange Book after a generic manufacturer filed its ANDA. See Apotex, Inc. v. Thompson, 347

Andrx moved for summary judgment under 21 U.S.C. § 355(j)(5)(B)(iii) that the district court shorten the second thirty-month stay. Id. at 1374. In granting the motion, the district court found Biovail had intentionally impeded and delayed the expeditious resolution of the patent actions between it and Andrx. Id. at 1374-75. The district court, thus, shortened the second statutory thirty-month stay to September 27, 2001. Id. at 1375.

On appeal, this court held that the district court exceeded its authority under 21 U.S.C. § 355(j)(5)(B)(iii), vacated the district court's order, and remanded for further proceedings. Andrx, 276 F.3d at 1370. This court found the district court's reading of the statute was overly broad. The district court concluded it could shorten the thirty-month stay due to the alleged delay in the resolution of both patent disputes between the parties. Id. at 1376. The district court, however, erred by basing its decision on Biovail's positions before the FDA. Id.

Unlike Andrx, in this case, the district court extended the statutory thirty-month stay based on its findings of Teva's lack of cooperation in expediting the patent litigation in its court. The court's findings were not based on Teva's filing with the FDA. Moreover, as discussed, the district court's decision was supported by the record, its factual findings, and proper application of the law.

F.3d 1335, 1341 (Fed. Cir. 2003); Robert A. Matthews, Jr., Annotated Patent Digest § 10:154 (2007). In late 2003, Congress amended 21 U.S.C. § 355(j)(5)(B)(iii) to eliminate the thirty-month stay for any patent the NDA holder acquired after the generic manufacturer filed its ANDA. Pub. L. No. 108-173, § 1101(a)(2)(A)(ii), 117 Stat. 2448 (2003).

III

Because the district court did not abuse its discretion with its discovery findings and extending the statutory thirty-month stay to March 9, 2009, this court affirms. Given the short timing of this appeal, under Federal Rule of Appellate Procedure 40, a petition for panel rehearing or rehearing en banc must be filed within seven days after entry of judgment.

AFFIRMED

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PROST, Circuit Judge, dissenting.

The thirty-month stay described in 21 U.S.C. § 355(j)(5)(B)(iii) may be extended for one reason and one reason only: "because either party to the action failed to reasonably cooperate in expediting the action." Because I believe that the majority misapplies the law and misapprehends the facts in affirming the district court, I respectfully dissent.

I

The question here is one of statutory construction, which we review de novo. Although the majority is correct in that a district court's decision to issue a stay is generally reviewed for abuse of discretion, see, e.g., Cherokee Nation v. United States, 124 F.3d 1413, 1416 (Fed. Cir. 1997), the power to issue a stay in most cases arises under district courts' "broad discretionary powers to control their dockets," Gould v. Control Laser Corp., 705 F.2d 1340, 1341 (Fed. Cir. 1983). Where, as here, the stay is explicitly tied to a statutory standard, that standard must be properly construed. See In re Princo Corp., 478 F.3d 1345, 1353–55 (Fed. Cir. 2007) (construing a statute that

requires a stay by reference to dictionaries and legislative history, among other things). In the past, we have recognized that interpretation of the stay provided in 21 U.S.C. § 355(j)(5)(B)(iii) is a question of law reviewed without deference. Andrx Pharm., Inc. v. Biovail Corp., 276 F.3d 1368, 1375 (Fed. Cir. 2002). In Andrx, Biovail appealed a district court's decision to grant partial summary judgment, shortening the thirty-month stay and requiring the Food and Drug Administration ("FDA") to approve Andrx's Abbreviated New Drug Application ("ANDA"). We stated that "[i]nterpretation of statutes governing the grant of summary judgment presents threshold questions of law that are reviewed without deference," then proceeded to do just that, ultimately vacating and remanding. Id.

But even under an abuse of discretion standard, the district court's decision should not stand. Let us be clear about what the district court "found." The district court never made any finding related to the statutory standard, i.e., whether Teva reasonably cooperated in expediting the action. The court briefly described the background of the case and the parties' relative positions, and noted that the magistrate judge had ordered Teva to produce various documents prior to August 18, 2008. Although Teva did not complete production until September 5, 2008, the court did not purport to base any finding that Teva "failed to reasonably cooperate in expediting the action" on this eighteen-day delay. Instead, the court's findings were limited to the following:

> As this Court observed in its order granting a limited extension of the statutory stay in Eli Lilly & Co. v. Barr Laboratories, Inc., it appears "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 definitively established." That proposition similarly applies here. In light of the fact that Teva has recast its product more than eighteen months after it provided the original sample to Lilly and only eight months before trial is set to commence, we find that,

> in preparation for trial, Lilly is entitled to have a sufficient opportunity to identify the nature and composition of the raloxifene product as Teva intends for it to be sold.
>
> Teva argues that the circumstances in [Barr] are distinguishable from the situation at hand because the defendant in Barr had failed to provide Lilly with even one sample of its generic drug product, whereas here, on December 12, 2006, Teva provided Lilly with its original raloxifene sample, and has since produced to Lilly three samples of the altered product (the first on July 28, 2008, the second on August 19, 2008, and the third on September 17, 2008). Therefore, Teva contends that an extension of the statutory stay here is unnecessary because it has fully disclosed all the required information to Lilly in an expeditious fashion. Although Teva correctly cites the factual differences between the case at bar and the situation in Barr, those differences are not viewed by us as determinative on this issue. In Barr, we did not simply extend the statutory stay through the date on which the defendant produced a sample of its product to Lilly. Instead, our order provided that, after the defendant produced the sample, the stay would extend through "a reasonably expeditious time period for preparing for trial."
>
> A similar extension is warranted here in order to provide Lilly with 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, which is set to commence on March 9, 2009. For the foregoing reasons, the Court hereby EXTENDS until March 9, 2009, in this action the period under 21 U.S.C. § 355(j)(5)(B)(iii) during which the FDA is barred from approving ANDA No. 78-193.

Eli Lilly & Co. v. Teva Pharm. USA, Inc., No. 1:06-CV-1017, 2008 WL 4809963, at *2 (S.D. Ind. Oct. 29, 2008) (citations and footnotes omitted) ("Order Extending Stay"). Not once in this order did the court indicate, much less unambiguously state, that it found Teva had failed to reasonably cooperate in expediting the action.[1] The court provided at most two justifications for extending the stay: (1) to provide Lilly "a sufficient

[1] If anything, statements by the district court suggest that the court agreed that Teva reasonably cooperated by expeditiously "disclosing all of the required information," but extended the stay regardless. Order Extending Stay, 2008 WL 4809963, at *2. Specifically, Teva claimed that an extension of the stay was unnecessary because it fully disclosed all of the required information in an expeditious fashion. The court stated that "[a]lthough Teva correctly cite[d] the factual differences between the case at bar and the situation in Barr, those differences are not . . . determinative on this issue." Id. (emphasis added).

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." Id. Neither of these reasons remotely resembles the statutorily required finding.

It is clear from the record, in my view, that the district court never related Teva's conduct to the statutory standard. But even if the court had made a conclusory statement regarding Teva's cooperation, that alone would not suffice. In Gechter v. Davidson, we clarified that although "we review decisions, not opinions," a district court opinion "must contain sufficient findings and reasoning to permit meaningful appellate scrutiny." 116 F.3d 1454, 1458 (Fed. Cir. 1997). We went on to state the following:

> A district court therefore may not merely state its findings in conclusory terms, but must provide sufficient detail to elucidate the reasoning by which the court reached its ultimate finding on an issue of fact or conclusion on an issue of law; otherwise, the appellate court is unable to carry out its appellate review function. Indeed, as to the facts it must also find subsidiary facts "specially," and not just the ultimate fact, here of anticipation. If it fails to do so, its decision will ordinarily be vacated.

Id. In fact, in Nazomi Communications, Inc. v. Arm Holdings, PLC, our court vacated a district court's claim construction, an issue that we examine de novo, stating,

> This court's review of a district court's claim construction, albeit without deference, nonetheless is not an independent analysis in the first instance. Moreover, in order to perform such a review, this court must be furnished "sufficient findings and reasoning to permit meaningful appellate scrutiny." This requirement for sufficient reasoning applies with equal force to issues of law, such as claim construction, and issues of fact, such as infringement.
>
> . . . Unlike Gechter and Graco, where the records were devoid of any claim construction analysis, the district court in this case provided some claim construction analysis. Nonetheless this analysis is inadequate because it does not supply the basis for its reasoning sufficient for a meaningful review.

403 F.3d. 1364, 1371 (Fed. Cir. 2005) (citing Gechter, 116 F.3d at 1458; Graco, Inc. v. Binks Mfg., 60 F.3d 785, 791 (Fed. Cir. 1995)) (citations omitted). As in Nazomi, the district court here did not provide sufficient findings and reasoning to permit meaningful appellate scrutiny. Thus, regardless of whether we review the district court's order de novo or for an abuse of discretion, the order should be vacated.

II

The consequences of the majority opinion are of particular importance here. Rarely have district courts had the opportunity to address the circumstances under which the thirty-month stay may be extended or shortened.[2] Those courts that have addressed the issue have recognized the statutory standard and strictly abided by it in determining whether to modify the stay. See Zeneca Ltd. v. Pharmachemie B.V., 16 F. Supp. 2d 112 (D. Mass. 1998); In re Brimonidine Patent Litig., No. 07-md-1866, 2008 WL 4809037 (D. Del. Oct. 31, 2008); Novartis Corp. v. Dr. Reddy's Labs., Ltd., No. 04-Civ-0757, 2004 WL 2368007 (S.D.N.Y. Oct. 21, 2004); Minn. Mining & Mfg. Co. v. Alphapharm Pty. Ltd., No. CIV-99-13, 2002 WL 1299996 (D. Minn. Mar. 8, 2002); Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., No. IP99-0038-C-H/G, 2001 WL 238090 (S.D. Ind. Mar. 8, 2001).

Appropriate findings by the district court are especially important where, as here, Congress set forth a clear statutory timeframe and provided one narrow exception to the

[2] Even commentators have noted that "[s]tatutory stay adjustments have not been frequent." Gerald Sobel et al., Hatch-Waxman Litigation from the Perspective of Pioneer Pharmaceutical Companies, in Patent Litigation Strategies Handbook 183, 196–97 (Barry L. Grossman & Gary M. Hoffman eds., 2d ed. 2005).

general rule.[3] Only once has this court examined the matter directly. In Andrx, we analyzed a single question: whether the district court had the authority to shorten the stay period based on one party's conduct before the FDA. 276 F.3d at 1376. We expressly limited our review, declining to reach the question "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." Id. In short, this court has not previously provided any guidance to the district courts as to what qualifies as a "fail[ure] to reasonably cooperate in expediting the action." To affirm in this case is to effectively eliminate the statutorily required finding, and to prematurely terminate the development of appropriate standards governing modification under 21 U.S.C. § 355(j)(5)(B)(iii).

For the foregoing reasons, I respectfully dissent.

[3] The legislative history indicates that the thirty-month stay was a hard-won compromise between brand-name manufacturers, generics manufacturers, and other stakeholders. The length of the stay was the subject of heated debate in the House. 130 Cong. Rec. H24426–31 (Sept. 6, 1984). Initially, the House version of the bill provided for a stay of just eighteen months. H.R. 3605, 98th Cong. § 101 (as reported by H. Comm. on the Judiciary, Aug. 1, 1984). The Senate version, which ultimately prevailed, described a thirty-month stay. S. 2926, 98th Cong. § 101 (1984). In light of this fact, we should be especially careful when reviewing district courts' decisions to modify the statutory period. That period ceases to have meaning when district courts are able to modify the stay without articulating why the narrow circumstances described in the statute are present.