United States Court of Appeals for the Federal Circuit

01-1650, 02-1025

ANDRX PHARMACEUTICALS, INC.,

Plaintiff-Cross Appellant,

v.

BIOVAIL CORPORATION,

Defendant-Appellant,

v.

TOMMY G. THOMPSON, Secretary of Health and Human Services,
BERNARD A. SCHWETZ, Acting Principal Deputy Commissioner,
U.S. Food and Drug Administration, and U.S. FOOD AND DRUG ADMINISTRATION,

Defendants-Appellees.

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BIOVAIL LABORATORIES, INC.,

Plaintiff/Counterclaim Defendant,

and

BIOVAIL CORPORATION,

Counterclaim Defendant-Appellant,

v.

ANDRX PHARMACEUTICALS, INC.,

Defendant/Counterclaimant-
Cross Appellant.

Louis M. Solomon, Solomon, Zauderer, Ellenhorn, Frischer & Sharp, of New York, New York, argued for plaintiff-cross appellant 01-1650, and for defendant/counterclaimant-cross appellant in 02-1025, Andrx Pharmaceuticals, Inc. Of counsel were Colin A. Underwood, Teresa A. Consalves, and Jennifer R. Scullion. Also of counsel was Gerald J. Houlihan, Houlihan & Partners, P.A., of Miami, Florida.

Michael A. Cardozo, Proskauer Rose LLP, of New York, New York, argued for defendant-appellant in 01-1650, and plaintiff/counterclaim defendant, and counterclaim defendant-appellant in 02-1025, Biovail Corporation and Biovail Laboratories, Inc. Of counsel were Ronald S. Rauchberg, Nancy A. Kilson; and Alec W. Farr, Proskauer Rose LLP, of Washington, DC.

Howard S. Scher, Attorney, Appellate Staff, Civil Division, Department of Justice, of Washington, DC, argued for defendants-appellees, Tommy G. Thompson, Secretary of Health and Human Services, et al. Of counsel was Douglas N. Letter, Attorney.

Appeals from: United States District Court for the Southern District of Florida

Judge William P. Dimitrouleas

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DECIDED: January 17, 2002

Before BRYSON, LINN, and DYK, Circuit Judges.

DYK, Circuit Judge.

Biovail Corporation ("Biovail") appeals an order of the United States District Court for the Southern District of Florida. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), the district court (1) shortened the statutory thirty-month delay of approval of Andrx Pharmaceuticals, Inc.'s ("Andrx") pending Abbreviated New Drug Application ("ANDA") by the Food and Drug Administration ("FDA") and (2) ordered that the ANDA be approved by the FDA. Andrx Pharms., Inc. v. Biovail Corp., No. 01-6194, 2001 U.S. Dist. LEXIS 16904 (S.D. Fla. Sept. 19, 2001). We hold that the district court exceeded its authority under 21 U.S.C. § 355(j)(5)(B)(iii). Accordingly, we vacate the district court's order and remand for further proceedings.

I

This case requires an interpretation of the statute which governs new and generic drug approvals and the enforcement of patents related to such drugs. This court has recently described the background and operation of this statute in Mylan Pharmaceuticals, Inc. v. Thompson, 268 F.3d 1323, 1325-27, 60 USPQ2d 1576, 1577-79 (Fed. Cir. 2001). We briefly review it again here.

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, and 35 U.S.C. §§ 156, 271, (the "Hatch-Waxman Amendments" to the Federal Food, Drug and Cosmetic Act ("FFDCA")), Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market. Under the Hatch-Waxman Amendments, a manufacturer that seeks to market a generic drug may submit an ANDA for approval by the FDA, rather than submitting a full New Drug Application ("NDA") concerning the safety and efficacy of the generic drug, and it may rely on safety and

efficacy studies previously submitted by the pioneer manufacturer by submitting information showing the generic drug's bioequivalence with the previously approved drug product. See 21 U.S.C. § 355(j)(2)(A).

Also under the Hatch-Waxman Amendments, a pioneer drug manufacturer that holds an approved NDA is required 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). The FDA lists such patents in its Approved Drug Products With Therapeutic Equivalence Evaluations (otherwise known as the "Orange Book"). Under 35 U.S.C. section 71(e)(1), it is not patent infringement to conduct otherwise infringing acts necessary to prepare an ANDA. Under section 271(e)(2), however, a generic drug 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). An applicant whose ANDA is pending when a pioneer drug manufacturer lists additional patents in the Orange Book must make amended certifications addressing the newly listed patents claiming the drug, unless the patents are listed more than thirty days after they were issued. 21 C.F.R. § 314.94(a)(12)(vi). In either case, the ANDA applicant must certify that (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). These are commonly referred to as paragraph I, II, III, and IV certifications.

When an ANDA contains a paragraph IV certification, the ANDA applicant must give notice to the patentee and the NDA holder and provide a detailed basis for its belief

that the patent is not infringed, invalid, or unenforceable. 21 U.S.C. § 355(j)(2)(B)(i); 21 C.F.R. § 314.95(c)(6). The patentee then has forty-five days to sue the ANDA applicant for patent infringement, and the ANDA applicant may not file a declaratory judgment during this time (based on the filing of the ANDA application). 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee does not sue, the ANDA will be approved. 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 in which the suit is pending may order a shorter or longer stay if "either party to the action fail[s] to reasonably cooperate in expediting the action . . . ." Id.

II

The present controversy arose against this statutory background. Biovail's affiliate, Biovail Laboratories, Inc.,[1] currently holds an approved New Drug Application for a drug used to treat hypertension and angina, which it markets as Tiazac. The active ingredient in Tiazac is diltiazem hydrochloride. Andrx has filed an ANDA with the FDA for approval of a generic version of Tiazac.

The parties have been litigating patent infringement issues related to Andrx's ANDA for some time now. Biovail received approval for its NDA on September 11, 1995. Subsequent to FDA approval of the NDA, Biovail certified to the FDA that U.S. Patent No. 5,529,791 (the "'791 patent"), which issued on June 25, 1996, claimed the drug for which Biovail submitted the NDA. The FDA listed the '791 patent in the Orange Book as claiming Tiazac.

[1] For ease of reference, both Biovail Corporation and Biovail Laboratories, Inc. are referred to as Biovail.

On June 22, 1998, Andrx filed its ANDA application, which included a paragraph IV certification addressing the '791 patent. The certification stated that Andrx did not infringe the patent and that the patent was invalid. Andrx notified Biovail of its paragraph IV certification and, on October 7, 1998, Biovail sued Andrx in district court for infringement of the '791 patent. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), the filing of the patent infringement action triggered an automatic stay of the approval of Andrx's ANDA for thirty months after Biovail received notice of Andrx's paragraph IV certification (i.e., until February 25, 2001) or until the patent litigation was resolved. After a bench trial, the district court entered a judgment of noninfringement in favor of Andrx, and this court affirmed on February 13, 2001. Biovail Corp. Int'l v. Andrx Pharms., Inc., 239 F.3d 1297, 57 USPQ2d 1813 (Fed. Cir. 2001). Thus, but for the present dispute, the FDA would have approved Andrx's ANDA on or shortly after February 13, 2001.[2] However, the present dispute intervened.

On May 1, 1997, non-party Arnold Lippa filed a provisional application in the United States Patent and Trademark Office. On April 28, 1998, within the one-year window available to claim priority to the provisional application, Mr. Lippa filed a utility patent application. That application resulted in the issuance on December 19, 2000, of U.S. Patent No. 6,162,463 (the "'463 patent"), which claims an extended release formulation of diltiazem, the active ingredient in Tiazac. The parties apparently agree that Biovail did not participate in the prosecution of applications leading to the '463 patent, but in January 2001 Biovail acquired an exclusive license for the patent.

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[2] In September 2000 Andrx had received tentative approval of its ANDA from the FDA, pending expiration of the statutory stay period.

On January 8, 2001, Biovail filed a certification with the FDA supporting the listing of the '463 patent in the Orange Book. In a February 2, 2001, letter to Andrx the FDA stated that because of the listing of the '463 patent, it no longer intended to approve Andrx's ANDA upon the expiration of the thirty-month stay triggered by the infringement dispute concerning the '791 patent. In a letter to the FDA dated February 1, 2001, Andrx protested the listing of the '463 patent, claiming that the patent did not claim Tiazac, and requested that the FDA delist the patent from the Orange Book. The FDA twice sought a response from Biovail concerning Andrx's protest to the listing of the '463 patent in the Orange Book. On March 26, 2001, Biovail recertified that the '463 patent claims the drug for which it submitted its original NDA. This alone was apparently sufficient for the FDA. The FDA continued to list the '463 patent in the Orange Book without further inquiry or investigation, even though Biovail conceded in its statement of disputed material facts to the district court that the "FDA filings in this case preliminarily stated that the ['463] patent does not claim the approved drug product in the Tiazac NDA."

Apparently, after issuance of the '463 patent, Biovail changed its process for manufacturing Tiazac and sought approval to market this new formulation of Tiazac. Biovail, in its statement of disputed material facts in the district court, stated, somewhat confusingly, that it "recently changed its manufacturing process for Tiazac" and that "[t]his change . . . brings Tiazac within the scope of at least claim one of the ['463] patent." In seeking approval for the new formulation, Biovail argued to the FDA that the manufacturing change did not affect the safety and efficacy of Tiazac, and therefore that Biovail was not required to supplement its Tiazac NDA. The FDA's Director of Cardio-Renal Drug Products in the Office of Drug Evaluation (the "Director"), however, disagreed in a March 23, 2001, letter to Biovail, and stated that the "FDA has concluded that the approved drug application does not provide for those manufacturing changes . . . ." The Director required

Biovail to submit a supplement to its NDA, which would have to be approved before Biovail would be permitted to market the drug product prepared according to the new manufacturing changes. Biovail, however, continued to protest that it did not need to supplement its NDA for the new formulation to be approved. According to Biovail and the FDA, proceedings in the matter are still ongoing at the FDA.

While these administrative proceedings were pending, Andrx filed the present suit in the Southern District of Florida on February 9, 2001, naming as defendants Biovail, the Secretary of Health and Human Services, the Acting Principal Deputy Commissioner of the FDA, and the FDA. Andrx sought a declaratory judgment that it did not infringe the '463 patent, and that the '463 patent was invalid, and alleged antitrust and various violations of state law. Additionally, Andrx sought the relief of "delisting" the '463 patent from the Orange Book and of shortening the thirty-month statutory period.

Andrx also filed a paragraph IV certification with the FDA, dated February 16, 2001, stating that it did not infringe the '463 patent and that the '463 patent was invalid. Biovail received notice of the certification on February 20, 2001. Forty-four days later, on April 5, 2001, Biovail filed suit in the Southern District of Florida, alleging that Andrx's paragraph IV certification constituted infringement of the '463 patent under 35 U.S.C. § 271(e)(2). Biovail urged that this triggered a thirty-month statutory stay period under 21 U.S.C. § 355(j)(5)(B)(iii).

The district court consolidated the two actions. The district court dismissed the counts of Andrx's complaint asserting a private cause of action under the FFDCA to delist the '463 patent from the Orange Book. Andrx Pharms., Inc. v. Biovail Corp., No. 01-CV-6194, slip op. at 9, 15-17 (S.D. Fla. Sept. 19, 2001). In dismissing this part of the cause of action, the district court thus correctly anticipated this court's recent holding in Mylan, 268 F.3d at 1332-33, that a generic drug manufacturer cannot bring a declaratory judgment

action or an injunctive action against a NDA holder under either the FFDCA or the patent laws requiring it to take steps to "delist" a patent from the Orange Book. However, the district court allowed Andrx's declaratory counts to be treated as counterclaims to Biovail's infringement suit. Andrx, slip op. at 14. The district court additionally dismissed the federal defendants from the lawsuit because Andrx failed to state a claim for relief against those defendants under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702-706. The court found that Andrx's amended complaint:

> [w]hile implying certain procedural facts that may give rise to an APA claim . . . did not put the Federal Defendants on notice of their alleged violations of the APA, even under the liberal notice pleading standard of the Federal Rules of Civil Procedure. Thus, this Court will grant the Federal Defendants' motion to dismiss the Amended Complaint as to the Federal Defendants, without prejudice.

Andrx, slip op. at 7-8.

Andrx moved the district court to shorten the thirty-month statutory period, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), thus triggering the particular dispute that is now before us. That statute provides:

> (iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph 2(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action . . . .

21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added). Andrx urged that Biovail had already been granted one thirty-month stay (involving the '791 patent) and was not entitled to a second one (involving the '463 patent). Andrx also argued that after Biovail licensed the '463 patent it deliberately changed its formulation of its Tiazac drug product to fall within the claims of the '463 patent so that it could claim an additional stay period. On September

19, 2001, the district court granted Andrx's motion for summary judgment on the thirty-month stay issue.

The district court explained:

> Even if all of Biovail's filings in these two cases are not frivolous, its overall conduct in listing the '463 patent based upon a manufacturing change that the FDA has concluded is a "major" change requiring a supplement to Biovail's New Drug Application, and that with this change, Biovail's Tiazac drug is not an approved drug, was not done to reasonably cooperate in expediting the action. Whether or not the listing of the '463 patent is a "sham listing" as Andrx urges this Court to conclude, it is clear that Biovail's actions with regard to obtaining the '463 patent after tentative approval of Andrx's generic drug and changing the formulation of its own approved drug, Tiazac, to come within the newly obtained patent were done to impede or delay the expeditious resolution of the patent actions between Biovail and Andrx over approval of Andrx's generic equivalent to Tiazac.

Andrx, slip op. at 19 (emphasis added). The district court also rejected Biovail's argument "that it limit its analysis [of its authority to shorten the stay] to only the specific filings in . . . the actual infringement action. Such a myopic approach to each listed patent would lead to a potentially endless listing of patents to prolong FDA approval of a generic competitor." Id. at 20.

The second thirty-month stay (based on the '463 patent) would have ended on August 8, 2003. The district court ordered that "under 21 U.S.C. § 355(j)(5)(B)(iii) the statutory stay should end on September 27, 2001, and the FDA . . . should approve Andrx's ANDA." Id. at 20-21. The district court then granted Biovail's emergency motion to stay its order until October 1, 2001, to allow Biovail to seek a stay of the district court's order from this court. This court granted a stay in order to "preserve the status quo while the court is considering the parties' papers." Biovail appealed the district court's order to this court, and moved for a further stay of the district court's order, pending disposition of its appeal. Andrx opposed Biovail's motion. Biovail replied. Andrx moved for leave to file a surreply, with the surreply attached, which we have granted. The Biovail stay motion was referred to

a motions panel. We reconstituted the motions panel as a merits panel and ordered oral argument, directing the parties to prepare to argue the merits of the case. We also allowed the FDA to appear and present oral argument. We heard oral argument from the parties on December 14, 2001, and we now decide the merits. We vacate the order of the district court and dismiss Biovail's motion for a stay of the district court's order as moot.[3]

III

We review a district court's grant of summary judgment without deference. Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1302, 50 USPQ2d 1429, 1434 (Fed. Cir. 1999), cert. denied 528 U.S. 1115 (2000). We draw all reasonable inferences in favor of the non-movant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Interpretation of statutes governing the grant of summary judgment presents threshold questions of law that are reviewed without deference. Barton v. Adang, 162 F.3d 1140, 1144, 49 USPQ2d 1128, 1132 (Fed. Cir. 1998); Madison Galleries, Ltd. v. United States, 870 F.2d 627, 629 (Fed. Cir. 1989).

IV

Biovail makes two primary arguments as to why the district court erred in shortening the stay period under section 355(j)(5)(B)(iii). First, Biovail argues that the district court erred in its interpretation of that statute because the statute allows the thirty-month stay to be shortened only if the parties fail to expedite the infringement action once filed. In fact, the statute may be susceptible to another interpretation that would allow the district court to inquire both (1) whether the suit was filed expeditiously after the patent issued (and

[3] Andrx appealed the dismissal of its claims which sought an injunction to require delisting of the '463 patent from the Orange Book. That appeal was docketed in this court on October 18, 2001, but was stayed pending resolution of this appeal on November 21, 2001. Andrx Pharms., Inc. v. Biovail Corp., No. 02-1065, slip op. at 2 (Fed. Cir. Nov. 21, 2001) (unpublished order).

perhaps even whether the patent application was filed and prosecuted expeditiously so as to lead to a prompt infringement action filing) and (2) whether, once filed, it was prosecuted expeditiously. Moreover, while the statute provides that FDA approval "shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of [the] forty-five day[]" period, 21 U.S.C. § 355(j)(5)(B)(iii), it does not explicitly provide that a filing within the forty-five day period will eliminate any question relating to expeditious filing of the action. However, we do not 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, for example, because of delay in the prosecution and/or issuance of the patent or in the filing of the infringement action.

Biovail's second argument is that the district court shortened the period based on Biovail's conduct in the FDA proceedings. Here, we agree that the district court erred. The district court shortened the stay period because it found that Biovail's "actions with regard to obtaining the '463 patent after tentative approval of Andrx's generic drug and changing the formulation of its own approved drug, Tiazac, to come within the newly obtained patent [was] done to impede or delay the expeditious resolution of the patent actions between Biovail and Andrx . . . ." Andrx, slip op. at 19. The court's ruling was based on what we believe was an overly broad reading of the statute. First, whether the patent claims the drug product that is being actually marketed has nothing to do with the propriety of the listing of the patent in the Orange Book. Rather, the critical question is the relationship of the patent to the drug products and drug substances covered by the NDA. See post n.5. Thus, Biovail's changing of its manufacturing process could not have been

designed to justify the listing of the '463 patent in the Orange Book.[4] Second, under our decision in Mylan, the district court has no authority in the infringement action, as opposed to an action under the Administrative Procedure Act, to shorten the thirty-month stay because of allegedly improper conduct before the FDA. Third, the district court appeared to conclude that it could shorten the period because of delay in the resolution of the overall patent dispute between Biovail and Andrx. We find no such authority in the statute, which is addressed only to delay related to the particular infringement action. Thus, the district court exceeded its authority in shortening the thirty-month stay.

V

Andrx argues that the district court's decision may be affirmed on the alternative ground that Andrx properly stated a claim under the Administrative Procedure Act and that the FDA's refusal to issue the ANDA was either contrary to law or arbitrary and capricious because the FDA should not have treated Biovail's filing of the '463 patent in the Orange Book as invoking a new thirty-month stay period under 21 U.S.C. § 355(j)(5)(B)(iii). Andrx argues that the FDA should not have stayed the approval of Andrx's ANDA based on Biovail's filing of the '463 patent because either (1) in this case the '463 patent did not claim the drug approved in the original NDA as required by section 355(b) or (2) section 355 does not permit Biovail to benefit from an additional thirty-month stay based on the patent listed in the Orange Book after Andrx submitted its original ANDA application and paragraph IV certification because 21 U.S.C. § 355(j)(5)(B)(iii) (the thirty-month stay provision) refers to granting a stay from the time of "notice [from the ANDA applicant to the

[4] To be sure, Biovail's efforts to secure approval for the marketing of the new formulation of its drug product may affect the FDA's interpretation of what is covered by the NDA, but it is the scope of the NDA that is pertinent to Orange Book listing, not the formulation of the drug product being sold.

NDA holder] provided under paragraph (2)(B)(i)"; and (2)(B)(i) only refers to certifications submitted in connection with the original ANDA application, in contrast with certifications submitted in connection with amended applications.[5]

The FDA apparently declines to consider such issues. 21 C.F.R. § 314.53 provides a person may protest the listing of a patent submitted by the NDA holder if the person disputes the accuracy or relevance of the patent information submitted to the FDA. If such a protest is filed, the FDA will request the NDA holder to confirm the correctness of the information submitted. According to the regulation, however, "[u]nless the application

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[5] The FDA's current regulations require listing of every patent that "claims a drug (the drug product or drug substance that is a component of the drug product) on which investigations that are relied upon by the applicant for approval of its application were conducted . . . ." 21 C.F.R. § 314.50(i)(1)(i)(A) (2001) (emphasis added). This rule was made final in November 1994 and represented a change from prior FDA regulations. The old regulations tracked the statutory language of 21 U.S.C. § 355(b)(1) which requires listing of any patent that "claims the drug for which the [NDA] applicant submitted [an] application . . . ." According to at least one district court, prior to making the new rule final in 1994, "the FDA interpret[ed] the term 'drug' as used in § 355(b)(1) . . . to mean the 'drug product' for which the NDA was filed, arguing that although an NDA must include information on the active ingredient or 'drug substance' involved, an approved NDA covers only a specified drug product . . . ." Pfizer, Inc. v. FDA, 753 F. Supp. 171, 174 (D. Md. 1989) (upholding the FDA's decision not to list a patent which claimed the active ingredient of the approved drug product but did not claim the approved drug product because such an interpretation of the statute was reasonable). Thus, the new 1994 rule represented a change in FDA procedures concerning what patents must be listed in the Orange Book. The FDA's current, more liberal construction of the statute, of course, leads to more patents' being listed in the Orange Book. This change in FDA procedure and its effect on patent listings in the Orange Book has been noted by at least two district courts. See Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 10 F. Supp. 2d 446, 455-57, 49 USPQ2d 1920, 1927 (D.N.J. 1998) (noting change in the regulation and, after distinguishing Pfizer, upholding FDA's decision to list a patent claiming a drug substance because the "FDA's construction of the statute to require listing of certain drug substance patents as well as drug product patents is a permissible reading of the statute"); Watson Pharms., Inc. v. Henney, Civ. No. S00-3516, 2001 U.S. Dist. LEXIS 2477 (D. Md. Jan. 18, 2001) (distinguishing Pfizer because it was decided before the current FDA regulations were made final and rejecting ANDA holder's protest, brought under the APA, of FDA's listing of a drug substance patent in the Orange Book). The district court's decision in Watson is separately pending on appeal in this court. That appeal was docketed for appeal by this court on April 10, 2001. That appeal was stayed, however, pending final resolution of the Mylan appeal. Watson, No. 01-1285, slip op. at 2 (Fed. Cir. June 26, 2001) (unpublished order).

holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list." 21 C.F.R. § 314.53(f). In adopting that regulation, the FDA defended its decision not to "establish a mechanism for review of submitted patent information to determine, at least on a very general basis, applicability to the particular NDA in question" on the ground that the "FDA does not have the expertise to review patent information." 59 Fed. Reg. 50,338, 50,343 (Oct. 3, 1994).[6]

Apparently the FDA also disagrees with Andrx's second statutory argument, since it has treated the listing in the Orange Book of the '463 patent as requiring a new thirty-month stay of its approval of Andrx's ANDA.

Biovail argues that this court in Mylan held that a private party could not assert an APA claim for delisting against the FDA. We disagree. In Mylan, the ANDA applicant sued the FDA and the NDA holder, alleging that the pertinent patent had been improperly listed in the Orange Book, and moved for declaratory and injunctive relief including an injunction against the NDA holder to take measures to delist the patent from the Orange Book and an injunction against the FDA to immediately approve the ANDA. The district court issued the injunctions against both the private defendant and the FDA requiring the private defendant to withdraw the Orange Book listing and the FDA to approve the ANDA.

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[6] One commentator has noted that "Orange Book listing elevates every patent as a potential source of delay to generic competition," because listing gives "the patentee/NDA holder almost automatic injunctive relief for even marginal infringement claims." Terry G. Mahn, Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process, 54 Food Drug L.J. 245, 250 (1999). The commentator recognizes that the effect of the FDA's policy not to decide the merits of a protestor's challenge to the listing of a patent and to continue to list the patent if the NDA holder does not voluntarily remove it is to encourage NDA holders to "evergreen their drug patents" by filing a series of applications for different patents covering the same basic drug and thereby delay issuance of an ANDA indefinitely. Id. The commentator then suggests patent claim drafting techniques to best achieve such evergreening and to maximize the number of Orange Book listings. Id. at 251.

Mylan Pharms., Inc. v. Thompson, 139 F. Supp. 2d 1, 29 (D.D.C. 2001). The private defendant appealed, arguing that the FFDCA did not grant a private right of action, but the FDA did not appeal. On appeal, the appellee ANDA holder urged that its cause of action arose under the patent laws (Title 35 of the United States Code) as a defense to patent infringement, because listing in the Orange Book was an element of any patent infringement cause of action which the NDA holder might have asserted. Mylan, 268 F.3d at 1330-31. We rejected the ANDA holder's attempt to bring its action under the patent laws because we concluded that its cause of action was not tied to any recognized patent infringement defense but rather was "an attempt to assert a private right of action for 'delisting' under the FFDCA." Id. at 1332. We also made clear that there was no private cause of action for delisting under the FFDCA. Id. However, we did not hold or suggest that an ANDA applicant may not sue the FDA directly under the APA to compel the FDA to approve the ANDA if the FDA's action in denying the ANDA is arbitrary, capricious, or not in accordance with law. Because the FDA did not appeal the injunction against it in Mylan, we stated that "[w]e therefore do not address any cause of action that Mylan has or may assert against the FDA." Id. at 1329. Indeed, we note that at oral argument the government in this case agreed that Mylan did not bar such a claim and that the APA provides an appropriate mechanism for reviewing the lawfulness of the FDA's action.[7] Nor did our decision in Mylan preclude consideration of Andrx's second argument if brought under the APA.

Under the APA, a person "adversely affected or aggrieved by agency action," including a "fail[ure] to act," is entitled to "judicial review thereof." 5 U.S.C. § 702. Agency

[7] Of course, the government denies that the FDA here acted in any way contrary to law.

action, or failure to act, is reviewable only if the action is a "final agency action for which there is no other adequate remedy in a court . . . ." 5 U.S.C. § 704. If a party has standing and prevails under its APA claim, it is entitled to a remedy under the statute, which normally will be a vacatur of the agency's order. Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1084 (D.C. Cir. 2001). The Supreme Court has long recognized that decisions of the FDA are subject to review under the APA. See Abbott Labs., Inc. v. Gardner, 387 U.S. 136, 140-41 (1967) (FDA decisions and regulations under the FFDCA are reviewable under the APA); Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 627 (1973) (holding that an FDA order that a drug is a "new drug" within the meaning of FFDCA and therefore requires the filing and approval of an NDA "is reviewable by the district court under the Administrative Procedure Act"). The District of Columbia Circuit has recognized that claims may be brought under the APA to compel the FDA to act in accordance with the Hatch-Waxman Amendments on several occasions. For example, in American Bioscience, a patentee sued the FDA, alleging that the FDA had acted contrary to law when it approved an ANDA despite the listing of a pertinent patent in the Orange Book. The FDA had concluded that the patent had been listed more than thirty days after its date of issuance and that under 21 C.F.R. § 314.94(a)(12)(vi) it had therefore been improperly listed and that the ANDA applicant was not required to file a certification. The patent holder sought a declaratory judgment under the APA that the FDA erred in concluding that the patent had been listed more than thirty days after it issued, and in approving the ANDA. The court agreed that the FDA's approval of the ANDA was arbitrary and capricious and ordered that it be vacated. Id. at 1086. See also Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1069, 46 USPQ2d 1385, 1391-92 (D.C. Cir. 1998) (affirming a successful APA challenge to the FDA requirement that the first applicant to file an ANDA must first

successfully defend a patent infringement suit before it can be granted 180-day period of marketing exclusivity with respect to other ANDA applicants).

Although we agree that claims might properly be brought under the APA in this case to challenge the FDA's failure to issue the ANDA,[8] we do not agree that Andrx has filed such a claim under the APA. Although Andrx's amended complaint alleged that the court had jurisdiction, inter alia, "pursuant to . . . 5 U.S.C. §§ 702-706," the complaint did not allege that any of the claims arose under the APA or that the FDA had acted arbitrarily, capriciously, or not in accordance with law in denying approval of the ANDA. Moreover, the district court found that Andrx's "Amended Complaint does not list a specific count alleging any wrongdoing by the Federal Defendants," Andrx, slip op. at 6, and therefore dismissed the federal defendants from this action. That dismissal is not challenged on this appeal. An APA claim can hardly lie when the government is no longer a party to the action.

VI

For the foregoing reasons, we vacate the decision of the district court and remand for further proceedings. This action is without prejudice to (1) any future order of the district court, not inconsistent with this opinion, shortening the thirty-month period pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) on the ground that the parties are not complying with the statutory requirement to "reasonably cooperate in expediting the action"; (2) any effort by Andrx to amend its complaint to state a proper claim against the FDA under the Administrative

[8] We, of course, express no opinion here as to whether the FDA's action in refusing to inquire into the correctness of a listing, which then caused the FDA to stay the approval of an ANDA, might represent action that is arbitrary, capricious or not in accordance with law.

Procedure Act for the FDA's refusal to issue the ANDA. We dismiss as moot Biovail's request for a stay of the district court's order.

VACATED AND REMANDED

COSTS

No costs.