United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 17, 1997 Decided January 16, 1998

No. 96-1256

MD PHARMACEUTICAL, INC.,
PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION,
RESPONDENT

MALLINCKRODT CHEMICAL, INC.,
INTERVENOR FOR RESPONDENT

On Petition for Review of an Order of the
United States Drug Enforcement Agency

John R. Fleder argued the cause for petitioner, with whom *Tish E. Pahl* was on the briefs.

Lena Watkins, Associate Deputy Chief, United States Department of Justice, argued the cause for respondent, with

whom *John C. Keeney,* Acting Assistant Attorney General, was on the brief.

Steven J. Poplawski and *Scott M. Badami* were on the brief for intervenor.

Before: WILLIAMS, SENTELLE and ROGERS, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* SENTELLE.

SENTELLE, *Circuit Judge*: This case arises out of the Drug Enforcement Administration's ("DEA") approval of an application submitted by Mallinckrodt Chemical, Inc. ("Mallinckrodt") for registration as a bulk manufacturer of methylphenidate, a generic form of the drug commonly known by the brand name of Ritalin. MD Pharmaceutical, Inc. ("MD"), a current producer of methylphenidate, petitions for review of three decisions made by DEA, namely: (1) the decision to permit withdrawal of Mallinckrodt's two previous applications for registration as a bulk manufacturer of methylphenidate; (2) the order terminating the hearings on those two applications upon their withdrawal; and (3) the order approving the issuance of the certificate of registration to Mallinckrodt. We conclude that MD, as a current manufacturer of the drug, has standing to seek review of the actions taken by DEA. We also conclude that MD's objections to DEA's decisions are without merit, and accordingly deny the petition for review.

I.

The Controlled Substance Act ("CSA") establishes a comprehensive regulatory system that controls the manufacture, distribution, and use of hazardous drugs. 21 U.S.C. § 801 *et seq.* The level of restriction on any given drug is determined by its classification into one of five schedules. The Administrator of DEA, having received authority from the Attorney General by delegation, 28 C.F.R. § 0.100(b), is required to classify each drug into a schedule, depending upon factors such as its potential for abuse and its risk to the public health. 21 U.S.C. § 811. Methylphenidate is a Schedule II drug, which means that it has a high potential for abuse, that it has a currently accepted medical use, and that abuse of the

drug may lead to severe psychological or physical dependence. *Id.* at § 812(b)(2).

A company seeking to become a manufacturer of a Schedule II drug must apply for and obtain a certificate of registration from DEA. 21 U.S.C. § 822(a). The Administrator grants a certificate only if he determines that "registration is consistent with the public interest" when measured against a six-part test created by Congress. 21 U.S.C. § 823(a)(1)-(6). When DEA receives such an application for registration, it must publish a notice in the Federal Register, and send individual notices to other applicants and to currently registered bulk manufacturers of the drug. 21 C.F.R. § 1301.43(a) (1996). The other applicants and registrants are free to file comments on the proposed registration within 60 days. *Id.* Registered manufacturers had the additional right, prior to July 20, 1995, to request and obtain an evidentiary hearing on an applicant's proposed registration. 21 C.F.R. § 1301.43 (1994). Ultimately, DEA either issues the certificate of registration, or issues an order to show cause as to why the application should not be denied. 21 U.S.C. § 824(c).

On May 13, 1994, DEA announced that Mallinckrodt had applied for registration as a bulk manufacturer of methylphenidate. MD, as a registered manufacturer of the drug, received notice of the application and promptly requested an evidentiary hearing. On January 30, 1995, Mallinckrodt filed a second application for registration, this time for methylphenidate and other drugs. MD once again objected to Mallinckrodt's application with respect to methylphenidate. The parties agreed to consolidate the proceedings for the two applications. An Administrative Law Judge ("ALJ") presided over the first stage of an evidentiary hearing from May 2-5, 1995, but did not announce a decision at that time.

On June 20, 1995, DEA issued a final rule altering the certification process in two pertinent respects. Under the amended regulations, which went into effect on July 20 of that year, registered manufacturers retained the right to comment on another firm's application, but no longer had the right to a hearing on an application other than their own. 60

Fed. Reg. 32,099-101 (codified at 21 C.F.R. § 1301.43(a)) (1996). The second alteration concerned an applicant's ability to withdraw a pending application. Under the old rules, an application could be withdrawn without the Administrator's permission at any time before the date on which an applicant receives an order to show cause, or before the date on which a notice of hearing on the application was published, whichever came first. 21 C.F.R. § 1301.37(a) (1994). Because the new regulations eliminated the opportunity for third parties to obtain a hearing, the new rules stated that an application could be withdrawn without the permission of the Administrator at any time before the applicant receives an order to show cause. 21 C.F.R. § 1301.37(a) (1996). Under both the old and the new regulations, an applicant could also amend or withdraw an application "with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest." 21 C.F.R. § 1301.37(a) (1994); 21 C.F.R. § 1301.37(a) (1996).

On July 20, 1995, the date that the new regulations went into effect, Mallinckrodt submitted a letter to DEA requesting withdrawal of its 1994 and 1995 applications. On the same day, Mallinckrodt submitted a new application for registration as a bulk manufacturer of methylphenidate under the newly amended regulations. MD strenuously opposed the withdrawal of the applications, arguing that Mallinckrodt was simply trying to circumvent the hearing requirement under the old rules. DEA nonetheless approved the withdrawal of Mallinckrodt's first two applications. The ALJ subsequently terminated all proceedings with respect to those two applications. DEA later announced that Mallinckrodt's third application would be considered under the amended rules.

MD filed two petitions for review with this court, challenging DEA's decision to permit withdrawal of the first two applications and to terminate the hearings. We dismissed the petitions on ripeness grounds, explaining that DEA had not yet ruled on Mallinckrodt's third application for registration. *MD Pharmaceutical, Inc. v. Drug Enforcement Administration,* Nos. 95-1474, 95-1475, 1996 WL 135318 (D.C. Cir. Feb. 2, 1996). We made clear that the dismissal was "without

prejudice to any right MD may have to challenge Mallinckrodt's withdrawal of its original application to bulk manufacture methylphenidate by way of a petition for review of the DEA's final resolution of Mallinckrodt's pending application." *Id.*

In a subsequent comment arguing against Mallinckrodt's third application, MD raised a number of issues, including Mallinckrodt's alleged history of noncompliance with DEA and FDA regulations. MD also took the position that there was no need for an additional manufacturer of this drug because the market was sufficiently competitive. On January 31, 1996, Mallinckrodt filed a fourth application adding other drugs to its methylphenidate application. MD filed comments and incorporated by reference its earlier objections. On July 16, 1996, DEA granted Mallinckrodt's fourth application to be a bulk manufacturer of methylphenidate. The agency published a Notice that briefly explained its decision and responded to a number of issues raised by MD. 61 Fed. Reg. 37,079-81. The agency declined to take action on the third application filed July 20, 1995.

In the present action, MD seeks review of three decisions by DEA: first, the decision to permit withdrawal of Mallinckrodt's first two applications; second, the decision to terminate the hearings on those two applications; and third, the order approving Mallinckrodt's registration as a producer of methylphenidate.

II.

Before reaching the merits, we must address the issue of whether MD has standing to challenge the actions taken by DEA. The government takes the position that MD has not satisfied the requirements of either constitutional or prudential standing. We reject both contentions.

The well-established "irreducible constitutional minimum" of standing requires three elements:

> First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a)

> concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant.... Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992) (internal citations and punctuation omitted). DEA does not allege that MD has not suffered an injury in fact, nor that the action taken by the government has not caused the alleged injury. Indeed, such arguments would be unavailing in this case. We have previously held that "increased competition represents a cognizable Article III injury," *Liquid Carbonic Industries Corp. v. FERC,* 29 F.3d 697 (D.C. Cir. 1994), and MD's competitive injury is fairly traceable to DEA's decision to issue a certificate of registration to Mallinckrodt.

DEA, however, claims that MD lacks standing under Article III because its alleged injury is not redressable by the relief it seeks in this case. The government's argument is based upon 21 U.S.C. § 824(c), which provides that denial, revocation, or suspension of registration shall not occur until the Administrator "serve[s] upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended." *Id.* The statute, in other words, precludes the Administrator from denying a registration until it has issued an order to show cause. The government submits that MD's alleged injury is not redressable because we cannot grant relief resulting in the outright denial of Mallinckrodt's registration. Whether we remand for further review, or vacate the order granting registration, Mallinckrodt's registration cannot be denied without the Administrator taking the additional step of issuing an order to show cause. The decision to issue an order to show cause, the argument proceeds, is a discretionary act akin to the decision to initiate an enforcement proceeding, which courts presumptively lack the authority to mandate. *See Heckler v. Cheney,* 470 U.S. 821 (1985). Because denial of the registration cannot occur without issuance of an order to show cause, and

because the decision to issue such an order is presumptively unreviewable, a decision from us could not possibly provide a remedy that would redress the injury alleged by MD.

The government's argument breaks down at the outset because it mischaracterizes the relief sought by petitioner. A central premise of the government's argument is that MD is seeking the outright denial of the registration of Mallinckrodt. In fact, MD's petition seeks not the denial of Mallinckrodt's registration, but rather the reversal of DEA's decision to approve Mallinckrodt's application. *See* MD Reply Br. at 4 ("Vacating Mallinckrodt's approval is precisely the relief MD seeks."). MD is challenging, in other words, an affirmative licensing decision already made by DEA. The sort of problem encountered by the Court in *Heckler* thus does not arise in this case, both because petitioner is not challenging the agency's refusal to act, and because the requested relief does not depend upon the exercise of discretion by the executive branch. MD's alleged injury, in sum, is redressable because vacating the approval of Mallinckrodt's application would secure the "relief from competition to which it says it is entitled under the statute." *Bristol-Myers Squibb Co. v. Shalala,* 91 F.3d 1493, 1499 (D.C. Cir. 1996).

The government also takes the position that MD lacks prudential standing under the zone of interests test, which asks whether "the interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute ... in question." *Association of Data Processing Serv. Orgs., Inc. v. Camp,* 397 U.S. 150, 153 (1970). This test is designed to exclude those plaintiffs with interests "so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Clarke v. Securities Indus. Ass'n,* 479 U.S. 388, 399 (1987). The United States argues that MD does not fall within the zone of interests of the statute at hand because "there is nothing in the CSA or its legislative history which indicates an intent to protect the competitive advantage of a single registrant."

Our decisions have made clear, however, that a competitor need not be an intended beneficiary to fall within the zone of interests of an entry-restricting statute. We have previously said that litigants fall within the zone of interests if they are regulated by the particular agency action being challenged, or if they are considered to be protected by the statute in question. *First National Bank and Trust Co. v. National Credit Union Admin.*, 988 F.2d 1272, 1275 (D.C. Cir. 1993). Litigants are considered to be "protected" by the statute if they are intended beneficiaries of the legislation, or if they are suitable challengers of the agency action because their interests are sufficiently congruent with the interests of the intended beneficiaries. *Id.*

We hold that MD, as a manufacturer facing potential competition from Mallinckrodt, is a suitable challenger and thus falls within the zone of interests of the statute. When a regulatory system "by its very nature restricts entry into a particular field or transaction," firms that are already operating in the regulated industry have an interest in enforcing the restrictions on potential market entrants. *Panhandle Producers and Royalty Owners Assoc. v. Economic Regulatory Admin.,* 822 F.2d 1105, 1109-10 (D.C. Cir. 1987). Even though competitors may be motivated by something other than a desire to advance the public interest, they nonetheless fall within the zone of interests of an entry-restricting statute because their interests "are generally congruent with a statutory purpose to restrict entry." *Id.* The Controlled Substance Act is a quintessential entry-restricting statute. Every firm that manufacturers a controlled substance must obtain a certificate of registration from the Administrator. 21 U.S.C. § 822(a). When considering an application, the Administrator must decide whether registration would be in the public interest, taking into account whether effective controls against conversion could be achieved by limiting the total number of registered manufacturers. *Id.* at § 823(a)(1). The Administrator is also required to set the aggregate quantity of drugs that are produced each year, and to establish individual production quotas for each registered manufacturer. *Id.* at § 826(a) & (b). Even more so than traditional licensees, registered manufacturers of controlled substances

have an interest in limiting the number of producing firms, because each new market entrant will produce a percentage of the aggregate production quota that would otherwise be produced by existing firms. There is every reason to believe that MD's "interest in patrolling a statutory picket line will bear some relation to the congressional purpose" of the CSA. *See First National Bank,* 988 F.2d at 1278. We think that MD, as a registered manufacturer challenging another firm's entry into the market, at least "arguably" falls within the zone of interests sought to be protected by the entry barriers of the CSA. *Association of Data Processing Serv. Orgs.,* 397 U.S. at 153.

III.

Turning to the merits, we first consider MD's objections to the approval of Mallinckrodt's final application to become a registered manufacturer of methylphenidate. MD makes two basic arguments against DEA's decision to register Mallinckrodt. First, MD takes issue with the administrative record compiled by DEA, claiming that portions of the record were improperly withheld from public view, and that the record did not contain all relevant evidence. Second, MD asserts that DEA failed to issue an adequate explanation for its decision to approve Mallinckrodt's application.

A.

MD makes two objections to the Certified List of Record submitted by DEA to this court pursuant to Fed. R. App. P. 17(b). The first objection is that DEA has refused to disclose to MD five of fifteen documents included in the Certified List—a letter of admonition from DEA to Mallinckrodt, Mallinckrodt's responsive letter, and three internal DEA documents. MD takes the position that it must have complete access to all documents considered by DEA, even if they are deemed sensitive and contain confidential or trade secret information. In MD's view, DEA has a duty to divulge to interested persons all documents that were part of the record, lest the agency's action be shrouded in administrative secrecy.

We find nothing in the statute or the regulations that gives third parties such sweeping access to sensitive agency materials. The amended regulations do allow registered bulk manufacturers to file comments on or objections to a proposed registration, 21 C.F.R. § 1301.43(a) (1996), and MD has repeatedly availed itself of that opportunity. The regulations do not, however, give manufacturers the right to a hearing on another firm's application, nor the right to discover documents considered by DEA during the application process. *Id.* Indeed, even in those instances in which a hearing is required, participants are not entitled to inspect "[a]ny confidential or trade secret information disclosed in conjunction with an application," nor "[a]ny material contained in any investigatory report, memorandum, or file, or case report compiled by the Administration." 21 C.F.R. § 1316.46(b)(3)-(4). MD has pointed us to no countervailing authority in the statute or the regulations that would confer on it an entitlement to view such documents.

Without any support in the statute or regulations, MD relies upon three cases that dealt with disclosure of agency materials: *Louisiana Assoc. of Independent Producers and Royalty Owners v. FERC,* 958 F.2d 1101 (D.C. Cir. 1992); *United States Lines, Inc. v. Federal Maritime Comm'n,* 584 F.2d 519 (D.C. Cir. 1978); and *Home Box Office, Inc. v. FCC,* 567 F.2d 9 (D.C. Cir. 1977). We view such cases as readily distinguishable. MD finds principal support in *U.S. Lines,* in which we reviewed an order from the Federal Maritime Commission approving an amendment to a joint service agreement between two common carriers. The Commission addressed a crucial overtonnage issue by stating only that it had "examined that problem carefully, in the light of the data then available to the Commission," which consisted of "the submissions of Protestant and Proponents, the identities of Protestant and Proponents, and [t]he reliable data reposing in the files of the Commission." *U.S. Lines,* 584 F.2d at 533. Rejecting the agency's decision, we held that we could not determine whether the action was arbitrary or capricious because the data relied upon by the Commission were neither

included in the record nor disclosed to this court. *Id.* We observed that we "simply cannot determine whether the final agency decision reflects the rational outcome of the agency's consideration of all relevant factors when we have no idea what factors or data were in fact considered by the agency." *Id.* Unlike the situation in *U.S. Lines,* the documents relied upon by DEA in this case are not a complete mystery: ten of the fifteen documents have been placed in the public file, and the remainder have been identified but not disclosed because they contain sensitive material. The agency in *U.S. Lines* did not justify its refusal to disclose identified documents because they were confidential. That agency issued a substantive decision asserting as its operative basis undisclosed and indeed unidentified "reliable data" in its files. *U.S. Lines,* then, is in no way parallel to the present case and offers no support for MD's position. It did not in any fashion deal with the question of whether a third-party challenger must have complete access to all documents (including those that are sensitive) that contributed to an agency's decision-making process.

MD's reliance on the other two cases is equally misplaced. *Home Box Office* involved a challenge to a final rule that was based in part upon information that the Federal Communications Commission gathered from the public through *ex parte* communications. *Home Box Office,* 567 F.2d at 51-59. MD latches onto a number of passages from our opinion, including the observation that "where, as here, an agency justifies its actions by reference only to information in the public file while failing to disclose the substance of other relevant information that has been presented to it, a reviewing court cannot presume that the agency has acted properly...." *Id.* at 54. Such comments must be understood, however, within the context of a discussion of the propriety of *ex parte* communications when an agency is engaged in notice and comment rulemaking governed by Section 553 of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553, which makes it quite distinct from the case at hand. *See Elcon Enterprises, Inc. v. Washington Metropolitan Area Transit Authority,* 977 F.2d 1472, 1481 (D.C. Cir. 1992) (reading *Home Box Office* as applying only to rulemaking).

The last case cited by MD, *Louisiana Assoc.,* did deal with the disclosure of materials considered by an agency when making a licensing decision. 958 F.2d at 1115. That case involved a challenge brought by a group of environmentalists to FERC's decision to certify a proposed pipeline. The environmentalists argued, among other things, that the Commission's decision was not supported by substantial evidence because they "did not have an adequate opportunity to criticize the evidence submitted by Project proponents." *Id.* We rejected the environmentalists' challenge on the grounds that they in fact had access to the information they were seeking. *Id. Louisiana Assoc.*, however, did not deal with the question of whether a third party has a right to obtain confidential information considered by an agency in the course of making a licensing decision. MD, in other words, has presented us with no support for the proposition that a party challenging an agency's decision to issue a license to another firm must have unfettered access to all information considered by the agency.

Such a proposition, we should note, would be rather remarkable. Even under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et seq.*, an agency is not required to release materials that are considered "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4).

MD's second objection goes to the contents of the administrative record. MD claims that DEA's decision to register Mallinckrodt must be set aside as arbitrary and capricious because DEA failed to compile a complete administrative record. In particular, MD faults DEA for not including the record from the hearing that occurred in May of 1995, in which MD presented evidence against Mallinckrodt's first two applications. MD also suggests that DEA violated Fed. R. App. P. 16(a) by omitting the order under review, which is the decision to approve Mallinckrodt's fourth application on July 16, 1996. In MD's view, the failure of DEA to include these (and perhaps other) documents in the administrative record demonstrates that DEA approved Mallinckrodt's application without having considered all relevant evidence.

The contents of the record provide no basis for vacating the registration of Mallinckrodt. MD does not allege that DEA failed to include information that it submitted regarding Mallinckrodt's fourth application, which is the application that DEA ultimately approved. What MD alleges is that DEA did not additionally include materials that were compiled with respect to Mallinckrodt's first two applications. More specifically, MD is under the impression that DEA was required to include in the record information presented at a hearing in May of 1995, even though such evidence was offered with respect to Mallinckrodt's first two applications, which were later withdrawn. If MD believed that such information would be material to DEA's consideration of the fourth application, MD had every opportunity to include evidence from the 1995 hearing in the comments subsequently submitted to DEA. To the extent that such information was not submitted to DEA with respect to Mallinckrodt's fourth application, that failure runs to MD, and not to DEA. DEA cannot be faulted for omitting evidence from the record that was never submitted in response to Mallinckrodt's fourth application.

The omission of the order under review from the record is also not fatal to the registration of Mallinckrodt. The Federal Rules of Appellate Procedure provide that the record shall consist of "[t]he order sought to be reviewed or enforced, the findings or report on which it is based, and the pleadings, evidence and proceedings before the agency." Fed. R. App. P. 16(a). In lieu of filing the record with the court, the agency may file "a certified list of all documents, transcripts of testimony, exhibits and other material comprising the record, or a list of such parts thereof as the parties may designate, adequately describing each, and the filing of the certified list shall constitute filing of the record." Fed. R. App. P. 17(b). MD protests that the certified list submitted by DEA did not include the order that approved Mallinckrodt's fourth application. As a factual matter, MD is correct in pointing out that the certified list does not include the agency's decision of July 16, 1996, to register Mallinckrodt. Yet this omission is of little consequence, and cer-

tainly does not warrant vacatur of the registration. The Rules allow parties to supply materials that were improperly omitted from the record. Fed. R. App. P. 16(b). Logically, this liberality would encompass materials omitted from the certified list; particularly so as the parties did include the order in the Joint Appendix, making it available for our perusal. We attach no material significance to the fact that DEA neglected to include the order under review when it certified a list of all documents comprising the record in this case.

B.

MD also takes the position that DEA's approval of Mallinckrodt's application was arbitrary and capricious because the agency did not provide a reasoned explanation for its decision, in violation of the APA, 5 U.S.C. § 706(2)(A). MD emphasizes that it submitted detailed comments to DEA regarding Mallinckrodt's proposed registration, which received, in MD's estimation, only short-shrift attention from the agency. 61 Fed. Reg. 37,079-81 (July 16, 1996). Petitioner reiterates several of the objections that it unsuccessfully raised before DEA, including Mallinckrodt's alleged history of noncompliance with DEA and FDA regulations, and evidence suggesting that there is adequate competition in the methylphenidate market. MD faults DEA for not dealing with these and other objections in greater detail and with greater specificity. Petitioner also criticizes the agency for failing to identify specific facts to support its conclusion that registration of Mallinckrodt would be consistent with the public interest.

The judiciary has a responsibility under the APA to set aside agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983). We will not disturb the decision of an agency that has "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a

rational connection between the facts found and the choice made." *Id.* (internal quotation marks and citations omitted).

We hold that DEA gave an adequate explanation for its decision to register Mallinckrodt. DEA published an explanation that spans almost eight columns in the Federal Register, and is largely devoted to answering the many objections raised by MD during the application process. 61 Fed. Reg. 37,079-81. Regarding the issue of regulatory violations, for example, DEA stated that it had investigated Mallinckrodt, including "inspection and testing of the company's physical security systems, audits of the company's records, verification of the company's compliance with state and local laws, and a review of the company's background and history," and concluded that registration of Mallinckrodt would be in the public interest. *Id.* at 37,080. DEA explained that Mallinckrodt is currently registered to manufacture other Schedule II drugs, that its past regulatory problems were not significant, and that the company acted expeditiously to address those problems to the satisfaction of DEA. *Id.* DEA also explained that Mallinckrodt has "demonstrated its technical and manufacturing expertise with respect to other controlled substances" over the past twenty-five years, that there is every reason to believe that the company will continue this practice in the future, and that the registration of Mallinckrodt will not undermine the agency's efforts to maintain effective controls against diversion. *Id.* at 37,080-81. Taken as a whole, DEA's explanation demonstrates that it examined the data, considered the relevant factors, and made a reasonable judgment based on the record. We conclude that the explanation offered by DEA passes muster under the APA.

IV.

We now turn to MD's objections to the handling of Mallinckrodt's first two applications to become a registered manufacturer of methylphenidate. MD takes issue with two decisions that were made during the application process, namely DEA's decision to permit Mallinckrodt to withdraw its first two applications, and the subsequent termination of the hearings with respect to those applications. MD argues

that withdrawal of the applications was improper because DEA did not adequately discuss the grounds for withdrawal, and because DEA failed to distinguish cases suggesting that an applicant cannot unilaterally withdraw an application once hearings have begun. MD also argues that termination of the hearings was unlawful because it was based upon a retroactive application of the amended regulations, which stripped third parties of the right to a hearing on another firm's application.

We decline to reach the merits of MD's objections, however, because there is no longer any live issue with respect to Mallinckrodt's first two applications. MD challenged DEA's decision to approve the fourth application submitted by Mallinckrodt, and we have concluded that DEA's registration decision was in accordance with law. Mallinckrodt is a registered bulk manufacturer of methylphenidate. All questions concerning Mallinckrodt's first two applications are moot. The object of those applications—receipt of a certificate of registration—has been lawfully achieved via DEA's approval of Mallinckrodt's fourth application. If we were to hold that DEA acted unlawfully, and thus require the agency to reopen the hearings and consider the first two applications, there would be nothing at stake with respect to those applications because Mallinckrodt has already achieved the status of a registered manufacturer. Insofar as MD claims that DEA's disposition of the first and second applications somehow tainted the grant of the third, such a claim must rest on the theory that third parties acquire, at the time an application is filed, a vested right in the procedural rules then applicable, which somehow is forever attached to later applications on the same subject. This is altogether untenable. *See Bergerco Canada v. United States Treasury Dep't,* 129 F.3d 189, 194-95 (D.C. Cir. 1997). Accordingly, we will not further discuss the issues relating to the first two applications submitted by Mallinckrodt.

V.

For the foregoing reasons, MD's petition for review is denied.