# United States Court of Appeals

**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

---

Argued March 12, 2007 Decided April 27, 2007

No. 06-1270

JOHN DOE, INC.,
PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION,
RESPONDENT

---

Consolidated with
06-5201

---

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

---

*Samuel H. Israel* argued the cause for petitioner/appellant. With him on the briefs were *Joseph P. Esposito* and *Terence J. Lynam*.

*Alisa B. Klein*, Attorney, U.S. Department of Justice, argued the cause for respondent/appellees. With her on the brief were *Peter D. Keisler*, Assistant Attorney General, *Jeffrey A. Taylor*, U.S. Attorney, *Mark B. Stern*, Attorney, and *Daniel Dormont*, Senior Attorney, Drug Enforcement Administration.

Before: GINSBURG, *Chief Judge*, and BROWN and KAVANAUGH, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* BROWN.

Brown, *Circuit Judge*: John Doe, Inc.[1] seeks review of the DEA's denial of a permit to import for bioequivalency testing a generic version of an FDA-approved drug. Doe challenges the permit denial as contrary to law, arbitrary and capricious, and violative of the Fifth Amendment to the United States Constitution. Doe further argues the district court erred in dismissing its complaint for lack of jurisdiction. We conclude the district court correctly determined exclusive jurisdiction over Doe's claims lies in the courts of appeals pursuant to 21 U.S.C. § 877. We further conclude the DEA acted within its discretion in denying Doe's permit application. We accordingly affirm the district court and deny Doe's petition.

## I

Doe, a drug manufacturer, hopes to market a generic version of the drug Marinol — an FDA-approved drug containing the same active ingredient as marijuana and used to treat nausea and loss of appetite in cancer and AIDS patients. To get approval to market its generic alternative, Doe must successfully complete "bioequivalency" studies, demonstrating to the FDA that its drug is in all relevant aspects equivalent to Marinol. In order to conduct the necessary bioequivalency testing, Doe seeks to immediately import over half a million capsules of its drug from its overseas manufacturing partner.

---

[1] This case was filed under seal pursuant to Petitioner/Appellant's request. Accordingly, the Petitioner/Appellant is referred to as "John Doe, Inc." or "Doe" throughout this opinion.

Doe's plans, however, have been stymied by the DEA. Pursuant to the Controlled Substances Act ("CSA"), the DEA regulates importation of "controlled substances." 21 U.S.C. § 952.[2] Under the CSA, controlled substances are categorized into five schedules based on their potential for abuse or dependence, their accepted medical use, and their accepted safety for use under medical supervision. Schedule I is the most stringently controlled, and schedule V the least. *Id.* § 812. Only schedules I and III are at issue here. Schedule I substances are subject to very strict controls because they have "no currently accepted medical use in treatment in the United States," have "a lack of accepted safety for use . . . under medical supervision," and have "a high potential for abuse." *Id.* § 812(b)(1). Schedule III substances, in contrast, have "a currently accepted medical use in treatment in the United States," and less potential for abuse. *Id.* § 812(b)(3). Controlled substances were initially allocated to the various schedules by Congress when it first enacted the CSA. *Gettman v. DEA*, 290 F.3d 430, 432 (D.C. Cir. 2002). Thereafter, Congress assigned primary responsibility to the DEA to add or remove substances from the schedules, or to transfer a drug or substance between schedules. *Id.* (citing 21 U.S.C. § 811(a)).

Dronabinol, the active ingredient in both Marinol and Doe's generic alternative, has been assigned to schedule I since Congress first enacted the CSA in 1970. *See* CSA, Pub. L. No. 91-513, § 202, schedule I ¶ (c)(17), 84 Stat. 1236, 1249 (1970). Dronabinol remains in schedule I today, with one notable exception. The FDA, after extensive testing and research, approved the drug Marinol — described as "[d]ronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule" — for treatment of nausea associated with cancer

[2] The CSA grants regulatory authority to the Attorney General, 21 U.S.C. §§ 821, 871(b), who has in turn delegated that authority to the Administrator of the DEA, 28 C.F.R. § 0.100(b).

patients and anorexia associated with weight loss in AIDS patients. 51 Fed. Reg. 17,476, 17,478 (1986). As a result of this FDA approval, the DEA eventually assigned "Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule *in a U.S. Food and Drug Administration approved product*" to schedule III. 21 C.F.R. § 1308.13(g)(1) (emphasis added); 64 Fed. Reg. 35,928 (1999). DEA was careful to stress, however, that it was rescheduling dronabinol only "in a FDA approved drug product." 51 Fed. Reg. at 17,477. All other "mixtures, compounds and preparations" containing dronabinol "remain[ed] in Schedule I." *Id*. In practical effect, only the brand name drug Marinol was moved to schedule III.

When Doe applied for a permit to import its drug containing dronabinol, it was registered with the DEA to import schedule III, but not schedule I, substances. On February 28, 2006, Doe applied for a permit to import 1,200 capsules of its drug to begin equivalency testing. On its permit application, instead of using the general DEA code number for dronabinol, Doe listed the DEA code number for "Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product." The DEA issued the permit, and Doe imported the 1,200 capsules.

Shortly thereafter, Doe sought another permit to import 525,000 capsules of its drug, again using the DEA code number for "Dronabinol . . . in a U.S. Food and Drug Administration approved product." This time, however, the large quantity prompted further investigation by the DEA. When the DEA learned that the substance Doe sought to import was not in fact Marinol, the DEA denied Doe's permit application. Because Doe's drug containing dronabinol has not been approved for marketing by the FDA, the DEA classifies the drug as falling within the general category of "dronabinol" in schedule I, not schedule III's narrow description of "[d]ronabinol . . . *in a U.S.*

*Food and Drug Administration approved product*." 21 C.F.R. § 1308.13(g)(1) (emphasis added). Thus, Doe found itself in a catch-22 of sorts: while it sought to import its drug under schedule III so it could conduct testing necessary to obtain FDA approval, the DEA's interpretation of its regulatory provision effectively prohibits importation of a drug containing dronabinol under schedule III *until* the drug is FDA approved.

The DEA provided Doe written notice of its permit denial on June 12, 2006. The letter advised that Doe could request an agency hearing within thirty days. Doe opted not to pursue further agency consideration, but instead sought immediate redress from the courts.[3] Because the law governing such appeals is unsettled, Doe filed two actions — one in district court, *see John Doe, Inc. v. Gonzalez*, No. 06-966, 2006 WL 1805685 (D.D.C. June 29, 2006), and one directly in this court.

On June 29, 2006, the district court dismissed Doe's case for lack of subject matter jurisdiction. In a lengthy and well-reasoned opinion, the court considered whether the DEA's denial of Doe's permit was sufficiently "final" to permit judicial review under the Administrative Procedure Act ("APA"), *see* 5 U.S.C. § 704, and, even if sufficiently final, whether 21 U.S.C. § 877 nonetheless divests the district court of original jurisdiction over Doe's claims, *see id.* (locating original jurisdiction in the courts of appeals over "[a]ll final determinations, findings, and conclusions" of the DEA under the CSA). Ultimately, the district court concluded it lacked jurisdiction. The court reasoned that, at least insofar as Doe's claims are concerned,

[3] Because Doe chose to forgo its administrative remedies, the agency's decision became final thirty days after Doe's receipt of the DEA's June 12, 2006 letter. *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA Office of Diversion Control, to John Doe, Inc. (June 12, 2006) (Administrative Record at 117) (hereinafter June 12, 2006 Letter); 21 C.F.R. § 1312.44.

§ 877's reference to "final determinations, findings, and conclusions" encompasses the APA's requirement of final agency action. Thus, either the permit denial wasn't sufficiently final to confer jurisdiction under the APA, or, in the event it was sufficiently final, proper recourse lay in the court of appeals pursuant to § 877. Either way, the district court concluded it did not have jurisdiction, and dismissed Doe's complaint.

Doe appealed the dismissal. That case has been consolidated with Doe's petition seeking direct review in this court under 21 U.S.C. § 877, and we address both here. While the district court found it possible to resolve Doe's case without reaching a definitive conclusion on the issues of finality and the scope of our exclusive direct-review jurisdiction under 21 U.S.C. § 877, we must decide both issues.

## II

Doe continues to press the argument that the DEA's denial of Doe's permit was not a "final determination[], finding[], [or] conclusion[]" sufficient to trigger this court's original jurisdiction under 21 U.S.C. § 877. But if the permit denial wasn't a "final determination[]" under § 877, it may also fail to constitute "final agency action" sufficient to comprise a claim under the APA, 5 U.S.C. § 704, effectively denying Doe *any* judicial review of its permit denial. Indeed, the district court expressed serious reservations about this possible lack of finality.

Doe's briefing addresses the finality question in a single sentence in a footnote, declaring the district court's concerns about finality "now moot" because the DEA concedes its permit denial constituted final agency action. Pet'r's Br. 22 n.9. Finality is not synonymous with jurisdiction. When judicial review is sought under the APA, for example, the requirement of "final agency action" is not jurisdictional. *See Trudeau v.*

*Fed. Trade Comm'n*, 456 F.3d 178, 183-84 (D.C. Cir. 2006); *Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt.*, 460 F.3d 13, 18 n.4 (D.C. Cir. 2006). But when, as here, review is sought under a specific statute prescribing finality as a prerequisite of judicial review, it is. *See, e.g.*, *North Am. Catholic Educ. Programming Found. v. FCC*, 437 F.3d 1206, 1209 (D.C. Cir. 2006); *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 426 (D.C. Cir. 2004); *Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999). While a nonjurisdictional requirement may be waived, *Arbaugh v. Y & H Corp.*, 126 S. Ct. 1235, 1245 (2006), because § 877's "final decision" requirement is jurisdictional, the parties' agreement here as to finality does not settle the issue. *CTIA – The Wireless Ass'n v. FCC*, 466 F.3d 105, 108 (D.C. Cir. 2006) (quoting *Midwest Indep. Transmission Sys. Operator, Inc. v. FERC*, 388 F.3d 903, 908 (D.C. Cir. 2004) (citing *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94–95 (1998))).

> To evaluate finality, this court applies a two-part test:
>
> First, the action under review must mark the consummation of the agency's decisionmaking process — it must not be of a merely tentative or interlocutory nature. Second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow.

*Nat'l Ass'n of Home Builders v. Norton*, 415 F.3d 8, 13 (D.C. Cir. 2005) (citations and internal quotation marks omitted) (summarizing the test articulated by the Supreme Court in *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)).[4]

[4] Both *Norton* and *Bennett* construe the APA's requirement of "*final* agency action." 5 U.S.C. § 704 (emphasis added). Here we are evaluating finality under 21 U.S.C. § 877's limitation of review to a "*final* decision" (emphasis added). We see no reason, however, that the word "final" in § 877 should be interpreted differently than the

In *Ciba-Geigy Corp. v. United States EPA*, 801 F.2d 430 (D.C. Cir. 1986), a case pre-dating *Bennett*, we applied a complementary analysis in a case presenting a finality question similar to that presented here. In *Ciba-Geigy*, the EPA had advised certain pesticide manufacturers of required labeling changes in a series of letters. *Id.* at 432–33. The manufacturers filed suit seeking a declaration that the EPA had failed to follow the procedures required by law when changing labeling requirements. *Id.* at 433. The district court dismissed the suit for lack of subject matter jurisdiction, concluding the agency had "neither issued a final order . . . nor taken any other final action which is reviewable by the Court." *Id.* at 434 (citation and internal quotation marks omitted).

Noting the Supreme Court's instruction to "apply the finality requirement in a 'flexible' and 'pragmatic' way," this court reversed on appeal. *Id.* at 435 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149–50 (1967)). In analyzing finality, the court looked "primarily to whether the agency's position is 'definitive' and whether it has a '"direct and immediate effect on the day-to-day business"' of the parties challenging the action." *Id.* at 436 (citations and alteration omitted). Explaining that the EPA's letters in *Ciba-Geigy* staked out the agency's position clearly and gave no indication the agency's position was "subject to further agency consideration or possible modification," *id.* at 437, the court determined the letters were final agency action fit for judicial review, *id.* at 437-38.

Both *Bennett* and *Ciba-Geigy* firmly support a finding of finality here. The DEA's action in this case was not merely

---

word "final" in the APA. *Cf. Indep. Equip. Dealers Ass'n*, 372 F.3d at 428 (construing the Clean Air Act's "final action" term as "synonymous with the term 'final agency action' as used in Section 704 of the APA"). Thus, the cases applying the finality aspect of the APA guide us in construing finality under 21 U.S.C. § 877.

tentative, but rather definitive: the DEA affirmatively denied Doe's permit application. Moreover, the DEA candidly acknowledged before the district court that its position would not change in further administrative proceedings. *See* Defs.' Opp'n at 18 (June 2, 2006) (noting that "[t]hrough [the administrative] process, Plaintiff would be informed *again* that [its] April 18, 2006 application was denied because the product Plaintiff sought to import is a schedule I controlled substance that Plaintiff is not registered to handle") (footnote omitted) (citing Decl. of Matthew Strait, Chief of the DEA's Quota and United Nations Reporting Unit, attached as Ex. B to Defs.' Opp'n (hereinafter Strait Decl.)). And the permit denial, which became final thirty days after its issuance, clearly "determined" Doe's rights, *Bennett*, 520 U.S. at 178, establishing "legal consequences" by prohibiting importation, *id.* Finally, the permit denial had a "direct and immediate effect" on Doe's business by stopping in its tracks Doe's plans to establish its drug's bioequivalency to Marinol. *Ciba-Geigy*, 801 F.2d at 436.

Moreover, this court has recognized that "[a]n agency's past characterization of its own action, while not decisive, is entitled to respect in a finality analysis." *Nat'l Ass'n of Home Builders*, 415 F.3d at 14. Here, the DEA agrees its decision denying Doe's permit is "final." Resp't's Br. 23.

What arguably cuts against finality in this case is the lack of a comprehensive administrative record to assist judicial review. Because Doe opted to forgo further administrative review of its permit denial, the administrative record is — as the district court correctly observed — "largely devoid of an explicit analysis by the DEA laying out its reasoning" for the permit denial.

To allow the meager administrative record in this case to undercut finality, however, would confuse jurisdictional finality

with prudential concerns over the fitness of issues for judicial review. Finality, ripeness, and exhaustion of administrative remedies are related, overlapping doctrines that are analytically but not categorically distinct. Exhaustion focuses on the process a litigant must follow; ripeness describes the fitness of issues for judicial review; finality focuses on the conclusiveness of agency action. "Ripeness and exhaustion are complementary doctrines . . . designed to prevent unnecessary or untimely judicial interference in the administrative process." *Ticor Title Ins. Co. v. FTC*, 814 F.2d 731, 735 (D.C. Cir. 1987) (opinion of Edwards, J.) (internal quotation marks omitted) (quoting E. GELLHORN & B. BOYER, ADMINISTRATIVE LAW AND PROCESS 316-17 (1981)). Those prudential doctrines respond to pragmatic concerns about the relationship between courts and agencies, including "the agency's interest in crystallizing its policy before that policy is subjected to judicial review" and "the court's interests in avoiding unnecessary adjudication and in deciding issues in a concrete setting." *Id*. (quoting *Better Gov't Ass'n v. Dep't of State*, 780 F.2d 86, 92 (D.C. Cir. 1986)).

Thus, even if exhaustion, ripeness, and finality may be difficult to distinguish in some contexts, they must be carefully delineated when, as here, finality is a statutory jurisdictional prerequisite rather than merely a precaution related to concreteness and institutional capacity. An administrative order is final for jurisdictional purposes when it "imposes an obligation, denies a right or fixes some legal relationship as a consummation of the administrative process." *Am. Train Dispatchers Ass'n v. ICC*, 949 F.2d 413, 414 (D.C. Cir. 1991) (alterations and internal quotation marks omitted) (quoting *Chi. & S. Air Lines v. Waterman S.S. Corp*., 333 U.S. 103, 113 (1948)). As this case illustrates, an agency may have reached that point and generated only a sparse administrative record. Indeed, where the disagreement is largely a matter of law, an extensive administrative record may not be necessary for effective judicial

review. Where the record provides inadequate factual information to resolve novel legal claims, the court can dismiss those claims as unripe. But the fact that the administrative record is not sufficient to resolve *all* questions does not mean the court is deprived of jurisdiction to answer *any* question. The DEA action here at issue is sufficiently final to confer jurisdiction.

## III

Having concluded the DEA's permit denial was sufficiently final to permit judicial review, we must still decide where jurisdiction properly lies — in the district court pursuant to the APA, 5 U.S.C. § 704, or in this court pursuant to 21 U.S.C. § 877.

21 U.S.C. § 877 vests exclusive jurisdiction in the courts of appeals over "[a]ll final determinations, findings, and conclusions" of the DEA applying the CSA. Doe argues the district court erred in dismissing its complaint for lack of subject matter jurisdiction, because § 877 does not apply to the DEA's permit denial in this case. Instead, Doe argues, this case is reviewable under the APA as "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704.

If Doe is correct, the permit denial must be "final agency action" under § 704, but not a "final determination[], finding[], [or] conclusion[]" under § 877. On the plain terms of the two provisions, however, that assertion seems implausible. Perhaps "agency action" encompasses more than "determinations, findings, and conclusions," but the permit denial at issue here falls squarely within the plain meaning of "determination." *See* BLACK'S LAW DICTIONARY 480 (8th ed. 2004) (defining "determination" as "[a] final decision by a court or administrative agency"). Nonetheless, Doe correctly points out that, in a few cases, district courts have exercised jurisdiction over some

DEA decisions implementing the CSA, concluding there is a sphere of DEA activity that falls within the APA's "final agency action," but outside § 877's "final determinations, findings, and conclusions." *See, e.g.*, *PDK Labs Inc. v. Reno*, 134 F. Supp. 2d 24 (D.D.C. 2001); *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002), *vacated for lack of jurisdiction*, 368 F.3d 1118, 1121 n.1 (9th Cir. 2004), *aff'd*, 546 U.S. 243 (2006). Doe argues the reasoning in these cases, as well as in the Supreme Court's decision in *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991), supports the conclusion the permit denial here at issue falls within that interstitial space.

Before addressing Doe's argument, it is worth noting, as did the district court below, that as a matter of practice almost all cases challenging DEA decisions under the CSA have been filed directly in the courts of appeals pursuant to 21 U.S.C. § 877. *See, e.g.*, *Noramco of Del., Inc. v. DEA*, 375 F.3d 1148, 1152 (D.C. Cir. 2004); *Fry v. DEA*, 353 F.3d 1041, 1042–44 (9th Cir. 2003); *Humphreys v. DEA*, 96 F.3d 658, 659–60 (3d Cir. 1996); *Alra Labs., Inc. v. DEA*, 54 F.3d 450, 451 (7th Cir. 1995); *Nutt v. DEA*, 916 F.2d 202, 203 (5th Cir. 1990); *Reckitt & Colman, Ltd. v. Adm'r, DEA*, 788 F.2d 22, 23 (D.C. Cir. 1986). And, in the one instance where a court of appeals has directly (albeit summarily) addressed the scope of 21 U.S.C. § 877, it reversed the district court's prior assumption of jurisdiction, holding § 877 vested exclusive jurisdiction over the dispute in that case in the court of appeals. *See Oregon*, 368 F.3d at 1120 & n.1.

And yet a few district courts discern some play in the joints between "agency action" under the APA and DEA "determinations, findings, and conclusions" under 21 U.S.C. § 877. Those cases rely heavily on the Supreme Court's decision in *McNary*, which held that a narrow grant of individualized review, vested exclusively in the courts of appeals, did not preclude district court jurisdiction over a class action claiming

a pattern or practice of constitutional violations by the Immigration and Naturalization Service. 498 U.S. at 483-84. This case, however, is dissimilar from *McNary* in at least two important ways. First, 21 U.S.C. § 877's exclusive jurisdiction provision is much broader than the exclusive jurisdiction provision at issue in *McNary*. *See McNary*, 498 U.S. at 486. Second, and more important, the holding in *McNary* cannot be divorced from the Court's obvious concern that, absent district court review of the *McNary* plaintiffs' claims, meaningful judicial review would have been entirely foreclosed. *See McNary*, 498 U.S. at 484 ("Were we to hold otherwise and instead require respondents to avail themselves of the limited judicial review procedures set forth in § 210(e) of the INA, meaningful judicial review of their statutory and constitutional claims would be foreclosed."); *see also id.* at 488. That concern is wholly inapplicable here; Doe's claims are fully reviewable in this court by way of a § 877 petition.

We do not find the other reasons district courts have given for exercising jurisdiction any more persuasive. First, the opinions presume the applicability of 21 U.S.C. § 877 turns on whether the DEA complied with the procedural requirements for final agency "determinations, findings, and conclusions." *See, e.g.*, *PDK Labs*, 134 F. Supp. 2d at 29;[5] *see also Novelty, Inc. v.*

[5] This court did review a later phase of the *PDK Labs* litigation, *see* 362 F.3d 786, 792 (D.C. Cir. 2004), but did not comment on whether the district court's assertion of jurisdiction over the earlier phase was proper. It appears the issue was not even properly before this court in the later phase of the litigation. *Id.* In any event, this court's lack of comment cannot be construed as sanctioning the district court's earlier assertion of jurisdiction; "it is well settled that cases in which jurisdiction is assumed *sub silentio* are not binding authority for the proposition that jurisdiction exists." *Ticor Title Ins. Co.*, 814 F.2d at 749 (opinion of Williams, J.) (citing *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 119 (1984)).

*Tandy*, No. 1:04-cv-1502, 2006 WL 2375485, at *1 (S.D. Ind. Aug. 15, 2006) ("Novelty argues that the letters amount in substance to unilateral rulemaking, without notice and an opportunity for affected parties to comment. . . . Plaintiff has not challenged a final 'determination,' 'finding,' or 'conclusion' by the DEA *after formal procedures* that develop a record suitable for judicial review, so 21 U.S.C. § 877 does not apply . . . ." (emphasis added)). But this court's jurisdiction under a direct-review statute has never depended on agency compliance with procedural requirements. To the contrary, we have repeatedly invoked direct-review jurisdiction even where the agency's procedural lapses were blatant. *See, e.g.*, *CropLife Am. v. EPA*, 329 F.3d 876, 883–84 (D.C. Cir. 2003) (concluding the agency had wholly failed "to follow notice and comment procedures" required by law, yet rejecting the agency's argument that the agency action at issue wasn't a "regulation" subject to the court's direct-review jurisdiction); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023, 1028 (D.C. Cir. 2000) (likewise concluding that the agency had failed to comply with the "rulemaking procedures" required by law, yet rejecting the agency's argument that the agency action at issue wasn't subject to the court's direct-review jurisdiction). Thus, concluding 21 U.S.C. § 877's applicability turns on the DEA's compliance with its procedural obligations is incompatible with this court's established practice.

Similarly, concern over the lack of a comprehensive administrative record is not sufficient cause to narrow the scope of 21 U.S.C. § 877, as some district courts have attempted. *See Oregon*, 192 F. Supp. 2d at 1086; *Novelty*, 2006 WL 2375485, at *2–9. We agree the possibility of an inadequate administrative record is a troubling aspect of interpreting § 877 in accord with the plain meaning of its broad terms. But this court regularly reviews agency action with a limited or even non-existent administrative record under direct-review statutes

analogous to 21 U.S.C. § 877. *See, e.g.*, *CropLife Am.*, 329 F.3d at 883; *Appalachian Power Co.*, 208 F.3d at 1020; *Alaska Prof'l Hunters Ass'n v. FAA*, 177 F.3d 1030, 1036 (D.C. Cir. 1999).

Moreover, while in some cases an underdeveloped administrative record might prevent effective consideration of *any* legal issue, this is not one of those cases. The limited administrative record in this case establishes sufficient facts to squarely present the critical legal issue. And, in future cases where an insufficient administrative record is crippling, a court of appeals always has the option of either remanding to the agency for further factual development or invoking the prudential doctrine of ripeness. *See Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) ("[I]f the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation."); *Ciba-Geigy*, 801 F.2d at 435 (noting that in considering ripeness a court evaluates, *inter alia*, "whether consideration of that issue would benefit from a more concrete setting").

As the district court here rightly cautioned, adopting Doe's narrow interpretation of § 877 encourages forum shopping and encourages dissatisfied claimants to "jump the gun" by going directly to the district court to develop their case instead of exhausting their administrative remedies before the agency. Moreover, it encourages "duplicative and potentially conflicting review, and the delay and expense incidental thereto." *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 78 (D.C. Cir. 1984) (citation omitted); *cf. Fla. Power & Light Co.*, 470 U.S. at 745 ("Absent a firm indication that Congress intended to locate initial APA review of agency action in the district courts, we will not presume that Congress intended to depart from the sound policy of placing initial APA review in the courts of appeals.").

The DEA's denial of Doe's permit is properly reviewable in this court pursuant to 21 U.S.C. § 877.

## IV

This court reviews the DEA's interpretation of the CSA's provisions governing the scheduling of controlled substances under *Chevron*'s familiar two-step analysis. *See Gonzales v. Oregon*, 126 S. Ct. 904, 916–17 (2006). DEA's interpretation of its own scheduling regulations is controlling unless "plainly erroneous or inconsistent with the regulation." *Universal City Studios LLLP v. Peters*, 402 F.3d 1238, 1242 (D.C. Cir. 2005) (internal quotation marks omitted) (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)). We review the DEA's rationale for denying Doe's permit under the APA's familiar arbitrary and capricious standard. *Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005). In conducting our judicial review, we focus on the administrative record that formed the basis for the agency's decision, unless "there was such a failure to explain administrative action as to frustrate effective judicial review." *Tripoli Rocketry Ass'n v. Bureau of Alcohol, Tobacco, Firearms, & Explosives*, 437 F.3d 75, 83 (D.C. Cir. 2006) (citation and internal quotation marks omitted).

The DEA interprets its schedule III regulatory language — "Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product," 21 C.F.R. § 1308.13(g)(1) — as not encompassing Doe's dronabinol drug, because Doe's drug is not FDA "approved" for marketing. Doe argues this interpretation is contrary to law, arbitrary and capricious, and violates the due process clause of the Fifth Amendment. Doe's argument rests on two supposed parallels: (1) that Doe's drug is essentially the same as schedule III Marinol, and (2) that what the DEA did in this case is essentially the same as what it attempted in

*Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987). We address these key aspects of Doe's argument in reverse order.

In *Grinspoon*, the DEA took the position that two of the three findings necessary to place a drug on schedule I — i.e., that the drug has "no currently accepted medical use in treatment in the United States" and "a lack of accepted safety for use . . . under medical supervision," 21 U.S.C. § 812(b)(1) — were conclusively established by the drug's lack of FDA marketing approval. *Grinspoon*, 828 F.2d at 884. The First Circuit disagreed, explaining that "it is plainly possible that a substance may fail to obtain interstate marketing approval even if it has an accepted medical use." *Id.* at 887. The court vacated and remanded the case with instructions that "the Administrator will not be permitted to treat the absence of FDA interstate marketing approval as conclusive evidence that [the substance] has no currently accepted medical use and lacks accepted safety for use under medical supervision." *Id.* at 891.

Doe contends the DEA has done effectively the same thing here; that is, defined schedule III dronabinol so as "to exclude any product that does not yet have specific FDA marketing approval." Pet'r's Br. 15. But that is not what the DEA has done. Quite the opposite, the regulation simply includes a certain form of FDA "approved" dronabinol under schedule III; it does not affirmatively "exclude" any drug from schedule III. There is nothing in 21 C.F.R. § 1308.13(g)(1) that would pose an obstacle to Doe petitioning to have its dronabinol drug placed on schedule III.

Doe's comparison to *Grinspoon*, therefore, is inapt. In *Grinspoon*, the DEA equated the absence of FDA marketing approval with a lack of currently accepted medical use for purposes of placing a substance on schedule I and refusing to schedule it less restrictively. *Grinspoon*, 828 F.2d at 884. Here

the DEA, in less restrictively scheduling a specific dronabinol drug that is FDA-approved for marketing, has relied on FDA approval in determining the specific drug has "a currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(3)(B). Whereas the *absence* of FDA marketing approval may not be a reasonable proxy for a lack of currently accepted medical use, the *presence* of FDA marketing approval obviously *is* powerful evidence that a drug has currently accepted medical use and accepted safety for use under medical supervision. *See Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 939–40 (D.C. Cir. 1991) (recognizing that *Grinspoon* "never suggested the DEA Administrator was foreclosed from incorporating and relying on those standards employed by the FDA that are relevant to the pharmaceutical qualities of the drug"). The fact that the DEA has apparently accepted FDA marketing approval as *one* way to demonstrate currently accepted medical use is not the equivalent of a broad declaration saying FDA approval is the *only* way. As the DEA's counsel reiterated during oral argument, the DEA has not taken the position that Doe is barred by 21 C.F.R. § 1308(g)(1) from petitioning to have its dronabinol drug placed on schedule III, nor has it taken the position that such rescheduling would be contingent on FDA marketing approval. Rather, the DEA has simply taken the position that for a dronabinol drug to qualify for schedule III treatment under 21 C.F.R. § 1308.13(g)(1), the drug must have FDA marketing approval.

The DEA's interpretation of FDA "approval" in 21 C.F.R. § 1308.13(g)(1) therefore bars consideration of Doe's drug under *that* specific provision, but it does not bar Doe's drug from schedule III altogether. If Doe wishes to have schedule III revised to include its drug, it can petition the DEA and offer evidence that its drug meets the requirements for being placed in that schedule. *See* 21 U.S.C. § 811(a); 21 C.F.R. § 1308.43(a). Instead, Doe invites this court to eliminate a

limitation on an already existing schedule III category, effectively rescheduling Doe's drug without it making the statutorily required showing. We decline. *See* 21 U.S.C. § 812(b) ("[A] drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance.").

Doe's failed analogy to *Grinspoon* is not its only argument, however. Doe also argues the DEA's differential treatment of its drug and Marinol under 21 C.F.R. § 1308.13(g)(1) is arbitrary and capricious because its drug is "indisputably an identical formulation to Marinol." Pet'r's Br. 17. Not surprisingly, however, the DEA disputes the indisputable, calling Doe's claim "wishful thinking at best." Resp't's Br. 18. More important, we have scoured the record in vain, searching for evidence Doe's drug is in fact functionally equivalent to Marinol. While the record is replete with Doe's repeated and forceful *assertions* that its drug is the same thing as Marinol, Doe has not provided any *evidence* its drug is in all relevant respects identical. Doe therefore hasn't established — indeed, hasn't even attempted to establish — the factual predicate necessary for this court to resolve the legal question Doe asks us to resolve.

In one sense this is unsurprising. The whole reason Doe seeks to import its drug is to perform bio*equivalency* testing comparing its drug and Marinol. If equivalency was as "undisput[ed]" as Doe asserts, it is unclear why this testing would be necessary. Our best guess from the record, therefore, is that functional equivalency is a factual issue that remains to be determined. What that means for this case is that Doe has asked this court to decide an abstract legal question, unrelated to the actual established facts in this case. That we cannot do. Doe simply has not "present[ed] the court with the concrete facts that are necessary to an informed decision" on its equivalency claim,

and therefore that claim is not "ripe for adjudication." *Buckley v. Valeo*, 519 F.2d 821, 893 (D.C. Cir. 1975) (en banc) (per curiam), *rev'd in part on other grounds*, 424 U.S. 1 (1976); *Ciba-Geigy*, 801 F.2d at 434.

At oral argument, Doe's counsel protested that it was never asked to demonstrate its drug's equivalency to Marinol. But when the DEA first notified Doe of the permit denial, the DEA specifically invited Doe to "submit a letter explaining the Company's plans in exact and precise detail . . . ." Strait Decl. ¶ 18. Doe opted not to respond. *Id.* ¶ 22. Shortly thereafter, the DEA also advised Doe of its right to request a hearing challenging the permit denial. *See* June 12, 2006 Letter. Doe opted not to exhaust its administrative remedies, seeking instead immediate redress in the courts. Doe was given ample opportunity to demonstrate to the DEA that its drug was effectively the same thing as Marinol, and thereby build a record that would present this court with a ripe controversy.

In sum, we see nothing in 21 C.F.R. § 1308.13(g)(1) that is contrary to the Controlled Substances Act. Nor is the DEA's interpretation limiting that specific provision to drugs with FDA marketing approval plainly erroneous.[6] It is inappropriately restrictive for the DEA to say, as it did in *Grinspoon*, that FDA approval is the *only* way to demonstrate a drug is safe and has currently accepted medical use. But it is completely different (and eminently reasonable) for the DEA to require an importer, relying on functional equivalency as the basis for a drug's safety and current acceptance for medical use, to demonstrate that its drug is actually equivalent.

---

[6] Doe's Fifth Amendment claim likewise fails. Doe has not shown that the permit denial has changed its "formal legal status," or had the "broad effect of largely precluding" it from pursuing a business. *Kartseva v. Dep't of State*, 37 F.3d 1524, 1528 (D.C. Cir. 1994) (emphasis omitted).

* * *

Contrary to Doe's assertion that the DEA's interpretation of 21 C.F.R. § 1308.13(g)(1) leaves Doe with "requirements [that] are impossible to satisfy," Pet'r's Reply Br. 7, Doe does have options: (1) petitioning to have its dronabinol drug rescheduled, or (2) obtaining schedule I registration. We are not, however, unsympathetic to Doe's predicament. The DEA's interpretation obviously does make it harder (and costlier) for Doe to obtain final FDA approval to market its generic drug. As Doe has pointed out, this result runs counter to Congress's purpose manifested in the so-called Hatch-Waxman Amendments, Pub. L. No. 98-417, 98 Stat. 1585 (1984), "to make available more low cost generic drugs." *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1316 (D.C. Cir. 1998) (internal quotation marks omitted) (quoting H.R. REP. NO. 98-857, pt. 1, at 14 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2647). Imperfect or even unwise regulations are not necessarily illegal, however. To the extent the DEA's interpretation is bad policy, that must be addressed by the agency or Congress.

V

The petition for review is denied, and the judgment of the district court is affirmed.

*So ordered.*