EXHIBIT A

No. 15-1933

IN THE UNITED STATES COURT
OF APPEALS FOR THE FOURTH CIRCUIT

MALLINCKRODT INC.,

Plaintiff-Appellant,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION
and UNITED STATES OF AMERICA,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

APPELLANT MALLINCKRODT INC.'S MEMORANDUM IN RESPONSE TO SUGGESTION OF MOOTNESS

Daniel G. Jarcho
Emily C. McGowan
ALSTON & BIRD LLP
The Atlantic Building
950 F Street, N.W.
Washington, D.C. 20004
(202) 239-3254 (telephone)
(202) 239-3333 (fax)
daniel.jarcho@alston.com

Attorneys for Appellant

Mallinckrodt challenges two separate final agency actions in this case. The first is FDA's reclassification of Mallinckrodt's drug. The second is FDA's issuance of a bioequivalence guidance. Mallinckrodt challenges the guidance on two independent grounds: (1) as an invalid final agency action; and (2) as an unlawful premise for the reclassification action. (JA 20 ¶¶ 58–60; *see also* Mallinckrodt Br. at 53–54 & n.24; Mallinckrodt Reply Br. at 29.) A live controversy exists with respect to both the reclassification action and the guidance.

I. THE PARTIES HAVE A LIVE DISPUTE OVER THE LAWFULNESS OF THE BIOEQUIVALENCE GUIDANCE

The District Court properly held that Mallinckrodt's challenge to the bioequivalence guidance is judicially reviewable (as an agency action independent of the reclassification decision (JA 221 n.3)) and then reached the merits of Mallinckrodt's challenge to the guidance (JA 243–255). The parties plainly have a live controversy in this Court over the validity of the District Court's merits ruling.

FDA's Suggestion of Mootness does not even mention the parties' dispute over the bioequivalence guidance. And for good reason—the issues discussed in the Suggestion of Mootness are not relevant to the guidance dispute. FDA's publication of the withdrawal notice has no effect on the guidance, which remains fully in effect. The guidance will remain in effect unless and until this Court resolves the parties' current controversy, by holding that the guidance is a legislative rule subject to notice and comment procedures.

II. THE PARTIES HAVE A LIVE DISPUTE OVER THE LAWFULNESS OF THE RECLASSIFICATION ACTION

The reclassification action also presents a live dispute. FDA's publication of the withdrawal notice did not affect the parties' dispute over the lawfulness of the reclassification action. The BX classification remains in the Orange Book today. The harmful consequences of that action continue unabated, regardless of FDA's

publication of the withdrawal notice. The continuing injury to Mallinckrodt will persist unless and until this Court vacates the reclassification action.

A. The Reclassification Claim is Not Moot Simply Because FDA Might Reclassify Mallinckrodt's Drug to "AB" at the Conclusion of the Withdrawal Proceedings

The fact that FDA might reclassify Mallinckrodt's drug to "AB" at the conclusion of the withdrawal proceedings has no bearing on mootness of the reclassification claim. Suggestion of Mootness at 4. Withdrawal proceedings, like other litigations, may be terminated (through settlement or otherwise) without a ruling that reaches the ultimate merits question (here bioequivalence). If the withdrawal proceedings terminate before conclusion, they may have no effect on the current dispute over reclassification. Even if the withdrawal proceedings reach conclusion, and Mallinckrodt prevails, and Mallinckrodt's victory results in a reclassification to "AB," the parties have an open, live dispute with respect to reclassification in the meantime. There is no basis for finding mootness now.[1]

[1] There also is no basis for concluding that the appeal is moot simply because FDA might later withdraw approval for Mallinckrodt's drug. Suggestion of Mootness at 4, 6. In the interim, a live dispute over the BX classification persists.

B. The Reclassification Claim is Not Moot Simply Because FDA Might Issue a New BX Classification Following this Court's Remand to the Agency

Mallinckrodt's challenge to the reclassification action also is not moot simply because FDA might issue a new BX classification on other grounds (if this Court vacates the current BX classification and remands the matter to FDA). Suggestion of Mootness at 5–6. It is well settled that parties have a live, justiciable controversy even if the agency may reach the same result (for different reasons) following a remand. *See, e.g., Fed. Election Comm'n v. Akins*, 524 U.S. 11, 25 (1998) (confirming justiciable controversy "even though the agency (like a new jury after a mistrial) might later, in the exercise of its lawful discretion, reach the same result for a different reason"). If the possibility of reaching the same result on remand mooted a controversy, Administrative Procedure Act challenges would virtually always be moot, because the *typical* Administrative Procedure Act remedy involves a remand to the agency for further proceedings. *Florida Power & Light Co. v. U.S. Nuclear Regulatory Comm'n*, 470 U.S. 729, 744 (1985).

Furthermore, there is no way to know with certainty whether a future FDA classification decision, following a remand, would be "BX." *See, e.g., PDK Labs. Inc. v. U.S. Drug Enforcement Admin.*, 362 F.3d 786, 798 (D.C. Cir. 2004) (refusing to conclude that result of remand to agency could be foreseen because "[w]e know no such thing"). FDA only asserts that a future classification would be "BX" if the agency relied on the current factual record. Suggestion of Mootness at 6. Yet the withdrawal process that FDA has initiated may easily trigger changes in the record. Mallinckrodt has the opportunity to present evidence to FDA in response to the withdrawal notice. *See* Withdrawal Notice, 81 Fed. Reg. 71737 (Oct. 18, 2016) (requiring Mallinckrodt to "[s]ubmit all data, information, and analyses upon which the request for a hearing relies by December 19, 2016"). At a

hearing Mallinckrodt would have an additional opportunity to supplement the record. There is no way of knowing what a future reclassification decision would be, because there is no way of knowing what the underlying factual record would be at the time of that decision.[2]

Finally, given the potential for an evolving record, this case is not moot simply because the Orange Book says issuance of a withdrawal notice "ordinarily" coincides with a reclassification to "BX." Suggestion of Mootness at 5. That Orange Book statement does not say that initiating the withdrawal process *inevitably* leads to such a reclassification. The statement also does not say that FDA is *prohibited* from changing a "BX" classification during a withdrawal proceeding (based on new facts found during that proceeding). And even if it did, the Administrative Procedure Act would prohibit such an unconditional rule. The Administrative Procedure Act's "arbitrary and capricious" standard requires FDA officials considering reclassification to consider all of the relevant information available to them (including any information submitted by Mallinckrodt) at the time of any future reclassification decision. *See, e.g., Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005) (substantial evidence justifying agency action cannot be established "'merely on the basis of evidence which in and of itself justified [the agency's decision], without taking into account contradictory evidence or other evidence from which conflicting inferences could be drawn"); *Ass'n of Data*

[2] Although the withdrawal proceedings are distinct and independent of any reclassification decision (for the reasons explained below at pages 5–7), it appears that the same FDA officials (at the Office of Generic Drugs) are involved in both withdrawal and reclassification. As a result, changes in the record in the withdrawal proceedings would change the evidence upon which those officials would premise a future reclassification decision.

Processing Serv. Orgs., Inc. v. Bd. of Governors of the Fed. Reserve Sys., 745 F.2d 677, 683–84 (D.C. Cir. 1984) (equating substantial evidence test and arbitrary and capricious standard). There is no way of knowing with certainty what the result that future decision might be.

III. THE WITHDRAWAL NOTICE DOES NOT UNDERMINE THE FINALITY OF FDA'S RECLASSIFICATION ACTION

FDA's mootness argument is so weak, and the Eleventh-hour timing of the withdrawal notice so curious, that it is legitimate to ask whether the new Federal Register notice serves an FDA purpose in addition to supporting a mootness defense. And indeed it does. FDA is arguing, through nuance and implication, that extra-record facts recited in that notice support the *merits* of its defense, by allegedly confirming that the reclassification action does not meet the "consummation" prong of the test for a final agency action. *See* Suggestion of Mootness at 3–4, 7. The Court should not adjudicate FDA's defense based on extra-record facts.

A. The Withdrawal Notice is Not Relevant to the Finality of the Reclassification Action

1. As a Matter of Law, the Reclassification Action is Completely Independent of Any Action Withdrawing Approval

The Court should first conclude that the withdrawal notice is not relevant to the finality of the reclassification action. In particular, contrary to FDA's assertion, reclassification is not a preliminary action that is a prelude to withdrawal. *See* Suggestion of Mootness at 3–4, 7. As a matter of law, reclassification is completely independent of any action withdrawing approval. FDA plainly may withdraw approval (following a hearing) without first reclassifying a drug; FDA's withdrawal regulations do not even mention Orange Book classification. *See* 21 C.F.R. §§ 314.150, 314.200. Conversely, FDA may

reclassify a drug in the Orange Book without initiating the process for withdrawing approval, as it did when it reclassified Mallinckrodt's drug almost two years ago. The Orange Book specifies that "[i]nclusion of products on the [Orange Book] List is *independent of* any current regulatory action through administrative or judicial means against a drug product." (JA 27 (emphasis added).) Only an unsupported assertion by FDA suggests that there is a necessary connection between the two actions.

The Orange Book elaborates on the distinction between its classifications (on the one hand) and independent regulatory actions that would remove a product from the market (on the other). The Orange Book specifically states that if FDA takes a regulatory action to "secur[e] removal of [a drug listed in the Orange Book] from the market," the regulatory action is "independent of the inclusion of [the drug] on the [Orange Book] List." (JA 35–36.) Indeed, FDA continues to list drugs in the Orange Book even if FDA believes that they violate FDA regulatory standards, as long as they have "an effective approval that has not been withdrawn for safety or efficacy reasons," because "other legal mechanisms are available to the Agency to prevent the product's actual marketing." (JA 36.) According to the Orange Book, FDA "*may* . . . change a product's therapeutic equivalence rating if the circumstances giving rise to the violation change or otherwise call into question the data upon which the Agency's assessment of whether a product meets the criteria for therapeutic equivalence was made." (JA 36 (emphasis added).) Or FDA may not. The bottom line? An Orange Book listing is independent of an FDA withdrawal.

The independence of Orange Book classifications and withdrawals derives from the fact that different statutory provisions govern each type of action. FDA's statutory authority to classify drugs in the Orange Book (21 U.S.C. § 355(j)(7)) lends no support whatsoever to the idea that reclassification is the first step in the

withdrawal of drug approval.[3] Similarly, FDA's statutory authority to withdraw drug approvals (21 U.S.C. § 355(e)) does not even mention the Orange Book.

Finally, FDA's Suggestion of Mootness (page 7) cites the specific judicial review provision granting the courts of appeals exclusive jurisdiction to review withdrawal orders (21 U.S.C. § 355(h))—but that provision actually *supports* the fact that approval withdrawals are entirely different actions than reclassifications. Section 355(h) jurisdiction is narrowly construed; FDA actions that neither refuse nor withdraw drug approvals fall outside the scope of section 355(h) and are reviewable in District Court under 28 U.S.C. § 1331. *See, e.g., Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 651 (1973); *Cutler v. Hays*, 818 F.2d 879, 887 n.61 (D.C. Cir. 1987); *Genentech, Inc. v. Bowen*, 676 F. Supp. 301, 311 (D.D.C. 1987); *Barnes v. Shalala*, 865 F. Supp. 550, 555–57 (W.D. Wis. 1994). The reclassification action is such an action—wholly separate and currently reviewable.

2. The Subject Matter of the Withdrawal Proceeding Does Not Undermine the Finality of the Reclassification Action

The withdrawal proceeding also does not undermine the finality of the reclassification action simply because the subject matter of both is the bioequivalence of Mallinckrodt's drug. *See* FDA Suggestion of Mootness at 4. As long as the reclassification action meets the Supreme Court's *Bennett v. Spear* two-part test for finality, it is reviewable regardless of its subject matter. The wholly independent withdrawal proceeding simply is not relevant to reviewability.

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[3] If FDA conducts withdrawal proceedings and issues an order withdrawing approval, the statute directs that FDA must remove the drug from the Orange Book entirely, publishing a notice of the removal in the Federal Register. *Id.* § 355(j)(7)(C).

In *Dow Agrosciences LLC v. Nat'l Marine Fisheries Serv.*, 637 F.3d 259, 261 (4th Cir. 2011), this Court held that a "Biological Opinion" that particular insecticides would harm specific fish species was final and reviewable, notwithstanding the fact that a later final agency action would address the very same harm (from the very same insecticides). The later final agency action was an EPA pesticide "reregistration" analogous to an FDA drug approval withdrawal decision. Like an FDA withdrawal decision, the EPA pesticide reregistration action was directly reviewable in a court of appeals under a statutory exclusive jurisdiction provision. This Court held that the Biological Opinion was judicially reviewable in district court because it met *Bennett*'s two-part test for final agency action. It did not matter that a later final agency action (also subject to judicial review) would address the very same subject matter in a slightly different context. *Id*. at 265.[4] This Court should reach the identical conclusion here.[5]

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[4] The Court also held that the Biological Opinion was ripe for review and that there was no basis for deferring resolution of the pesticide issue until judicial review of the later reregistration decision. 637 F.3d at 269.

[5] In *Dow Agrosciences*, the Court also discussed the question whether district court review was precluded because the statutory jurisdiction provision (providing for court of appeals review) was another adequate remedy. This Court held that the exclusive statutory review provision was not another adequate remedy, and that the Biological Opinion therefore was reviewable in district court under the Administrative Procedure Act. *Dow Agrosciences*, 637 F.3d at 265–68. In the present case, the exclusive statutory review provision also is not another adequate remedy. The provision simply does not apply to reclassification actions. *See supra* at 7. In addition, because reclassification is entirely independent of withdrawal, reclassification is not an inherent aspect of withdrawal that would be subject to judicial review as part of the withdrawal decision. *See Dow Agrosciences*, 637 F.3d at 265–67.

B. The Court Should Reject FDA's Efforts to Inject New Extra-Record Facts into the Court's Resolution of this Appeal

The Federal Register notice attached to FDA's Suggestion of Mootness recites facts regarding new bioequivalence analyses, sponsored and performed by FDA after the agency reclassified Mallinckrodt's drug. There is no evidence in the appellate record concerning these new analyses. It is axiomatic that the Court should not review extra-record facts in resolving the merits of an appeal. *See, e.g.*, *Fassett v. Delta Kappa Epsilon*, 807 F.2d 1150, 1165 (3d Cir. 1986) ("The only proper function of a court of appeals is to review the decision below on the basis of the record that was before the district court.") *cert. denied* 481 U.S. 1070 (1987); *Gardner v. Bishop*, 983 F.2d 1056, 1993 WL 7947, at *3 n.10 (4th Cir. Jan. 19, 1993) (unpublished table opinion) (citing *Fassett* and concluding that the court of appeals "should not consider [additional facts] because they were not before the district court"). This settled rule does not apply any differently simply because FDA has summarized the extra-record facts in a publicly-available Federal Register notice.[6] The Court should either ignore the extra-record facts or remand to the District Court so that they may be properly developed for judicial review.

If the Court ignores the extra-record facts, it should rule for Mallinckrodt on the "consummation" prong of the test for a final agency action. All of the undisputed facts in the record—including an FDA official's admission that the reclassification is final—demonstrate that the reclassification action was the

[6] The Federal Register notice was undoubtedly drafted by agency counsel with knowledge of the finality issues in this appeal. Post-hoc explanations by agency counsel are not a proper basis for a court to adjudicate an Administrative Procedure Act case. *Cf. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

consummation of the agency's reclassification process, not tentative or interlocutory. Mallinckrodt Br. at 31–36; Mallinckrodt Reply Br. at 14–19.

Alternatively, if the Court concludes that the extra-record facts summarized in the Federal Register should be considered, the Court should remand for further factual development in the District Court, including discovery. *See, e.g.*, *Al Shimari v. CACI Premier Tech., Inc.*, 758 F.3d 516, 521, 531 (4th Cir. 2014) (remanding because a "thorough analysis . . . [could not] be achieved simply by reviewing the plaintiffs' pleadings and the limited record on appeal, but also [would] require factual development of the record and possibly additional jurisdictional discovery"). This Court has held that finality is jurisdictional. Mallinckrodt Br. at 41. It is well established that Mallinckrodt should have an adequate opportunity to discover jurisdictional facts before a jurisdictional defense is adjudicated. Mallinckrodt Br. at 37–39; Mallinckrodt Reply Br. at 19–20.[7] Any remand order therefore should provide for discovery, specifying that Mallinckrodt may discover the details of the analyses and underlying data referred to in the Federal Register notice.

[7] The ordinary rule is that adjudication of an Administrative Procedure Act case is limited to the administrative record, and that discovery is unavailable. That rule would not prevent the jurisdictional discovery at issue. The administrative record only embraces the facts before the agency at the time of the decision being challenged. *Dow Agrosciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462, 467 (4th Cir. 2013). The analyses and data at issue are by definition outside the administrative record, because they postdated the November 2014 reclassification and guidance actions challenged here. If the Court is to consider those facts at all, discovery limitations based on administrative record considerations do not apply.

Respectfully submitted,

/s/ Daniel G. Jarcho

Daniel G. Jarcho
Emily C. McGowan
ALSTON & BIRD LLP
The Atlantic Building
950 F Street, N.W.
Washington, D.C. 20004
(202) 239-3254 (telephone)
(202) 239-3333 (fax)
daniel.jarcho@alston.com

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Attorneys for Appellant